

**COMMITTEE ON PUBLIC
UNDERTAKINGS
(1975-76)**

(FIFTH LOK SABHA)

EIGHTIETH REPORT

ON

HINDUSTAN ANTIBIOTIC LIMITED

(MINISTRY OF CHEMICALS AND FERTILISERS)



**LOK SABHA SECRETARIAT
NEW DELHI**

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EIGHTEETH REPORT OF THE COMMITTEE
ON PUBLIC UNDERTAKINGS ON
HINDUSTAN ANTIBIOTICS LTD.

<u>Page</u>	<u>Para</u>	<u>Line</u>	<u>For</u>	<u>Read</u>
3	2.5	8	<u>Add</u> the word 'one' before the word 'fermentor'	
11	2.18	6	Penicillin	Penicillin G
12	2.21	7	<u>delete</u> the word 'in' occurring after the word 'whether'	
16	2.32	1	<u>Add</u> the word 'seen' after the words 'it is'	
18	2.35	2	of	at
25	2.47		<u>for</u> existin; line 1 <u>read</u> "2.47"	
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39	2.85	4	or	our
44	-	6	<u>delete</u> the word 'on' occurring after the word 'wise'	
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53	2.125	5	were	want
53	2.126	15	want	went
53	2.127	4	therapeutical	therapeutically
53	2.127	9	fair	fairly
54	2.129	3	to solve	to b solved
55	2.132	6	planet	plant
55	2.132	26-		
		27	anticipate	anticipated
55	2.133	3	toxity	toxicity

<u>Page</u>	<u>Para</u>	<u>Line</u>	<u>For</u>	<u>Read</u>
6	2.136	4	expediment	experiment
1	2.152	15	for	foreign
2	2.156	4	most	cost
2	2.156	8	ourside	outside
3	-	last	<u>delete</u> "2.157"	
1	2.176	7	enthusiase	enthusiastic
8	-	3	Xanamycin	Kanamycin
8	2.194	1	not	note
0	2.197	2	Xanamycin	Kanamycin
4	2.209	2	pharmacopoeia*	pharmacopia
4	2.211	1	regard	regret
5	2.216	7	of	by
7-89	last three lines on page 87 and first eight lines on page 88 to be read below the years 1972-73, 1973-74 and 1974-75 on page 89.			
2	2.223	9	conductive	conducive
7	2.236	1	delete 'ha' after	(March 1972)'
7	2.237	10	absolute	obsolete
8	2.240	4	personaly	personally
08	3.9	6	wih	with
12	3.18	23	prevides	provide
13	3.21	12	<u>insert</u> 'I' after	'industry'
22	3.40	5	<u>delete</u> 'a' after	'overall'
22	3.41(6)	1	for speci	specially for
27	3.54	17	correspondants	corresponds
28	3.56	1	tables	table
33	3.69	1 12	<u>for</u> existing line <u>read</u>	"for tableting in the case of Penicillin V ranged from 10% in"
33	3.70	5	<u>for</u> existing line <u>read</u>	"for Formulations. The percentage of orders cancelled to the orders"
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73	5.38	9	fitted	lifted
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<u>Page</u>	<u>Para</u>	<u>Line</u>	<u>For</u>	<u>Read</u>
178	5.48(m)	1	lables	labels
185	(18)	9	Amylolucosidase	Amyloglucosidase
194	6.23	4	-rarecusly	-ranecusly
207	(v)	2	Systeme	System
214	8.24	3	seapratly	separately
227	-	3	ctages	stages
237	-	1	negotiate	negotiation
242	Sub Para 2	Last but four line	would	should
247	S. No.24	18	confirm	confirmed
255	S. No.37 Sub Para 1	last but one line	endure	ensure
255	S. No.37 Sub Para 2	last but one line	remdial	remedial
260	-	14	reduce	reduced
285	-	5	Porcess	Process

CONTENTS

	PAGE
COMPOSITION OF THE COMMITTEE	(iii)
COMPOSITION OF THE STUDY GROUP	(v)
INTRODUCTION	(vii)
I. INTRODUCTORY	I
II. PERFORMANCE ANALYSIS	
A. Penicillin	3
B. Streptomycin	32
C. Hamycin	48
D. Vitamin-C	56
E. Aurcofungin	69
F. Other Items	74
G. Rejections	80
H. Consumption of raw material	86
I. Utilisation of services	95
J. Machine/Labour Utilisation	99
III. FORMULATIONS	
A. Vialling	105
B. Tableting and Capsulation	126
C. Bulk <i>vis-a-vis</i> Formulations	134
IV. PRICING	143
V. MARKETING	
A. Market participation	158
B. Marketing	161
C. Discount on Sales	167
D. Appointment of Distributors	169
E. Exports	175
VI. RESEARCH AND DEVELOPMENT	181
VII. INVENTORY CONTROL	195

VIII. FINANCIAL MATTERS

A. Capital Structure	202
B. Working Results	204
C. Costing System	213
D. Credit Control	217
E. Book Debit	219
F. Savings in Foreign Exchange	220
G. Organisation Structure	221
H. Accounting System and Internal Audit	222

APPENDICES

I. Interim Report of the Task Force on Vitamin C—Hindustan Antibiotics Ltd.	224
II. Statement showing standard consumption, standard spillages and overages in Vialling operations and the actual consumption of Penicillin and Streptomycin	231
III. Cost of production of formulations since 1966-67	233
IV. Summary of conclusion/recommendation	235

COMMITTEE ON PUBLIC UNDERTAKINGS

(1975-76)

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Shri K. S. Bhalla—Senior Financial Committee Officer.

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2. Shri Sriman Profulla Goswami—*Alternate Convener*
3. Shri Bhogendra Jha
4. Shri V. Mayavan
5. Shri Natwarlal Patel
6. Shri Harsh Deo Malaviya
7. Shri Bhola Prasad

INTRODUCTION

1. The Chairman, Committee on Public Undertakings having been authorised by the Committee to present the Report, on their behalf, present this Eightieth Report on Hindustan Antibiotics Ltd.

2. This Report of the Committee is based on the comprehensive appraisal of the working of the Hindustan Antibiotics Limited as contained in the Report of the Comptroller & Auditor General of India for the year 1970-71—Union Government (Commercial), Part XI and also of an examination in depth of the working of Hindustan Antibiotics Limited upto the year ending 31st March, 1975.

3. The Committee took evidence of the representatives of the Hindustan Antibiotics Limited on the 23rd September, 1975 and of the then Ministry of Petroleum and Chemicals on the 15th November, 1975.

4. The Committee considered and adopted the Report at their sittings held on 19th and 20th February, 1976.

5. The Committee wish to express their thanks to the Ministry of Petroleum and Chemicals, the Hindustan Antibiotics Limited and the non-official organisations for placing before them the material and information they wanted in connection with the examination of Hindustan Antibiotics Limited. They wish to thank in particular the representatives of the Ministry and the Undertaking who gave evidence and placed their considered views before the Committee.

6. The Committee also place on record their appreciation of the assistance rendered to them by Comptroller and Auditor General of India in the examination of Hindustan Antibiotics Limited.

NEW DELHI;
March 11, 1976

Phalguna 21, 1897 (S)

NAWAL KISHORE SHARMA,
Chairman,
Committee on Public Undertakings.

INTRODUCTORY

The Hindustan Antibiotics Limited, a Government of India enterprise, was incorporated as a Company on 30th March, 1954 under the Indian Companies Act, 1913 to take over the control and management of the factory at Pimpri set up by the Government of India for the production of Penicillin with the assistance of UNICEF and W.H.O. by an agreement on 24th July, 1951 known as Joint Plan of Operations. UNICEF provided foreign exchange for purchase of machinery and equipment to the extent of US \$ 850,000 to be paid back "in kind" in the form of penicillin vials for treatment of children and pregnant mothers in the South-East Asian countries including India. This liability has since been fully liquidated. W.H.O. provided technical assistance at an estimated cost of US \$ 3,50,000 for the project. The capacity for production of Penicillin has been expanded from time to time and now it is 84 MMU of Penicillin G or 78 MMU per annum for Penicillin G and V.

1.2. In 1958, HAL entered into an agreement with M/s. Merk and Co. of USA for the manufacture of Streptomycin Sulphate under licence. The plant was set up in 1962, and its capacity was raised to 89-90 tonnes per annum in 1965.

1.3. The main objects of the Company are to produce, buy, sell, export, import and deal in Penicillin and its preparations, other antibiotics, sulpha drugs, preparations of anti-malarial products etc. So far, the Company has undertaken the production of antibiotics, particularly Penicillin and Streptomycin Sulphate.

1.4. In 1968 HAL set up a plant for production of Hamycin an antifungal antibiotics discovered in Research and Development Laboratories of HAL.

1.5. In 1973 HAL set up another plant for production of Vitamin C based on the know-how developed by National Chemical Laboratory.

1.6. In addition, H.A.L. is also engaged in the preparation of formulations in the form of capsules, tablets, ointments, etc. of

Penicillin Tetracycline, Hamycin, Ampicillin, Vitamin 'C', etc. The Company is also vialling a portion of its production of Penicillin and Streptomycin.

1.7. The working of Hindustan Antibiotics Ltd. was examined by the Public Accounts Committee in their Seventh Report (Third Lok Sabha—February, 1963).

H. PERFORMANCE ANALYSIS

A. Penicillin

The Penicillin Project was taken up with technical assistance provided by the WHO in 1954 and H.A.L. started production of its first product—penicillin bulk—in August, 1955.

2.2. The initial capacity of the plant at 25 million mega units (MMU) was subsequently expanded in three stages to 84 MMU of bulk penicillin G and V; the first stage of expansion raised the capacity to 40 MMU in 1960-61 and the second stage to 60 MMU in 1964-65. The third stage expansion raising the capacity to 84 MMU (as G equivalent) was finally completed in 1969-70 although the equipment for the production of first crystals was commissioned in January, 1966.

2.3. The fourth expansion raising the capacity to 160 MMU and setting up of a second plant having a capacity of 140 MMU has been included in the proposed Fifth Five Year Plan. Sanction of the Government for the project is however awaited.

2.4. Production of Penicillin and other antibiotics begins with biological fermentation. In general, the fermentation process consists of three steps viz. (1) seed growth, (2) production fermentation and (3) harvesting the fermented broth. From the fermented broth the mycelium is separated and Penicillin recovered from the filtrate by the solvent extraction process.

2.5. The Project Report for the Penicillin plant does not indicate either the installed capacity or the norms of production at different stages. The norms of production are fixed by the Management from time to time after taking into consideration the availability of fermentors and also the services such as refrigeration air, chilled water etc. Out of 20 fermentors (18 of 20,000 litres each and 2 of 60,000 litres each) for the manufacture of Penicillin (equivalent to 24 fermentors of 20,000 litres) fermentor of 20,000 litres is utilised for the manufacture of products other than Penicillin. The net available capacity is taken as 20.5 fermentors after allowing two fermentors, on an average, for annual overhaul and half fermentor for change of

filters. Based on a normal cycle of 148 hours (inclusive of 12 hours down time) for fermentation, 1200 fermentation batches are expected to be seeded in a year. Standard curves showing the rate of growth of titres are prepared by the Undertaking based on the results of sample batches. Decision to continue fermentation of broth or harvesting are taken by comparing performance from time to time of the batches against the standard curve.

Batches seeded and harvested:

2.6. The number of batches targeted for production (both original and revised), the number actually seeded, harvested and drained since 1966-67 are given below:

(Number of batches)

	Original targets	Revised targets	Actually seeded	Harvested	Drained	Percentage of drained batches to total number of batches seeded
	1	2	3	4	5	6
1966-67						
Pen. G	1095	854	828	796	32	3.9
Pen. V	160	231	238	226	12	5.0
	<u>1255</u>	<u>1085</u>	<u>1066</u>	<u>1022</u>	<u>44</u>	
1967-68						
Pen. G	946	638	565	554	11	1.9
Pen. V	320	221	233	225	8	3.4
	<u>1266</u>	<u>859</u>	<u>798</u>	<u>779</u>	<u>19</u>	

	1	2	3	4	5	6
1968-69						
Pen. G	833	763	834	814	20	2.4
Pen. V	240	223	171	161	10	5.8
	<u>1073</u>	<u>986</u>	<u>1005</u>	<u>975</u>	<u>30</u>	
1969-70						
Pen. G	773	796	858	818	40	4.7
Pen. V	300	239	252	228	24	9.5
	<u>1073</u>	<u>1035</u>	<u>1110</u>	<u>1046</u>	<u>64</u>	
1970-71						
Pen. G	935	879	786	771	15	1.9
Pen. V	255	208	249	243	6	2.4
	<u>1190</u>	<u>1087</u>	<u>1035</u>	<u>1014</u>	<u>21</u>	
1971-72						
Pen. G	898	737	744	731	13	1.7
	282	327	298	291	7	2.3
	<u>1180</u>	<u>1064</u>	<u>1042</u>	<u>1022</u>	<u>20</u>	
1972-73						
Pen. G	990	714	682	668	14	2.0
Pen. V	300	301	307	305	2	0.7
	<u>1200</u>	<u>1015</u>	<u>989</u>	<u>973</u>	<u>16</u>	
1973-74						
Pen. G	765	765	727	706	21	2.9
Pen. V	255	255	249	241	8	3.2
	<u>1022</u>	<u>1020</u>	<u>976</u>	<u>947</u>	<u>29</u>	
1974-75						
Pen. G	841	701	915	891	24	2.6
Pen. V	260	225	87	86	1	1.1
	<u>1101</u>	<u>926</u>	<u>1002</u>	<u>977</u>	<u>25</u>	

Note—Original targets are fixed around November of the preceding year and revised targets in December of the year.

2.7. It is noticed from the above statement that except in 1966-67, 1967-68 and 1972-73 the original targets were fixed below the capacity and the actual production fell short of the original targets except during 1969-70.

2.8. The Management explained in March, 1972 that in the years 1968-69 and 1969-70, the targets were fixed at lower levels for want of extraction capacities which continued to be low till March, 1970 on account of an accident in May, 1967 to the extractor.

2.9. In the year 1970-71, the new extractor (installed in March, 1970) had teething trouble in the beginning for quite some time. However, higher output per batch was achieved from 1967-68 onwards, which made up for lesser volume of batches.

2.10. In the absence of any norms laid down by the Management with regard to the number of batches harvested to the batches seeded, the efficiency of harvesting operations is not susceptible of evaluation.

2.11. The Management stated in March, 1972 that drainage of batches takes place due to contamination and that 5 per cent may be taken as a normal provision for draining. Even on this basis, the number of batches of Penicillin 'V' drained during 1968-69 and 1969-70 were in excess of the normal provision.

2.12. The Ministry also stated in September, 1973 that based on the previous experience, a norm of 2 to 3 per cent in the case of Penicillin and 5 to 10 per cent in the case of Streptomycin is considered reasonable.

2.13. Explaining the difference in the norms for draining fixed by the Management (5 per cent) and the Ministry (2 to 3 per cent) the Managing Director stated during evidence as follows:

"I may mention that the losses are due to fluctuation and shortage of power supply, obsolescence of equipments, etc. ****

These norms are also subject to proper functioning of the equipments, availability of technology and all that I do not think there can be any standard as such for all this. Each plant works out its own norm depending on its equipment, its technology, the operating conditions etc."

2.14. The Committee note that the Hindustan Antibiotics Limited (HAL) started production of bulk penicillin in 1955. The initial capacity of the Plant at 25 million mega units (MMU) has been expanded in three stages to 84 MMU of bulk Penicillin G or 78 MMU of bulk Penicillin G & V as at present. Production of penicillin and other antibiotics begins with biological fermentation which is done in three steps viz. (1) seed growth, (2) production fermentation and (3) harvesting the fermented broth. The Committee regret to note that the installed capacity or the norms of production at different stages have not been indicated in the Project Report. The norms of production at different stages are fixed by the Management from time to time after taking relevant factors into consideration. The Committee also note that, except in 1966-67, 1967-68 and 1972-73, the original targets for production of fermentation batches were fixed below the capacity and that the actual production fell short of the original targets except during 1969-70. It has been stated that the targets were fixed at lower levels for want of extraction capacities because of an accident in 1967 to the extractor which was replaced only in March, 1970. The Committee regret to note that it took the Company three years to replace the extractor, and the production was allowed to suffer during all these years. The Committee would like the reasons for delay in this regard to be enquired into and responsibility fixed for such excessive delay which resulted in heavy loss in production.

2.15. The Committee, however, find that higher output per batch was achieved from 1967-68 onwards and this made up for lesser volume of batches. If it be so, the Committee see no reason why such higher output could not be sustained. As in the absence of any norms with regard to the number of batches harvested to the batches seeded, the efficiency of harvesting operations is not susceptible of evaluation, the Committee recommend that the Management should not lose any further time in fixing the norms after a study of such standards obtaining both in India and abroad so that they can evaluate the efficiency of harvesting operations from time to time and take suitable remedial measures to prevent the efficiency going below the norms.

2.16. The Committee note that drainage of batches takes place due to contamination and according to the undertaking 5 per cent is a normal provision for draining. The Ministry however consider a norm of 2 per cent to 3 per cent as reasonable in the case of Penicillin. It has been stated by the Managing Director that the difference in the norms of draining is due to fluctuation and shortage of power

supply, obsolescence of equipment and operating conditions and that there cannot be a standard as such for this. The Committee do not see any reason why it should not be possible to fix suitable norms for draining on the basis of the experience during all these years and taking into consideration the state of equipment, operating conditions etc. The Committee would like the undertaking to take steps without further delay to fix appropriate norms for draining of batches so that deviations therefrom could be watched and timely remedial action taken so as to reduce the loss on account of drainage to the minimum.

2.17. *Titre yield and broth obtained.*—After mycelium content estimated at 15 per cent. (actual content depend upon the nature of strain and fermentation conditions) is separated from the harvested batches, titre yield of 7000 units per millilitre (ml) in case of Penicillin 'G' and 5000 units per millilitre (ml) in case of Penicillin 'V' till 1971-72 (except in the year 1966-67, when the expected titre yield was 6500 units and 4500 units respectively), and 10,000 units per millilitre (ml) in case of Penicillin 'G' and 6000 units per millilitre (ml) in case of Penicillin 'V' from 1972-73 onwards, is expected to be obtained according to the standard fixed by the Company. The following table indicates the volume per harvested batch, titre yield per millilitre and Penicillin broth obtained, both expected and actual quantities, during the years 1966-67 to 1974-75.

Year and Product	Expected volume per harvested batch (excluding mycelium) (litres)	Actual volume per harvested batch (excluding mycelium) (litres)	Expected litre yield per milli-litre (units)	Actual average yield per millilitre (units)	Expected Pencillin broth (MMU)	Actual Pencillin broth (obtained) (MMU)	Shortfall(-)/Excess (+) in broth realisation (MMU)
	2	3	4	5	6	7	8
1966-67							
Pen. G	17,000	17,377	6,500	6,484	87.95	89.69	(+) 1.74
Pen. V	17,000	17,469	4,500	4,184	17.29	16.52	(-) 0.77
1967-68							
Pen. G	17,000	17,778	7,000	7,021	65.92	69.15	(+) 3.23
Pen. V	17,000	17,201	5,000	4,876	19.13	18.87	(-) 0.26
1968-69							
Pen. G	17,000	18,148	7,000	7,141	96.87	105.49	(+) 8.62
Pen. V	17,000	17,337	5,000	5,064	13.69	14.13	(+) 0.44
1969-70							
Pen. G	17,000	17,929	7,000	6,828	97.34	100.14	(+) 2.80
Pen. V	17,000	17,740	5,000	4,349	19.38	17.59	(-) 1.79

I 2 3 4 5 6 7 8

1970-71								
Pen. G	6,978	91.75	95.25	(+) 3.50
Pen. V	4,492	20.66	19.31	(-) 1.35
1971-72								
Pen. G	7,128	86.99	92.90	(+) 5.91
Pen. V	4,730	24.74	23.59	(-) 1.15
1972-73								
Pen. G	9,234	113.56	107.56	(-) 6.00
Pen. V	5,125	31.11	24.42	(-) 6.69
1973-74								
Pen. G	16,485	120.02	114.72	(-) 5.30
Pen. V	16,283	24.59	21.79	(-) 2.69
1974-75								
Pen. G	8,015	151.47	138.41	(-) 13.06
Pen. V	4,670	8.77	7.52	(-) 1.25

MMU—Million mega units
 Mega Unit—10 lakh units
 One litre—1000 millilitres

Note : (1) Expected broth is arrived at by multiplying columns 2 and 4 with the number of harvested batches as given in sub-Para (a).

(2) Actual broth obtained has been arrived at by multiplying columns 3 and 5 with the number of harvested batches as given in sub-para (a).

2.18. It is seen that the actual volume per harvested batch and actual titre yield varied widely from year to year. The actual volume per harvested batch was always more than the expected volume while the actual titre yield was generally lower than the standard yield. The actual volume per harvested batch was more than the expected volume during 1972-73 in the case of Penicillin and during 1974-75 in respect of both Penicillin G and V. The actual titre yield was less than the expected titre yield and substantially came down in 1974-75 as compared with the earlier two years. The strain (H A 10) was introduced in 1962 and its titre yield was expected at 7000 units per ml. In December, 1971 a new strain (P.C. 11 and P.C. 12) was developed and introduced in a phased manner. According to Management the average titre yield per batch during 1972-73 increased by about 18 per cent in Penicillin 'G' and 3 per cent in Penicillin 'V' after introduction of the new strain.

2.19. Explaining the reasons for wide variations in the actual volume per harvested batch from year to year and lower titre-yield in all the years and sharp fall in the titre yield during 1974-75, the Managing Director stated during evidence that:—

“That (titre yield) depends on the nature of fermentation and the foaming that comes up. So many factors—raw materials, etc. are there which add to this problem. In fact there is a tendency for the strain to deteriorate in course of time. We introduced the strain in 1971.

In 1972-73 which was the first year, we watched its activity. Thereafter the strain showed some deterioration. You have to constantly watch the strain and keep the potency up. You have to come to R & D. They select some culture, out of them and keep up the potency.”

2.20. HAL added in another note that as a result of development by Research and Development wing of HAL, the activity of the strain obtained from UNICEF had increased from 2000 u/ml to an average of 9000 u/ml during the last three years ending March 1975. The R & D wing was continuing the development work. HAL, however considered that it would be financially advantageous to purchase improved strain and technology which could be introduced in the plant immediately and let the R & D maintain and develop further.

2.21. On an enquiry of the Committee whether HAL had the technology to maintain the strength and potentiality of the strain and whether all what was necessary was being done, the Managing Director stated during evidence that—they had the technology and the company applied that technology. They could not however maintain the stability, whereas in the case of lower strain they could do so. Asked whether in HAL made any attempt to procure improved technology from other countries before 1973, the Managing Director stated that—

“I can't say we have not tried. Because all I can say is, the company had its own strain in 1971 which was giving around 10,000 and the feeling then was that we have strain which is as good as what anybody would have. Then we came to know that in some other countries they have a strain which gives 2 or 3 times more of production. We talked to people. In early 1974 a delegation went in which I was also a member. We talked to different persons regarding actual proposal for transfer of strain and know-how technology.

2.22. The Secretary of the Ministry of Petroleum and Chemicals also stated in this regard as follows:—

“So far as penicillin is concerned, we have improved the strain from time to time, based upon the technology. It was a slow process but there was a certain human pride in doing things ourselves. They developed from 2000 and reached the level of 9000 over the course of years. In modern technology this is not adequate and therefore, we are negotiating with the Japanese party for a strain which would give us as much as 30,000. We hope these negotiations would be completed soon and as soon as this strain is obtained the penicillin production would be a great deal more.”

2.23. Asked about the improvements made by R & D of HAL, it was stated by the Managing Director that the R & D consisted of very good scientists of international repute and they wanted certain facilities which were given to them. In this connection—

"I do not think it would be fair or even correct to say that the technology of the HAL and the improvements of strains was stagnant. They start with 2,000 and, over the course of years, they built up to 9,000. This was their own effort. There was one simple way of getting advanced technology, that is, to buy from foreign countries. It is a very simple way. Most of the private companies do this. Sometimes, we have to make a hard choice, whether we want to develop our own technology or purchase the technology. Since in this particular case and in a number of cases in the public sector, we have taken a conscious decision to build up our own technology, this is *prima facie* a slower process. We just do not have the vast millions of dollars which are put in the R & D abroad. If we are able to build up our own technology there is a price to be paid for it. The process is bound to be a slower one. I do not accept that there has been stagnation there."

2.24. The Secretary added that—

"One would not say that the HAL's performance has been bad in this context. They have reached, to some extent, a stalemate in technology. They said that they must move faster and they would get the Japanese technology. It will be of enormous benefit. The moment they get Japanese technology, they will be far in advance of even the private companies in the country. There will be race between the two.

I must mention that this spectacular development of 30,000 is a fairly recent thing. It is not that ten years ago the Japanese had the 30,000 strain, it is within the last two to three years that the antibiotics technology there had been fantastic advance. When, through our process, we develop it from 2000 to 9000 it cannot be said that there was, at that time, the 30,000 technology in the world.

I do not think it would be quite right to say that, during the entire period of ten years, we were asleep to these developments."

2.25. The Committee note that titre yield of 7000 units per millilitre (ml) in case of Penicillin 'G' and 5000 units per ml. in case of Penicillin 'V' (except in the year 1966-67 when the yield was 6500 units and 4500 units respectively) was expected to be obtained till

1971-72 according to the standards fixed by the Undertaking. From 1972-73 onwards, the expected titre yield has been 10,000 units in case of Penicillin 'G' and 6000 in the case of Penicillin 'V'. The Committee find that the actual titre yield has always been lower than the standard yield except, during 1967-68, 1968-69 and 1971-72 in the case of Penicillin G and 1968-69 in the case of Penicillin V. It has been stated that the titre yield depended on the nature of fermentation and foaming, which again was dependent on raw materials etc. There was a tendency for the strain to deteriorate in course of time and the potency had to be watched and kept up. Penicillin strain was introduced in 1962 and a new strain was developed and introduced in December, 1971 in a phased manner. The Committee are also informed that as a result of development by Research and Development wing of HAL, the activity of the strain originally obtained from the UNICEF had increased from 2000 units/ml. to an average of 9000 units/ml. during the last three years ending March, 1975. As between developing its own technology and the purchase of a new technology, the Company is reported to have taken a conscious decision to build up its own technology though this was prima facie a slower process. The Committee regret to observe that in spite of the knowledge about the potency of the strain going down no serious attempts appear to have been made from 1962 to 1971 to improve the potency of strain for obtaining better titre yield. They learn that the Company is now negotiating with a Japanese party for a strain which has a yield of 30,000 units/ml. The Secretary, Ministry of Petroleum and Chemicals, had admitted during evidence that HAL had "reached, to some extent, a stalemate in technology.

2.26. In view of the fact that the country has all through this period been importing Penicillin (total foreign exchange outgo on this score being Rs. 1.92 crores from 1966-67 to 1971-72 as mentioned in paragraph 2.55 of this Report), in the opinion of the Committee, it would have been better and in the national interest if a new strain which is now sought to be imported had been imported much earlier and consequently production of Penicillin improved and import of Penicillin reduced to that extent. The Committee stress that the Government/undertaking should finalise without further delay the negotiation for import of the best suited and most efficient new Penicillin strain and take suitable measures to maximise the titre yield and the production of Penicillin.

2.27. The Committee would also like the Research and Development Wing of HAL to keep itself abreast of the developments else-

where so as to take advantage of any improvements in the technology from time to time.

2.28. The Committee also recommend that a case-study of the manufacture should be undertaken, so as to determine the national loss due to not keeping pace with the technical developments in improving the strains. The Undertaking should draw appropriate lessons from this experience in order to obviate recurrence of such a situation in pharmaceutical and other industries, where technological changes are rapidly taking place.

2.29. The Committee suggest that a study should be made and a report prepared once a year comparing the output and technology used in the Undertaking with other units in the country and if possible with efficient units outside the country, and considered in depth by the Board of Directors who should give their recommendations for improving efficiency and production.

Extraction of first crystals

2.30. The next stage of processing is the extraction of first crystals from the fermented broth in respect of which the Company has fixed a standard extraction efficiency of 70 per cent.

2.31. The yield of first crystals obtained during 1966-67 to 1974-75 is indicated below:—

Year		Expected yield (MMU)	Actual yield (MMU)	Percentage of actual yield of first crystals of fermented broth
1	2	3	4	5
1966-67	Pen. G	61.56	65.67	73.22
	Pen. V	12.10	10.79	65.31
1967-68	Pen. G	46.14	52.22	75.52
	Pen. V	13.39	12.78	67.73
1968-69	Pen. G	67.81	76.55	72.56
	Pen. V	9.58	9.61	68.01

1	2	3	4	5
1969-70	Pen. G	68.14	73.30	73.19
	Pen. V	13.57	11.81	67.14
1970-71	Pen. G	64.23	70.74	74.27
	Pen. V	14.46	12.05	62.40
1971-72	Pen. G	60.89	67.72	72.89
	Pen. V	17.32	14.33	60.74
1972-73	Pen. G	70.01	80.36	109.36
	Pen. V	20.28	18.80	94.85
1973-74	Pen. G	74.14	76.56	98.58
	Pen. V	15.18	12.77	88.31
1974-75	Pen. G	82.40	86.03	110.25
	Pen. V	4.58	3.97	100.00

Note —The expected yield of first crystals has been calculated on the basis of 70% of the expected fermented broth.

2.32. It is that the actual yield obtained in respect of Penicillin 'G' was always more than the standard extraction efficiency fixed by the Company. This was attributed by the Management (July, 1973) to better operational efficiencies. In fact during 1972-73 to 1974-75 the actual yield improved as compared to earlier years. The actual yield in the case of Penicillin 'V' was, however, less than the expected yield.

2.33. The Company has been progressively revising the standards of yield of first crystals per harvested batch from 1961-62 onwards. The last revision was made in 1972-73 when the standard yield of 8,000 mega units for Penicillin 'G' and 55,000 mega units per Penicillin 'V' was revised to 1,20,000 mega units and 60,000 mega units per harvested batch respectively. The actual average yield per

harvested batch obtained by the Company during 1966-67 to 1974-75 is given below:—

(Mega units)

	Penicillin G	Penicillin V
1966-67	74,223	47,760
1967-68	85,134	56,819
1968-69	89,526	59,682
1969-70	82,454	51,800
1970-71	84,459	50,291
1971-72	84,715	49,238
1972-73	1,20,300	61,662
1973-74	1,08,442	52,973
1974-75	92,139	47,003

2.34. The Committee note that the undertaking fixed a standard efficiency of 70 per cent for extraction of first crystals from the fermented broth. While the actual yield obtained in respect of Penicillin G ranged from 72 per cent in 1968-69 to 110 per cent in 1974-75 and was more than the standard yield of efficiency during all these years, the actual yield in case of Penicillin V ranged from 60 per cent to 68 per cent and was less than the standard yield, during 1966-67 to 1971-72 but it exceeded the standard yield during 1972-73 to 1974-75. The Committee are not sure about the basis on which the percentage of efficiency has been fixed at 70 per cent. The Committee feel that with the introduction of new strain in 1971 the Undertaking should review the performance and fix suitable standards with a view to assessing the performance with reference to such standards. The Committee also note that the Company had been progressively revising the standards of yield of first crystal per harvested batch from 1961-62, the last revision having been made in 1972-73. The actual average yield was however less than these standards in the case of Penicillin G during 1966-67, 1969-77, 1970-71, 1971-72, 1973-74 and 1974-75 and in case of Penicillin V during 1966-67, 1969-70, 1970-71, 1971-72, 1973-74 and 1974-75. The Committee feel that normally the yield should not be lower than standard yield and recommend that the Undertaking should identify the factors depressing

the yield so as to take suitable concerted measures for improving the performance. The Committee also recommend that for a realistic assessment of the yield of first crystals, the Undertaking should review the percentage of the standard for extraction efficiency and the yield and fix realistic standards for assessing the performance.

Utilisation of capacity.

2.35. The Company assessed the installed capacity of first crystals of 105 MMU.

The quantity budgeted (original and revised), the actual production and the percentage utilisation of installed capacity during 1966-67 to 1974-75 are given below:

(Figures in MMU)

Year		Penicillin G.	Repro- cessed Penicillin G	Pencillin V G	Pencillin V equivalent to Pen. G	Total in terms of Penicillin G. (Cels. 2+3+5)	Percentage utilisation of installed capacity
I		2	3	4	5	6	7
1966-67	O	88.00	4.20	8.00	12000	104.20	
	R	64.11	5.49	10.57	15.86	85.46	
	A	59.08	6.59	10.79	16.19	81.86	77.96
1967-68	O	74.88	5.20	16.00	24.00	104.08	
	R	53.99	2.64	12.10	1.15	74.78	
	A	47.16	5.05	12.78	19.17	71.38	67.98
1968-69	O	70.40	2.60	12.00	18.00	91.00	
	R	67.84	2.90	12.91	19.36	90.10	
	A	72.87	3.68	9.61	14.42	90.97	86.64
1969-70	O	65.70	2.40	15.00	22.50	90.60	
	R	63.35	4.78	12.14	18.21	86.34	
	A	67.45	5.85	11.81	17.72	91.02	86.69

	1	2	3	4	5	6	7
1970-71	O	79.50	1.50	14.00	21.00	102.00	
	R	73.73	1.96	10.84	16.26	91.95	
	A	64.42	6.32	12.05	18.08	88.82	84.59
1971-72	O	74.32	2.40	15.00	22.50	99.22	
	R	56.60	2.66	14.87	22.31	81.57	
	A	61.40	6.32	14.33	21.50	89.22	84.97
1972-73	O	72.00	2.00	15.00	22.50	96.50	
	R	83.00	2.90	18.47	27.70	113.60	
	A	82.99	2.90	18.81	28.21	114.10	108.67
1973-74	O	88.00	2.00	16.50	24.75	114.75	
	R	82.07	5.09	15.16	22.74	109.90	
	A	76.56	5.72	12.76	20.04	102.32	97.45
1974-75	O	96.71	5.00	16.00	24.00	125.71	
	R	66.28	4.76	11.62	17.43	88.47	
	A	79.88	6.92	3.97	5.93	92.75	88.33

Notes — 1. O: MMU of Penicillin 'V' is equivalent of 1.5 MMU of Penicillin. 'G'.

2. O=Original budget, R=Revised Budget

A=Actual.

2.36. It is seen that the original budgets have always been less than the installed capacity (except in 1973-74 and 1974-75) and the Revised budgets even less than the original budget, except in 1972-73). The actual production of Pen. G has also been less than the Revised budget (except in 1968-69, 1969-70, 1971-72 and 1974-75. The utilisation of installed capacity for the production of first crystals gradually increased from 68 per cent in 1967-68 to 87 per cent in 1969-70 but declined to 85 per cent in 1970-71 and showed the increasing trend upto 1972-73 when the capacity utilisation rose to 108.67 per cent and declined thereafter. The utilisation has been of the order of 88 per cent only in 1974-75.

2.37. It is also seen that in certain years the original targets exceeded the installed capacity as assessed by the Management. The actual production during 1972-73 also exceeded installed capacity.

The Management have stated in a written note that with a view to motivate the production personnel, the target is usually fixed as high as possible, and this resulted in its exceeding the installed capacity in certain years.

2.38. The yield of first crystals depends upon the activity of the strain in the fermenter. The installed capacity is fixed with reference to what the strain is normally capable of achieving. As a result, the actual yield can sometimes exceed the installed capacity under favourable conditions.

Efficiency of conversion of first crystal in the bulk penicillin

2.39. The Table below indicates the efficiencies accepted by the Management as norms for the conversion of first crystals into bulk Penicillin (with the addition of Potassium, Sodium and Procaine salts) and the actual efficiency achieved during 1966-67 to 1974-75:

Product	Standard efficiency Qty.	1966-67		1967-68		1968-69		1969-70		1970-71	
		Output consumed	Qty.	Output consumed	Qty.	Output consumed	Qty.	Output consumed	Qty.	Output consumed	Qty.
Procaine	90	36.047	30.933 (85.81)	32.669	29.988 (88.73)	35.418	31.877 (90.00)	37.873	33.667 (88.86)	37.888	33.124 (87.54)
Sodium	80	3.438	2.225 (64.75)	15.563	9.233 (59.33)	22.523	13.556 (60.19)	29.825	17.436 (58.46)	28.125	16.285 (57.90)
Potassium	80	36.595	29.886 (81.67)	11.809	8.959 (75.87)	5.948	4.770 (80.20)	2.473	1.687 (68.22)	3.986	2.936 (73.66)
Penicillin V	75	11.108 (67.83)	7.535	12.743 (73.35)	9.334	9.923 (77.48)	7.688	12.007 (75.67)	9.086	12.248	8.461 (69.08)

Product	Standard Efficiency	1971-72		1972-73		1973-74		1974-75		
		Qty. Con- sumed	Output							
Procaine	.	90	46.081	39.740 (86.23)	52.94	46.74 (88.30)	45.87	40.65 (88.60)	37.96	32.84 (86.50)
Sodium		70	22.965	14.611 (63.62)	26.32	17.48 (66.40)	31.97	21.26 (66.50)	35.88	25.77 (71.80)
Potassium		80	4.239	3.078 (72.61)	3.00	2.43 (81.00)	2.78	2.24 (80.60)	2.52	1.96 (77.80)
Penicillin	.	75	14.458	10.142 (70.15)	19.52	14.76 (75.60)	12.60	9.52 (75.60)	4.86	3.66 (75.30)

Note: — The figures in brackets indicate percentage of actual efficiency.

2.40. The installed capacity for production of bulk penicillin has been taken by Management as 84 MMU. The product mix envisaged being Procaine Penicillin 'G' as 48 MMU and Sodium Penicillin and Potassium Penicillin (G&V) as 36 MMU. For planning the production no *inter-se* proportions are fixed for manufactured of Sodium and Potassium Penicillin (G and V). The Ministry contended (August, 1973) that it is not possible to work out any *inter se* fixed ration beforehand and to stick to the same as the production of Sodium and Potassium Penicillin 'G' and 'V' has to depend on the market demand.

2.41. It is seen that the efficiency actually achieved was generally less than the standard efficiency of 90 per cent, 70 per cent, 80 per cent and 75 per cent fixed for conversion of first crystals into bulk Penicillin and with addition of Potassium Sodium and Procaine salts. The actual efficiency in the case of Sodium Penicillin varied from 58 per cent to 72 per cent and was appreciably lower than the standard efficiency from 1967-68 to 1970-71. The actual efficiency during 1970-71 in respect of Procaine Penicillin, Sodium Penicillin and Penicillin 'V' was lower as compared with 1969-70, whereas the efficiency achieved during 1969-70 was lower than 1968-69 in all cases.

2.42. On an enquiry whether the reasons for low efficiency were analysed, it was revealed that lack of enforcement of protocol laid down for optimum efficiency of production resulted in serious losses in production. Certain instances of not observing the protocol were by way of not following strictly the operating parameters like maintaining optimum temperatures and air pressures in the fermenters, uniformity of raw materials, addition schedule etc. It has been stated that the lack of enforcement of protocol was due to lack of facilities like temperature controls, monitoring agents, improper conditions like leakage of steam and non-availability of crucial raw materials, obsolescence of equipment and negligence on the part of employees.

2.43. On an enquiry of the Committee whether all that was necessary was being done in the matter, the Managing Director informed the Committee during evidence that:—

“...it was found that the proper procedures were not being followed by the operating personnel. There were certain reasons for them. Firstly there was lack of rigid control by the supervisory people and the second was obsolescence of equipments. Equipments 20 years old cannot be precisely controlled. When we went into this matter in depth these reasons came to light.

The Administration took a very serious note of it. The Head of Production and the Head of Engineering, both were removed. People were told that hereafter the responsibility will be fixed. Old equipments are being replaced in course of time. This is also being done. People have been told that they cannot get away with such things.

2.44. In regard to replacement of equipment, H.A.L. informed in a note that the Penicillin plant was commissioned in 1955. The normal life of the assets is about 15 years. Replacement of the assets became due during the last 5 years only. The expenditure on replacements already carried out was approximately Rs. 20 lakhs and it has been proposed to have further replacements during the next 3 years, i.e. 1975-76 to 1977-78 as follows:—

1975-76.....Rs. 9.5 lakhs.

1976-77.....Rs. 9.0 lakhs

1977-78.....Rs. 9.0 lakhs.

2.45. As regards obsolescence, it was explained that the existing plant was commissioned in 1955 when antibiotics manufactured was in the stage of its infancy in India and since then there had been several improvements in the design etc. of the equipment employed in antibiotics plant as a result of which the design of the existing plant had become outmoded. While replacing any equipment it had been ensured that to the extent possible, it was replaced by an improved design, e.g. the original extraction equipment which was Luwesta type equipment had been replaced by a Podbielnak, thus taking care of obsolescence to some extent. Similarly the old Rotary Vacuum filter was being replaced by Pre-coat rotary vacuum filter of improved design.

2.46. It was, however, mentioned that piecemeal replacement of equipment by equipment of improved design would not provide a substitute for a completely new plant of modern design, which would cost over Rs. 3 crores. In fact, this would amount to commissioning a new plant altogether.

existing plant and replace it by a new plant of upto date design with a view to eliminate the problem of obsolescence. However, in the expansion plan included in the Fifth Plan, some of the old fermenters of smaller size would be replaced the fermenters of bigger size and improved design and the old fermenters would be used for other expansion and diversification projects.

2.48. The Committee note that utilisation of installed capacity for production of first crystals gradually increased from 1966-67 to 1972-73 though there was a set-back in 1967-68 and 1970-71 but it again showed an increasing trend upto 1972-73 and thereafter declined. The Committee were informed that the target is fixed as high as possible to motivate the production personnel and the yield of first crystals depended on the activity of strain in the fermenter. The Committee are not convinced of this argument and feel that it should have been possible for the undertaking to take timely remedial measures to attain atleast the targeted capacity.

2.49. The Committee regret to note that the efficiencies actually achieved in the conversion of first crystals into bulk Penicillin (with the addition of Potassium, Sodium and Procaine salts) were generally less than the standard efficiencies of 90 per cent, 70 per cent, 80 per cent and 75 per cent fixed by the Management during the period 1966-67 to 1973-74 except in the case of Penicillin V where the percentage of efficiency was more than the standard in 1968-69, 1969-70, 1972-73, 1973-74 and 1974-75 and Sodium during 1974-75, Potassium during 1972-73 and 1973-74 . The Committee are informed that loss of production in this regard was due to lack of enforcement of protocol laid down for optimum efficiency of production e.g. non-observance to operating parameters like maintenance of optimum temperature and air pressures in the fermenters caused by lack of facilities like temperature controls, monitoring agents, leakage of steam, non-availability of crucial raw materials obsolescence of equipment and negligence on the part of employees. The Committee see no reason why the protocols laid down for optimum efficiency of production could not be enforced. The Committee feel that, had there been a proper and effective system of control over the different stages of production, it should not have been difficult for the management to have identified the causes of low efficiency and taken concerted measures to realise the protocol standards. It has been admitted during evidence that "it was found that proper procedures were not being following by the operating personnel. There was lack of rigid control by the supervisory people and there was also obsolescence of equipment."

2.50. The Committee are informed that the matter was gone into in depth and action had been taken to remove the Head of the Engineering Division and the Head of Production and also for replacement of equipments. The Committee recommend that the management should draw lessons at least now and introduce without any further delay an effective system of management control over the different stages of production so that deficiencies at each stage are identified promptly and suitable remedial measures taken without loss of time and production.

2.51. In regard to the replacement of equipment, the Committee are informed that an expenditure of Rs. 20 lakhs has already been incurred and it is proposed to have further replacements for the next three years by spending Rs. 27 lakhs. It has also been stated that the existing plant which was commissioned as far back as 1955 has become outmoded in design and therefore it is desirable that to the extent possible equipments are replaced by those of improved design. The Committee are also informed that piecemeal replacement of equipment of improved design would not provide a substitute for a completely new plant of modern design which would cost Rs. 3 crores and it is not proposed to discard the existing plant and replace it by a new plant of upto-date design. The Committee would like the comparative economics of replacement of equipments in piecemeal vis-a-vis wholesale substitution to be most carefully gone into with particular reference to the new strain proposed to be imported. The Committee would like to be informed of the result of such a study.

2.52. The Management stated in March, 1972 that operations of Potassium 'G' (having a higher efficiency and higher margin of profit) had to be reduced and the operations of Sodium 'G' (having a lower efficiency and lower margin of profit) progressively increased over the years in view of the shift in market demand. It is, however, observed that while there was no import of Potassium 'G' during 1969-70 and 1970-71, a quantity of 30 MMU (in the form of 1st

crystals) was imported in 1971-72 at a cost of Rs. 39.20 lakhs (CIF value) apparently to meet the internal demand and any possible requirement during emergency.

The actual production of bulk Penicillin during 1966-67 to 1974-75 as compared with the targeted production (both original in revised) and the installed capacity is given below:

Figures in MMO)

Production	Installed capacity equivalent to Pen. 'G'	Original estimates	Revised estimates	Actual production	Actual production equivalent to Pen. 'G'	Percentage of production to installed capacity
1966-67	Pen G. 66 Pen. V. 18	77.00 6.00	67.58 7.74	58.38 7.35	} 69.40	82.62
1967-68	Pen. G. 66 Pen. V. 18	70.55 12.00	49.98 9.13	45.16 8.01		
1968-69	Pen. G. 66 Pen. V. 18	70.00 9.60	46.90 10.63	47.15 8.63	} 60.10	71.55
1969-70	Pen. G. 66 Pen. V. 18	55.50 12.00	55.29 9.38	51.04 9.30		
1970-71	Pen. G. 66 Pen. V. 18	64.45 10.00	50.98 7.85	50.70 7.53	} 62.00	73.81
1971-72	Pen. G. 66 Pen. V. 18	58.55 10.00	52.92 10.57	56.35 9.97		
1972-73	Pen. G. 66 Pen. V. 18	59.44 12.00	67.75 14.40	66.97 14.90	} 89.32	106.33
1973-74	Pen. G. 66 Pen. V. 18	73.50 13.50	71.80 12.87	66.31 8.81		
1974-75	Pen. G. 66 Pen. V. 18	87.00 12.00	53.37 8.07	58.10 4.73	} 65.20	77.61

NOTE :—The figures of actual production as given in this table) do not agree with those indicated in sub para 2.9 on account of the fact that the former figures do not include the working-progress.

2.53. The original targets for Penicillin 'G' were higher than even the installed capacity during 1966-67 to 1968-69 and during 1973-74 to 1974-75. On the other hand, the original targets for Penicillin 'V' were always lower than the installed capacity. The revised targets were mostly lower than the original targets (except in few cases) and the actual production was still less than even the revised targets (except during 1968-69 and 1971-72 and 1974-75 in the case of Penicillin 'G' and during 1972-73 in Penicillin 'V'.

2.54. The reasons for sortfalls as explained by the Management are:—

1966-67

- (i) Production of bulk Penicillin, specially of Procaine, was deliberately cut down as the demand was much less than anticipated and the capacity was diverted to the production of Aureofungin.
- (ii) Interruptions in the supply of power, shortage of services like compressed air, chilled water, steam, etc. and break down of plant and machinery.

1967-68

- (i) Accident in May, 1967 to the extractor reduced the extraction capacity and consequently the utilisation of the fermentation capacity.
- (ii) Dislocation in power supply in December, 1967 and early part of January, 1968 due to earthquake.
- (iii) Lack of adequate services mostly due to breakdown of equipments. There were frequent breakdowns of production equipments also on account of considerable shortcoming in the working of Engineering Department.

Inadequacy of services due to shortcomings of the Engineering Department do not appear to have been investigated.

1968-69

Larger production of Sodium Penicillin to meet the demand. Efficiency of Sodium Penicillin was low as compared to the other products.

1969-70

Equipment breakdown and modifications in process equipment resulting in shutdown for some time.

1970-71

High percentage of rejects in Sodium operations due to teething trouble in the new unit commissioned in April, 1970 for "non-sterile to sterile" operations.

1971-72

- (i) Shortage of water during the first quarter resulting in prolonged Penicillin fermentation cycles which curtailed the number of batches that could be taken up.
- (ii) Frequent power fluctuation.
- (iii) Suspension of operations in the Penicillin recrystallisation section due to infiltration of insects in the working area.
- (iv) Breakdowns of extractors, air compressor services and refrigeration services.

1972-73

The setback to production due to mechanical failures, breakdown of air-compressor and in the steam plant problem of sterility due to leaks in airlines.

1973-74

- (i) Shortage of essential raw materials like butyle acetate and phosphoric acid.
- (ii) Grounding of Luwests extractor.
- (iii) Non-availability of Octodecanal (imported item).
- (iv) Low efficiencies.

1974-75

- (i) Shortage of essential raw materials, like butyle acetate, sulphuric acid, phenyl acetic acid.
- (ii) Failure of one big fermenter for a substantial period.
- (iii) Low efficiencies and mechanical break-down.

2.55. During the years 1966-67 to 1969-70 and 1971-72, Penicillin to the extent of Rs. 1.92 crores had to be imported, a part of which (Rs. 0.68 crore) could have been avoided if the Company had been able to produce according to its installed capacity.

2.56. In regard to the reasons for shortages of raw materials, HAL explained in a written note as follows:—

“The year 1974-75 has been a year of scarcity specially, for solvents due to heavy expots and abnormal increase in prices of naphtha. The Company is facing an acute shortage of cash, as a result of which suppliers bills remained outstanding for long due to which requirements of this Company received lower priority with the suppliers. As a result of this, it has not been possible to ensure uninterrupted supply of raw material specially of solvents. Its formulations are sold to Government Institution, which take about three months to pay.”

2.57. Noting that the breakdown of the machinery and equipment was one of the major causes for shortfall in production in May, 1971, the Management introduced a scheme of preventive maintenance of the entire plant and machinery. The introduction of the scheme was brought to the notice of the Board of Directors in September, 1971 and a review of progress/shortfall in implementation of the scheme is being placed before the Board at every meeting thereafter. During October, 1971 to March, 1975 the preventive maintenance schedule was implemented only to the extent shown below:—

1. Mechanical Equipment	80 per cent
2. Electrical Equipment	88 per cent
3. Instrumentation	58 per cent

The shortfall in the preventive maintenance was attributed by the Management (December, 1971) to (i) the working units being few, any interruption would cause difficulties in production (ii) delay in delivery of new refrigeration units and (iii) high incidence of absenteeism in April and May, 1972.

2.58. In regard to non-implementation of maintenance schedule, H.A.L. stated in a written note that a system of Planned Preventive Maintenance for the entire plant and services had been introduced in a phased manner from 1971, and more and more equipments/sections had been covered under the Preventive Maintenance Scheme progressively. Thus, certain Category equipments where a certain amount of breakdown did not affect the operations at preceding and succeeding stages and ultimate output, were not covered under Preventive Maintenance scheme originally. As a

result of this, implementation of maintenance schedules was lower in the previous years and this was improved progressively, as shown below:

Year	Mechanical			Electrical			Instrumentation		
	1	2	3	1	2	3	1	2	3
1972 .	52	41	79%	38	28	74%	31	12	39%
1973 .	87	70	80%	70	61	87%	48	25	52%
1974 .	88	68	77%	91	84	92%	48	33	69%
1975 (Jan-June)	99	81	82%	101	97	96%	67	49	73%

1. Average number of equipments scheduled/week
2. Average number of equipments attended/week
3. Percentage Implementation.

2.59. Non-availability of certain vital spare parts and components at the right moment and necessity to employ the workmen for certain urgent jobs at times other than the scheduled preventive Maintenance jobs did affect full implementation of maintenance scheduled. Non-implementation of Preventive Maintenance schedules did affect production case the equipment in question was a vital one.

2.60. The Committee note that the original targets for Penicillin G were higher than the installed capacity during 1966-67 to 1968-69 and 1973-74 to 1974-75. On the other hand the original targets for Penicillin V were always lower than the installed capacity. The revised targets were mostly lower than the original targets (except in a few cases) and the actual production was still less than even the revised targets (except during 1968-69, 1971-72 and 1974-75 in the case of Penicillin G during 1972-73 in Penicillin V. In the opinion of the Committee targets fixed by the Undertaking represent what can actually be achieved. If so, the Committee see no reason why it should not have been possible to achieve such targets by concerted efforts instead of revising them downwards because of constraints or inefficiency in production.

2.61. The Committee are informed that shortage of essential raw materials like butyle acetate, phosphoric acid, sulphuric acid and phenyle acetic acid was one of the reasons for short-fall in production of Penicillin during 1973-74 and 1974-75. The shortage of raw

materials has been attributed to heavy exports of solvents, abnormal increase in price of naphtha and acute shortage of cash. It has been stated that as a result of the shortage of cash, the suppliers' bills remained outstanding for long due to which requirements of the undertaking received lower priority. The Committee are shocked at this state of affairs in the working of a Public Undertaking where credit worthiness of the undertaking has become so low as to have affected even the purchase of essential raw materials and production of an essential drug like Penicillin was allowed to suffer on this account. The Committee recommend that this matter should be enquired into and responsibility fixed. The Committee feel that these are matters which should have been gone into by Board of Directors particularly the Managing Director and the Government representative on the Board.

2.62. The Committee apprehend that the system of billing and realisation of dues of the company is not foolproof and effective follow up action had apparently not been initiated. The Committee have given specific recommendations on these aspects in a separate chapter of the Report. The Committee also recommend that a case study should be made to draw suitable lessons in order to obviate recurrence of such a situation in this or any other public sector undertaking. The Committee would like that this matter should be gone into in depth so as to take corrective action and to streamline procedure in order to ensure that such a situation does not recur.

2.63. The Committee also note that the break-down of the machinery and equipment was one of the major causes of short-fall in production almost through the period 1966-67 to 1974-75 resulting in lack of adequate services. The Committee are surprised to note that it was only in May, 1971, i.e. 16 years after the commissioning of the plant, that the Management took serious note of shortfall due to break-down of machinery and introduced a scheme of preventive maintenance of the plant and machinery. The Committee cannot but view it as an instance of gross negligence on the part of Management that they operated the plant for 16 years without any regular system of preventive maintenance. The Committee also find that frequent break-down of production equipments were reported to be due to considerable shortcomings in the working of engineering department which do not appear to have been investigated. The Committee recommend that the entire matter regarding lack of preventive maintenance for such a long time should be investigated immediately with a view to fix responsibility for the lapse.

2.64. The Committee also regret to note that even after introduction of the system of preventive maintenance in 1971 the preventive maintenance schedule has not been implemented fully during the period 1971 to 1975. It was implemented to the extent of 80 per cent in the case of mechanical equipment, 88 per cent in the case of electrical equipment and only 58 per cent in the case of instrumentation. Non-availability of certain vital spare parts and components at the right moment and necessity to employ the workmen for certain urgent jobs at times other than the scheduled preventive maintenance jobs are reported to have affected the full implementation of maintenance schedules. The Committee are not convinced by the reasons advanced for non-implementation of the maintenance schedules which, as the undertaking has confessed, affected production. The Committee cannot but deprecate the negligence shown by the Management first in not introducing any regular preventive maintenance schedules for 16 years and thereafter not implementing the schedules regularly. They recommend that the reasons for non-implementation of the maintenance schedules since 1971 should also be investigated with a view to fix responsibility and adequate measures taken to ensure that at least in future the schedules for maintenance of the plant and equipment are adhered to. The Committee also recommend that Government/Board of Directors would ensure that preventive maintenance protocols are in-built into the system right from the inception and such protocols are actually adhered to.

B. Streptomycin

2.65. In 1958 H.A.L. entered into an agreement with Messrs Merck & Co. of U.S.A. for the manufacture of streptomycin sulphate under licence. The plant was inaugurated in 1962. The original capacity of 40,000—45,000 Kgs. of the plant was increased to 80,000—90,000 Kgs. in November, 1965 (the first fermentor of the expansion project was commissioned in January, 1965). The expansion project was, however, finally completed in 1969-70.

2.66. In December, 1969, the Board of Directors approved further expansion of the capacity of this plant to 1,60,000—1,70,000 Kgs. per annum at an estimated cost of Rs. 350 lakhs (including foreign exchange component of Rs. 140 lakhs) and requested the Government to include the project in the Fourth Five Year Plan. Government's sanction was awaited still March, 1975.

2.67. The Management stated in May, 1973 that at the time of approaching the Government the profitability of the expansion project was worked out under the different methods one with the continued use of the strain then currently in use and the other

based on the use of an improved strain. Government decided to consider the project only after it became certain that the Company would acquire a new strain. The Company acquired a new strain in September, 1974.

2.68. Formulation. The first two stages in the production of Streptomycin *viz.* fermentation and extraction are similar to those in Penicillin. There are 10 fermentors, each with a capacity of 20,000 U.S. gallons (equivalent to 70,000 litres). Out of these, one fermentor has been allotted for preventive maintenance and 9 are available for production having a fermentation capacity of 1,80,000 U.S. gallons. Assuming a normal cycle of 260 hours (including 25 hours down time), the Management have estimated that 300 batches can be seeded in a year. Standard curves showing the rate of growth of titres are prepared by the Company based on the results of sample batches. Decisions to continue fermentation of broth or harvesting are taken by comparing performance from time to time of the batches against the standard curve.

2.69. The number of batches targetted for seeding, actual number seeded and harvested during the years 1966-67 to 1974-75 are shown in the statement below:

(No. of batches)

Year	Original targets	Revised targets	Actually seeded	Harvested	Drained	% of drained batches to seeded batches
1966—67	304	274	274	257	17	6.2
1967—68	302	279	284	273	11	3.9
1968—69	302	257	274	258	16	5.8
1969—70	307	300	310	301	9	2.9
1970—71	307	284	303	284	19	6.3
1971—72	305	293	302	293	9	3.0
1972—73	300	300	317	306	11	3.5
1973—74	300	300	364	356	8	2.2
1974—75	315	163	155	153	2	1.3

2.70. The percentage of drained batches to seeded batches has widely varied from year to year from 1.3 per cent in 1974-75 to 6.3 per cent in 1970-71. As no norms have been laid down by the

Management with regard to the harvesting of seeded batches, the efficiency of harvesting operations cannot be evaluated.

2.71. The original targets fixed in all the years exceeded even the capacity of fermentors as estimated by the Management except in 1972-73 and 1973-74. The number of batches actually seeded was less than the estimated capacity during 1966-67 to 1968-69 and in 1974-75 and was more during 1969-70 to 1973-74.

2.72. The Management stated in May 1972 that the number of batches targetted for seeding and the number actually seeded during 1969-70 to 1971-72 were more than the estimated capacity as attempts were made to reduce the normal cycle period of 260 hours. The number of batches seeded during 1966-67 to 1968-69 were less as the doubling of streptomycin plant, though commenced in 1965, could be completed only in 1969-70.

2.73. During evidence the Managing Director of Hindustan Antibiotics Ltd., explained:—

“If there is low activity of the strain, it would be highly uneconomical, particularly after inflation, to produce streptomycin and to sell it at a low price. In 1974-75, dextrose was not available at all due to non-availability of maize in Gujarat due to drought. And so we were asked to arrange for the maize from Punjab. Even we had to arrange for the wagons. We could not do anything. So, we had to go to Government. In fact, we were not only worried about our problems but we were also worried about the problems of the suppliers. When the need arose some time in 1974-75, we actually went to Government. We were wanting to shut down the streptomycin plant—the highly sophisticated equipment—to produce the streptomycin at this rate and sell it at the controlled price. The Government naturally told us that we should not shut down the plant because there would be a shortage of streptomycin and we might have to import it. In fact, Government promised us loans. At that time we were negotiating with Glaxo to get the new strain. We have now introduced the strain but, during the transition period, we had to go slow because production had to be stabilised. Production had suffered during the transition period. The cycle is now actually being adjusted with regard to new strains. And we shall be stabilising it this year.”

2.74. It was explained that the output would depend upon the quality of the strains. So, if there were more batches of better quality seeds than the output would automatically go up. If there were less number of batches, even with the better seeds, the output would go up. One had to look to both the things—output and the number of batches—because the number of batches multiplied by the quality of the strains would naturally increase the production. The Managing Director however added as follows:—

“In this industry the longer the cycle, the more the productivity if it is maintained at a certain level. For example to get 30,000 units, the plant may have to go upto 300 hours. Today our strain gives 10,000 units even if the plant may have to run half of it, that is, upto 150 hours.

The vital economics is when you start the batch you are to have all the raw material. If the batch is prolonged you will be having less and less of the output. This is what we are doing in the new strain of streptomycin.”

2.75. In regard to the problem of dextrose, the Managing Director informed the Committee during evidence that—

“Sir, we have replaced dextrose by starch and we are getting enough starch from Kerala. It is available in plenty. If that is not available we can buy maize starch. By this change we have achieved two objects—firstly, we have reduced the cost and secondly, we have now more sources of starch and do not depend on two manufacturers of Ahmedabad. This year we are in a much safer position than before.”

Titre yield and broth obtained:

2.76. During fermentation Streptomycin A & B are produced. The latter is biologically inactive and is therefore separated from the former during the process of recovery. The Company has fixed a standard titre yield of 7000 units of microgram per millilitre of broth. In a standard batch, the B content (to be removed) is about 12 per cent to 14 per cent. The quantity of broth expected to be

obtained and actually realised with reference to the calcium chloride complex (c.c.c.) content is given in the table below:

Year	Standard volume (broth) per harvested batch excluding B content @ 12% (litres)	Standard titre yield per Millilitre of broth (microgram)	Actual average volume (broth) per harvested batch (litres)	Actual titre yield per millilitre of broth (microgram)
1966-67 .	61,600	7,000	62,755	1,144
1967-68 .	61,600	7,000	61,012	7,084
1968-69 .	61,600	7,000	63,095	5,973
1969-70	61,600	7,000	64,076	6,423
1970-71	61,600	7,000	62,384	5,335
1971-72 .	61,600	7,000	61,638	6,044
1972-73 .	61,600	7,000	61,438	6,334
1973-74 .	61,600	7,000	67,989	6,560
1974-75	61,600	7,000	61,967	14,549

NOTE : 1 Litre = 1000 millilitres
1000 microgram = 1 milligram
1000 milligram = 1 gram

2.77. The actual volume (broth) obtained per harvested batch was generally more than the standard yield except in 1967-68 and 1972-73. It was the highest in 1973-74.

2.78. The titre yield per millilitre of broth which during 1966-67 and 1967-68 was more than the expected yield, came down in 1968-69; with some improvement in 1969-70, it again decreased in 1970-71 which was the lowest. It again registered an increase from 1972-73 onwards.

2.79. The substantial increase in titre yield during 1974-75 was mainly due to the introduction of a new strain.

2.80. The first strain for production of streptomycin was introduced in 1962 and the new strain in the year 1974.

2.81. Clause 4 of the agreement with Merck & Co. provided that:—

“During the ten (10) year period provided for in paragraph 8(b) MERCK shall keep The Company currently informed of any improvements made by MERCK in the process or subcultures for the production of streptomycin. The

Company shall likewise keep MERCK currently informed of any improvements it makes in the process or subcultures for the production of Streptomycin.

Also during such ten (10) year period MERCK and the Company shall have the right to visit each other's streptomycin plants for periods not to exceed one month per calendar year, in order to be kept currently informed of the other's use of the process in the production of streptomycin."

2.82. HAL informed the Committee in this connection as follows:—

"Production data was being exchanged regularly every quarter with the collaborators. From the quarterly report received from Merck, it was seen that they were getting a higher titre yield than that obtained by us. In 1971 the yield obtained by them was 1100 m/ml as against 8000 u/ml obtained by HAL. In November, 1971, the company deputed two of its officers to the works of the collaborators in USA. It was understood that the collaborators were using different strain from that supplied by them to HAL. They however, informed the officers deputed to their works that this strain was required by them from M/s. Glaxo and was not their own development and HAL would not, therefore, be entitled to it. Relevant clause (No. 4) of the Agreement stipulates that Merck shall keep HAL currently informed of any improvements made by (emphasis provided) Merck. It would thus appear that the position informed by them to the Company's nominees deputed to their plant was correct. During 1972-73 discussions were held with M/s. Merck & Co. regarding the possibility of obtaining the new technology from them and it transpired that there was possibility of getting the technology directly from M/s. Glaxo as M/s. Merck could not pass on the same to HAL under the agreement."

2.83. It was further stated by HAL in a written note that "On learning from Merck that the improved strain used by them in their plant was obtained by them from Glaxo the matter was pursued with Glaxo. From the information gathered from Glaxo, it was clear that the improved strain was supplied by Glaxo to Merck." As the agreement did not require Merck to supply the improved strain which had been obtained by them from Glaxo to HAL, the question of claiming compensation did not arise.

2.84. On an enquiry of the Committee during evidence as to how HAL assured itself that Merck were using the same strain which they had supplied to HAL and not a strain from elsewhere the Managing Director stated as follows:

“By sending our people to Merck and studying their process and also checking with Glaxo”.

2.85. On another query as to when Merck shifted to Glaxo strain, the Managing Director stated—

“According to our representatives who went there they switched around 1967. We sent our representatives in 1971 because we wanted to know how they are getting higher productivity when we are following their technology. Then our representatives came to know that they were using Glaxo strain.”

2.86. The Committee were also informed during evidence that “Merck used to send every three months their performance reports. That data was available.” It was admitted by HAL in a note—

“The performance reports received from Merck showed that they were obtaining a higher titre since 1967. The fact that this was due to use of a better strain acquired by Merck from Glaxo however came to be known only when two officers of the Company were deputed to Merck's plant in 1971. The question of delay in deputing officers of the Company to Merck's plant has not been investigated. Apparently the matter was not pursued as it should have been.”

2.87. On the Committee enquiring whether it was not desirable on the part of the Management to look to the improvement or to look to the quality of strain which Merck were using and how it was that it occurred to the Management in the year 1971 only to send two persons to find out the strain being used by Merck, despite the agreement that both shall have the right to visit each other's streptomycin plants for periods not exceeding one month per calendar year, the Managing Director stated—

“I cannot offer any valid reasons.”

2.88. In July, 1972 M/s. Glaxo Laboratories were approached for strain and technology and an agreement was finalised with them in November, 1973.

2.89. In regard to the agreement with Glaxo, the Managing Director informed the Committee—

“It is a rather peculiar agreement with Glaxo. Our Company does not pay anything to Glaxo. They supply us the strain, they send us their man; he introduces the strain and then our people work on it. There is no guarantee as to what they will do hereafter because it was a sort of *quid pro quo* or something which we got through Government's good offices. You can say, we got free. When you get free, you cannot impose any terms.”

2.90. In this connection the Secretary of the Ministry also informed the Committee that—

“It is not absolutely unconditional in the sense that we are not permitted to sell this strain to others. In fact we have got this strain free. We have not paid any money for it. We cannot sell the strain or pass it on to others. This is a normal condition.

2.91. As regards the titre yield of the new strain obtained from Glaxo, the Chairman stated during evidence that HAL got an average of 18,000 units/ml and occasionally 24-25,000 units/ml. from the new strain.

2.92. The quantity of broth expected to be obtained and actually realised with reference to the calcium chloride complex (c.c.c.) content is given at paragraph 2.76.

Extraction :

2.93. On the basis of standard volume (excluding B content and the standard yield as indicated in the table calcium chloride complex of Streptomycin per harvested batch works out to 430 kgs. Assuming an efficiency of 75 per cent the Management have fixed a standard yield of 320 kgs. of net c.c.c. 'A' content per harvested batch. The actual average yield obtained during 1966-67 to 1974-75 was 296 kgs., 291 kgs., 288 kgs., 303 kgs., 246 kgs., 255 kgs., 283 kgs., 276 kgs., and 526 kgs., respectively. However, standard yield had been achieved from certain batches during these years.” The increase in the yield in 1974-75 was due to introduction of a new strain.

Final Product :

2.94. The calcium chloride complex of Streptomycin is converted into Streptomycin Sulphate which is the ultimate product. On the

basis of 85 per cent efficiency, the standard yield of Streptomycin Sulphate from c.c.c. 'A' content has been fixed by the Management at 272 kgs. per harvested batch. The maximum annual production from the Streptomycin plant thus works out to 81,600 kgs. (300 batches X 272 kgs.). The targeted and the actual production of Streptomycin Sulphate during the years 1966-67 to 1974-75 are given below:

(Figure in kgs)

Year	Targeted production		Actual production	Shortfall as compared to original targets
	Original	Revised		
1966-67 . . .	80,400	68,425	60,670	19,730
1967-68 . . .	80,800	66,027	66,393	14,407
1968-69 . . .	81,000	67,005	70,253	10,747
1969-70 . . .	83,246	80,007	83,138	108
1970-71 . . .	83,246	62,578	60,971	22,275
1971-72 . . .	72,577	65,741	61,474 ^{564*}	10,539
1972-73 . . .	80,330	75,000	72,350	8,000
1973-74 . . .	80,000	72,150	64,027	15,973
1974-75 . . .	85,680	62,780	63,370	22,310

*feed grade

NOTE : The targets for 1971-72 were fixed at a figure lower than the maximum production of the plant on account of the problems faced from the use of indigenous soyabean meal during 1970-71

2.95. The following reasons have been attributed for shortfall in production:

1966-67—

- (i) Interruption in power supply, shortage of services, frequent break-downs of plant leading to lesser utilisation of the installed capacity.
- (ii) About 7 to 8 tonnes of Streptomycin could not be produced on account of shortage of methanol during July, August and September, 1966.

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1967-68—

(i) Lack of adequate services and frequent break-downs of equipment. Against 302 fermentors budgeted for the year, only 273 fermentors were harvested.

(ii) Shortage of quality raw materials.

1968-69—

Shortage of imported soyabean meal of the required quality in the first half year.

1970-71—

Mainly due to shortage of imported soyabean meal and its substitution by indigenous soyabean meal which considerably affected the process efficiency and also volume of products.

1971-72—

Quality of soyabean meal affecting operational efficiencies in Streptomycin plant.

1972-73—

(i) Non-availability of essential raw materials, e.g., hydrochloric acid and soyabean oil.

(ii) Break-down of air compressor and in the steam plant problems of sterility due to leaks in airlines.

1973-74—

Shortage of raw materials, e.g., sulphuric acid, dextrose, Octadecanol and ammonia.

1974-75—

(i) Introduction of new high yielding strain in the plant and necessary adjustments made in the process, resulting in stoppage of plant for a substantial period.

(ii) Substitution of expensive dextrose by starch hydralyante by a process developed by R. & D.

2.96. During 1969-70 the actual production was, however, higher than the targets on account of the availability of good quality soyabean meal throughout the year.

2.97. It is seen that some of reasons for shortfall in production of streptomycin sulphate during 1966-67 to 1973-74 would appear to

be of a nature which could, with timely action, have been avoided e.g., shortage of services, shortage of soyabean, etc. To this H.A.L. replied in a note as follows:—

3. Prior to 1971, there had been no system of planned preventive maintenance for the plant. This was first introduced from 1971 and gradually increased. In the absence of the same, there was frequently break-down in equipment which affected the availability of services. It is a true that had timely action been taken to introduce planned preventive maintenance, the shortage of services could have been avoided to a large extent. As regards soyabean meal, this item used to be imported in earlier years. As soyabean meal was cultivated in the country, it was decided to switch over to the indigenous product. The Government would not also permit import of the same. Although soyabean is cultivated in the country, its use so far had been restricted for commercial purpose. The quality of soyabean meal fit for use in the antibiotic industry had to be established through a series of trials of the product offered by different companies. Until adequate source of suitable quality of soyabean had been established, the material was in short supply. The problem has however been resolved successfully since.

2.98. In regard to the necessity for review of standard efficiency, standard yield, installed capacity, etc. at the different stages of production of streptomycin sulphate, as fixed by the Management, by an independent agency HAL stated in a note:

“The standards have been evolved based on the experience gained over the years. Review of these by an independent agency would not be feasible or even desirable as there is no independent agency as such available to our knowledge for these purposes and it would not obviously be desirable to entrust these to competitors as it cannot be expected that objective and disinterested advice would be received from them. Engagement of agencies engaged in purely academic work would not also be useful as such agencies would not have any practical experience and the standards suggested by them would not have any relationship to the conditions obtaining in this plant. The company is setting up an independent technological cell to review such standards from time to time.”

2.99. In regard to further expansion of this project, the Secretary, Ministry of Petroleum & Chemicals stated that Government had

reservations based purely on the question of demand. Now while, at one time, it was estimated that streptomycin demand might go up to 875 tonnes. this was scaled down ultimately by the Ministry of Health to 450 tonnes. But, in the last two years, the consumption has been stabilising round about 230—250 tonnes. Now, based on this, the question arises as to whether it would be wise on to go in for any massive investment. One reason for the slackening of demand appears to be this. Streptomycin, is an anti-biotic which is used practically for fighting TB. But, out of the streptomycin produced in the country, only about one-third goes directly as streptomycin for anti-TB operations and the balance two-third goes as a mixture of streptomycin and penicillin sold as strepto-penicillin for fighting other infections. Since these infections have competitive products, it is this two-thirds which is facing a growing difficulty in relation to demand. The quantum required for anti-T.B. operations will, of course, grow. But, since the total availability of streptomycin is not restricted to this perhaps, a much closer look is necessary at the future possibilities.”

2.100. While confirming the above position the Drug Controller informed the Committee that:

Now, so far as the requirement for TB was concerned, streptomycin would continue to be used as a drug for treatment to TB, although this is not the sole drug which is used. There were other drugs like INH and PAS which were also used. Further, in regard to its requirement for strepto-penicillin, it was generally observed that there is today a reluctance in the use of penicillin. This was also reflected in the requirement for penicillin, which had not reached a very high figure expected earlier. Doctors were reluctant to use penicillin because of penicillin anaphylactic reaction. It is found that the demand was going up very steeply for other drugs like ampicillin which were much safer. This demand for ampicillin was reflected in the slackening of demand for penicillin. In other words, the requirement of streptomycin which was used for strepto-penicillin is likely to be affected in the years to come.

2.101. On an enquiry of the Committee that with HAL acquiring a strain from Glaxo giving a titre yield of 18,000 millilitre per unit and with this reduction in demand, whether the improved titre yield

itself would not be sufficient, the Secretary of the Ministry stated—

“This was precisely the question which was raised by the Planning Commission, Ministry of Finance and others when the proposals came from the HAL for further investment. The question was put to them ‘Can you not, with your existing investment, improve the production by better strains, increasing productivity and by more efficient production?’. The point made by you was precisely in Government’s mind and we do believe that with the constraints on expansion and demand for streptomycin, we might perhaps be able to manage with improved productivity, of course, with marginal investments.”

2.102. During the period from 1966-67 to 1971-72 the total import bill of the country in respect of Streptomycin was Rs. 5,25 crores out of which import to the extent of Rs. 1.16 crore could have been avoided had the company been able to produce according to its installed capacity.

2.103. The Committee note that the management of HAL have estimated that 300 fermentation batches can be seeded every year assuming a normal cycle of 260 hours. Though the original targets fixed in all the years upto 1971-72 and in 1974-75 exceeded even the capacity of fermentors estimated by the Management, the number of batches actually seeded was less than the estimated capacity during 1966-67 to 1968-69 and 1974-75 and was more during 1969-70 to 1973-74. The percentage of drained batches to seeded batches has widely varied from 6.3 per cent in 1970-71 to 1.3 per cent in 1974-75. The Committee regret to note that no norms have so far been laid down by the Management with regard to the harvesting of seeded batches with the result that the efficiency of harvesting operations could not be properly evaluated. The Committee recommend that the undertaking should, after keeping in view the equipment, the technology, operating conditions etc. and after a study of the norms obtaining with the collaborator for such operations, fix appropriate norms for harvesting so as to evaluate the efficiency of harvesting operations from time to time and take suitable remedial measures to keep the drainage within limits.

2.104. The Committee were informed that the output depended on the quality of the strain. The Committee note that the first strain for streptomycin was obtained from Merck & Co. in 1962. According to the agreement with the Merck & Co., the latter had to keep HAL informed of any improvements made by them in the process

or sub-cultures for the production of streptomycin and HAL had the right to visit the streptomycin plants of Mercks every year in order to keep itself currently informed of their use of the process in the production of streptomycin. The Committee are also informed that production data were regularly exchanged every quarter with the Collaborators. Though HAL came to know from such reports that Mercks were getting a higher titre yield than that obtained by HAL, even from 1967, the Committee regret to observe that no attempts were made by HAL to ascertain the reasons for such higher titre yield nor did Mercks furnish information about improvements made in the process or sub-culture for production of streptomycin. It was only in November, 1971 when HAL deputed two of its officers to the works of its collaborators in USA, that it came to know that the higher titre yield was due to the use of a better strain than that supplied by the Collaborators to HAL and this strain was stated to have been acquired by the collaborators from M/s. Glaxo (in 1967). According to Mercks since it was not their own development HAL would not be entitled to it nor the question of payment of any compensation would arise.

2.105. The Committee would like the Ministry to examine critically in consultation with the authorities concerned as to how far the action of Mercks in not informing HAL about the improved strain was correct with reference to terms of collaboration agreement, so that suitable action may be initiated by HAL. The Committee also see no justification for the delay of 4 years on the part of HAL in deputing its officers to Merck & Co. when it was known that Mercks were getting higher titre yield even from 1967 and when the agreement gave the right to the officers of Company to visit the plant once a year. As admitted by HAL even the question of delay and negligence in this regard has not been investigated so far.

2.106. In the opinion of the Committee it should be the specific responsibility of Management, more specially of the heads of Research & Development and Production to keep themselves fully posted with the performance of similar units in India and abroad—particularly of the collaborators. The R&D should also keep a close watch on the trends of requirements of the undertaking with a view to taking timely action to regulate/modify/diversify the pattern of production. The Committee deprecate the complacency and the negligence on the part of HAL in not keeping itself concurrently informed of the developments and improvements in the strain of streptomycin by Mercks. The Committee recommend that Government should investigate the matter and fix responsibility for the lapse.

2.107. The Committee note that the undertaking had obtained a new strain from Glaxo through Government free of cost on the condition that it would not be sold or passed on to others, and HAL has been able to attain, on an average, a titre yield of 18,000 units/ml and occasionally 24-25,000 units/ml. from the new strain. The Committee see no reason why the Ministry/HAL could not have selected the technology and strain from Glaxo even in the initial stages instead of the Merck & Co.

2.108. The Committee would like HAL to take all the necessary measures not only to get the maximum yield from the new strain but also to improve the output and effect reduction in the cost of production. The undertaking should also review the performance with reference to the new strain and take action to revise the standards of titre yield with a view to evaluating the performance with reference to such standards.

2.109. The Committee note that on the basis of 85 per cent efficiency fixed by the management the maximum annual production from the streptomycin plant has been fixed at 81,600 kgs. and targets are fixed from year to year on this basis. The Committee find that the original targets have never been achieved ever since 1966-67 and the revised targets have been achieved only during 1967-68 to 1969-70 and 1974-75. Interruption of power supply, shortage of services, non-availability or shortage of raw materials (soya beans and dextrose) of the right quality and break-down of equipment were stated to be the main reasons for the shortfall except during 1974-75 when adjustments made in process resulting in stoppage of plant consequent upon the introduction of a new high-yielding strain have been responsible for the shortfall. The Committee are informed that because of stoppage of import of soyabean meal used for production of streptomycin, there was shortage in supply till the quality of soyabean meal fit for use in antibiotics industry was established in the country. The Committee feel that the undertaking should have taken timely action to identify suitable indigenous quality and built up sufficient stock when it was known that import of soyabean was to be stopped, although the problem is however now reported to have been solved. Similarly, the problem of dextrose, which also affected production is stated to have been solved with the replacement of dextrose by starch which is easily available. The Committee recommend that now, when HAL has located sources of good quality raw materials within the country, it should make long term arrangements for their timely supply and storage so that shortage of raw materials may not affect the production of this vital drug hereafter. The Committee would also like HAL to review the production per-

formance of streptomycin with reference to the new strain and revise the standard efficiency and capacity so that evaluation of production could be done in a meaningful way.

2.110. The Committee are also informed that prior to 1971, there had been no system of planned preventive maintenance for the plant and equipment with the result that there were frequent breakdowns which affected the availability of services. HAL has admitted that "It is true that had timely action been taken to introduce planned preventive maintenance, the shortage of services could have been avoided to a large extent". The planned preventive maintenance is reported to have been introduced since 1971. The Committee deprecate the neglect of so vital a plant for over 9 years and strongly reiterate, as already recommended in this Chapter, that a thorough investigation into this matter may be held expeditiously and responsibility fixed for not introducing a schedule of preventive maintenance right from the beginning. They would further recommend that the Corporation should take all possible measures to ensure that at least now the preventive maintenance schedule is strictly followed for all plant and machinery so that they can be kept in good running condition.

C. Hamycin

2.111. The Board of Directors decided in December, 1960 to undertake the production of Hamycin—an antifungal anti-biotic evolved by the Company's Research Division, in a pilot plant having a capacity of 15 kgs. per annum at an estimated cost of Rs. 5 lakhs. The industrial licence for the setting up of the plant was granted by Government in January, 1962. Before the project could be implemented, it was decided to undertake the production of Hamycin on commercial basis in a plant having the capacity of 50 Kgs. per annum to be set up at an estimated cost of Rs. 30 lakhs. The industrial licence for the increased capacity was issued in April, 1963.

2.112. The revised project was also not implemented and in May, 1964 it was decided to increase the production capacity to 250 kgs. per annum at a cost of Rs. 55 lakhs (revised to Rs. 77 lakhs in December, 1966 due to devaluation of rupee, revision of customs duty, etc.) for which the licence was issued in February, 1965. The Company again proposed further expansion of the capacity of the plant to 1,000 kgs. per annum in the Fourth Five Year Plan (1966—71) at an estimated cost of Rs. 83 lakhs and obtained a licence therefor in August, 1966. The Company has since discontinued the production

of Hamycin from December, 1974 due to the problem of toxicity which is still under examination.

2.113. The first expansion was undertaken on the basis of anticipated demand, particularly from the U.S.A. As it was anticipated that Hamycin with Dermostatin as an ointment had a much wider use in the treatment of dermatomycotin infections, further expansion of the capacity to 250 kgs. was undertaken and completed in November, 1968 at a cost of Rs. 65.55 lakhs even before the production commenced in the first stage. The third expansion for raising the capacity to 1,000 kgs. per annum was, however, postponed in December, 1969 and the licence therefor was also cancelled by Government in March, 1970 pending the assessment of demand pattern after receipt of approval of the Federal Drug Administration, U.S.A. for systematic use of Hamycin and its formulations.

2.114. The Company took up the production of Hamycin in 1963-64 in a pilot plant and produced a total quantity of 33.614 kgs. up to 1967-68 (3.298 kgs.+11.668 kgs.+7.716 kgs.+7.032 kgs.+3.900 kgs.); Out of this, a quantity of 29.405 kgs. (3.298 kgs.+9.778 kgs.+5.601 kgs.+7.093 kgs.+3.635 kgs.) was sold in bulk, other forms and transferred to research and development, thus leaving a stock of 4.209 kgs. as on 31st March, 1968.

2.115. The Hamycin plant was completed in November, 1968. The installed capacity, budgeted production and the actual chargeable quantities produced during the last seven years are given in the following table:

Year	Installed Capacity (Bulk)	Budgeted Production		Actual chargeable quantity
		Original	Revised	
	Kgs.	Kgs.	Kgs.	Kgs.
1968-69	125	10.00	15.00	18.239
1969-70	250	30.00	3.00	0.657
1970-71	250	15.00	18.00	17.429
1971-72	250	4.00	13.30	13.011
1972-73	250	Nil	3.86	6.755
1973-74	250	32.00	12.36	21.630
1974-75	250	20.00	0.28	0.490

NOTES—1. As the expanded capacity of 250kgs. became available in November, 1968, the installed capacity for 1968-69 has been taken as 125 kgs.

2. One Kg. of product is equal 1.75 Kgs. of chargeable quantity.

2.116. The main reason for under-utilisation of the capacity is stated to be the absence of demand. As against the total cost of production of Hamycin in bulk and other formulations from 1963-64 to 1974-75 of Rs. 21.31 lakhs, the margin amounted to Rs. 2.48 lakhs, after setting off sales realisation of Rs. 15.41 lakhs, Rs. 8.38 lakhs for transfer of bulk to research and development, the closing stock valuing Rs. 1.84 lakhs has been treated as scraps (excluding write-off of 3.479 kgs. on 31-3-72).

2.117. It will be seen that instead of gradually increasing the capacity of this plant after studying the demand pattern, the company took up the implementation of the Project outright for a capacity of 250 kgs.

2.118. The Ministry have stated in September, 1973 as follows:—

“In the light of the experience gained in the case of Hamycin. . . ., the Board of Directors have decided that no new product would be taken up for commercial production until it had been subjected to an independent quality audit.

Efforts are also in progress to increase the out-turn of the product by offering it to private pharmaceutical companies for the purposes of formulations as in the case of other antibiotics.”

2.119. During the evidence of the representatives of the Company, the Managing Director informed the Committee as follows:—

“This is about one of the antibiotics developed by the company. I would seek the indulgence of the Committee. You have to judge it in retrospect. We tried to venture into research and development and tried to put out a new drug in India for the first time. In that process, certain expectations we had were fulfilled and certain others were belied. At that time this was a new antibiotic for certain types of diseases prevalent in India. It was felt by the company that the demand will pick up and so we developed the capacity. In drugs, the gestation period and obsolescence period is very low. By the time a new drug comes, the old drug may go out of existence. So, you do not have the time to sit, assess and plan. This happens in other countries also.”

In regard to assurance from a firm in USA that they would buy Hamycin from HAL, the Managing Director stated

that—

“This Company had an agreement with Sherman Laboratories International of USA who were evaluating the demand pattern of this drug in USA. They gave some idea to this Company that this kind of demand pattern will be there in market. This drug was meant for treating some fungus diseases like vaginal, mionialisis, trichomonas, etc. So, they thought that in India this drug might be useful for treating these diseases but their expectations were completely belied.”

2.120. On an enquiry of the Committee whether it was because standardisation of the drug could not be achieved that the demand in USA could not pick up or it was because of the laxity on the part of the American firm which estimated the demand in America to be of that order and on which assumption HAL went ahead with such a big plant, the Managing Director stated:—

“In a drug, first you must have a standard drug and then a market should be available for it. Then, you must have the proper market organisation to promote and make it available to public and doctors. When you have all these things, only then the demand picks up. In this case, all these four factors were not there. For example, firstly, the drug was not standardised; secondly, no market was readily available for it. Then there was no proper marketing organisation to push it through. It is difficult to say why the demand could not pick up.”

2.121. Asked as to why these steps were not taken the Managing Director stated that—

“Standardisation should be made. That was the first step. But the company had probably felt that the drug was standardized.”

2.122. The Managing Director added that the toxicity problem was non-existent till 1973-74 but came up later. It was found that the technology had undergone some changes. While the company was trying to improve the technology it failed with the result that toxicity developed.

2.123. It was also stated that it was an expensive drug. Every kilogram of it costs Rs. 28,000. One of the main objectives of the company was to reduce the cost of production, because the company was not making profit and the volume of production was low. As such, the scientists were engaged in improving the technology and

the cost of production. While they were doing these things and in improving the output per batch the problem of toxicity came in, because the potency became more. The R. & D. Division are trying to solve this problem.

2.124. Asked whether the drug was developed only for U.S. market, the Managing Director stated it was a very specific drug against certain fungus diseases affecting human beings. The company wanted to develop a new anti-biotic. It came across this anti-biotics. The development of this drug was not mainly due to the possible demand for it in America. The Company wanted to produce the drug and diversify the production because it had some possibility of market in India. In addition, it had possibilities abroad. The Managing Director also informed the Committee that the company entered into an agreement with Sherman Laboratories. Then it was transferred to another, Cooper Laboratories. The Cooper Laboratories folded up and then Nox Laboratories came. They were no longer interested in the work.

2.125. In regard to the future of the product the Managing Director stated that—

“Our first target is to standardise the drug on which we are working. R&D is working on this subject. I have not gone into the very important aspect of what is meant by standardisation. Toxicity quality is one. Stability is another. We find this drug is not stable for any length of period. You have to store it in refrigeration temperature. How many chemists shops in village have refrigeration conditions? If its life period is one year or 18 months, what is the marketing operation which could ensure that after you made it in Pimpri, it is sent to all parts of the country and it is sold within the next three months in the conditions prevailing in Assam, Kerala, Orissa or Madhya Pradesh? These are the things which weighed with the company very seriously. After all, we have gone in a particular way. We have made some anticipations and we have invested money. Today we have to be doubly careful. This has given us a very good lesson. Now we have made quality control audit an independent authority. Unless they certify, we do not touch anything. Out of our experience we have now evolved these things.

So far as marketing to Canada or other countries is concerned, unless we standardise the potentialities, it would be diffi-

cult to get into those countries. Secondly, unfortunately, as it happens, in the case of drugs, once a drug has been in current use for 12 or 15 years, very few people would get attracted to it. It becomes old. Because, in the medical profession the doctors were something new, new development, new drug. No body would be interested in something which is 12 or 15 years' old. This will run into that difficulty in the future. People have known it. They are looking for something new, not very old."

2.126. The Secretary of the Ministry of Petroleum & Chemicals also informed the Committee in this connection during evidence that:

"When Hamycin was first discovered in HAL laboratories, there was a great sense of excitement because it was a tremendous breakthrough—discovery for the first time of an antibiotic in India. When this was shown to people, its efficacy was generally accepted. Even the Americans accepted it and an American Co. entered into a contract with HAL for formulating and marketing it in US. Lt. Gen. B. M. Rao, Adviser to the Defence Ministry, wrote very glowingly about it suggesting that we should increase the capacity to 1000 kg. straightway because of its tremendous importance particularly in treating skin infections. In the context of this kind of enthusiasm, they did not go in for 1000 kgs. but they want from 50 to 250 kgs. While the Committee may have the impression that it was a case of over enthusiasm. I admit it had not been properly established. But it was raised to 250 kg."

2.127. In regard to the demand for the product, the Secretary stated that:

"In the case of a new drug, demand is something which is stimulated. If it is therapeutical efficient and acceptable to the consumers, then the question comes of marketing. In fact, the whole secret of the multi-national is precise their ability to market a product. In the case of well known drugs like streptomycin, their market is stabilised and therefore it is fair easy to ascertain the possible consumption level. But in the case of a new drug, that is not possible. Even in the US, it is a matter of market strategy to bring it into the market. Therefore, in spite of strong demand from knowledgeable people to raise it to 1000 kg., Government did not think it wise to do so and was raised only to 250 kg."

2.128. In regard to expansion of the project, the Secretary stated that—

“With great respect, at that time, it was not really a question of expansion from 50 to 250. We were considering what should be the level we had not established 50 which was later expanded to 250; in deciding what should be the initial capacity, instead of 50, they said it should be 250, not 1000 as was demand. At that time, the technical problems that are as subsequently had not been anticipated. In retrospect, it appears to have been not wiser course, but still we feel that the efficacy of the drug remains established. The problem is about two things that have come up; stability and toxicity. I am told it is not stable for more than 6 months. That being so, you cannot market such a short life product. Secondly, it appears that when the potency is increased, toxicity increases. So the company took a deliberate decision to withdraw it from the market and continue research to solve these two problems. If we succeed in this, we can go ahead because the therapeutic efficacy of the product is not in doubt.”

2.129. The Secretary added that a separate task force had been established with Dr. Gotheskar as a member to go into the focus of R & D on this. These problems were expected to solve and then the product marketed. Meanwhile, the investment of Rs. 68 lakhs on this plant was not infructuous.

2.130. It was decided that till R & D was able to solve these problems, the equipment should be utilised for production of various other items, like penicillin V, first crystals, procain penicillin reprocessing, streptomycin sulphate reprocessing. The total value of these products was Rs. 30 lakhs from April 1974 till today. So the investment had not become infructuous and when the drug would be stabilised it would be put into the market.

2.131. In regard to the question of capturing the local market, the Secretary stated that—

“We do not want to have a consumer market in India with a standard lower than that abroad. So a deliberate decision was taken not to market in India until we can ensure its stability and non-toxicity. It was not that the private companies formulators are resisting it; we took a suo-

motu decision that we will not market a drug which is not yet stable.”

2.132. The Committee note that HAL decided to set up a pilot plant having a capacity of 15 kgs. per annum of Hamycin an anti-fungal antibiotic, evolved by the Research and Development Laboratory of HAL. Before the project could be implemented, it was decided to undertake production of Hamycin on a commercial basis in a plant having capacity of 50 kgs. per annum for which industrial licence was issued in April, 1963. The Committee do not see the rationale behind the decision to increase the capacity even before the pilot plant was set up and results of pilot plant study were known. While the Committee commend the development of this drug by the R & D Wing of the undertaking, they feel that HAL should have set up the 15 kg. plant as originally envisaged on a pilot basis, and after testing the product, stabilising it in consultation with the ICMR/IMA and Federal Drug Administration of USA, established the demand for the product after a proper demand survey and only thereafter gone in for production on a large scale. If this had been done, the undertaking would not have been faced with the problems of stability, toxicity, etc. which developed later. The Committee find that the undertaking took up the expansion of the capacity on the basis of an anticipated demand particularly from USA. Even before this project could be implemented it was decided in May, 1964 to increase the capacity to 250 kgs. in anticipation of increase in demand. The Committee regret to note that the undertaking went on increasing the capacity to 250 kgs. and even set up the plant with 250 kgs. capacity at a cost of Rs. 65 lakhs in November, 1968 merely on the basis of a demand from USA which was only “anticipate” but was not even got verified. In the mean time the undertaking again proposed further expansion of capacity to 1000 kgs. in Fourth Five Year Plan. However, this was postponed in December, 1968 pending the assessment of demand pattern after receipt of approval of the Federal Drug Administration of USA for the systematic use of Hamycin. The Committee fail to understand as to why the demand of the product could not have been assessed and firmed up even in the earlier stages before going in for increase of capacity and why the approval of the Federal Drug Administration of USA which is now considered necessary for the systematic use of Hamycin could not have been obtained.

2.133. The Committee were informed that while the scientists were engaged in improving the technology and potency of the product and reducing its cost of production the problem of toxicity came

in, though, the therapeutic efficiency of the product is stated to be not in doubt. Another problem was of the stability of the drug which, it is stated, is not stable for more than six months.

2.134. The Committee are also informed that an American firm Sherman Laboratories who were evaluating the demand pattern of this drug in USA and who had agreed to market it in that country changed hands twice and the last company which took over was not interested in the drug. The Committee further note that the demand for this drug did not pick up as the drug was not standardised and no market was available nor was there any efficient marketing organisation to promote it and push it up.

2.135. The Committee find that on account of the various problems, the production of Hamycin was discontinued from December, 1974, with the result that entire expenditure of Rs. 65 lakhs incurred in setting up the plant and the recurring maintenance charges incurred thereafter have proved to be infructuous. The Committee regret to observe that in spite of the long period of nearly eight years, the undertaking has not been able to get the problems solved. Since the chemical/drug technology is fast developing, the Committee feel that unless the problems are solved with expedition, the possibility of the technology on which the plant was based becoming obsolete and overtaken by latest advancements is not ruled out. The Committee would like the whole matter to be thoroughly investigated with a view to fix responsibility for the lapses.

2.136. The Committee also recommend that the undertaking should find the best alternative use to which the plant and machinery could be put. The Committee suggest that Ministry/Undertaking should draw a lesson from this expedient and ensure that whenever investments are made for manufacture of experimental drugs in future, the plant and machinery are such as could be used for more than one product.

D. Vitamin C

2.137. On the basis of a process developed by the National Chemical Laboratory, Poona for the production of Vitamin 'C', the Company was asked by the Government in March 1960 to prepare a project report for its production. The project report was prepared (June, 1960) for a capacity of 50 tonnes per annum at an estimated cost of Rs. 60 lakhs (including foreign exchange of Rs. 33 lakhs) after the management of HAL was satisfied about the successful

trials of production in NCL laboratory as well as in NCL pilot plant. Although the cost of production was estimated to be Rs. 71 per kg. as against the imported cost of Rs. 33 per kg. and the cost of production of Rs. 50 per kg. by an indigenous firm in the private sector, it was decided to take up the project and the 'go ahead' sanction was given by Government to the Company in March, 1962.

2.138. At about this time, the Research Division of the Company evolved the new antibiotic-Hamycin. The Board of Directors of the Company were very keen to go ahead with the project for the manufacture of this drug almost simultaneously with the project for Vitamin 'C'. At an inter-ministerial meeting held in February, 1963 where a representative of the Company was also present, the following decisions were taken:—

1. The Company should undertake commercial production of Hamycin;
2. Since the Company had no experience in the production of Vitamin 'C', it should first establish a pilot plant involving foreign exchange of Rs. 2-3 lakhs.

2.139. In July, 1963, another inter-ministerial meeting was held to consider whether it was necessary to have production of Vitamin 'C' on a pilot basis before its production on commercial scale and it was decided that:

- (a) the Company should establish a pilot plant for the production of Vitamin 'C' in about four months;
- (b) the Company will complete the pilot plant runs and submit a joint report with the National Chemical Laboratory to Government by January, 1964.

2.140. It was also decided in that meeting that the decision regarding large scale undertaking would be taken after a Technical Committee appointed by the Government had examined the joint report on above by HAL and NCL. The joint report was submitted in August, 1965 which *inter-alia* concluded that "on the whole it could be stated that the efficiencies indicated in the original report (prepared in 1960) have by and large been achieved and there is every justification to expect that in a properly designed and installed plant this can be bettered."

2.141. In the meanwhile, certain developments in the demand of Vitamin 'C' had taken place and the Ministry of Petroleum and Chemicals estimated in March, 1968, on the basis of indications given by the Development Council for Drugs, the country's requirement of Vitamin 'C' at 375 tonnes per annum towards the end of the then Fourth Plan period (1970-71). It was, therefore, envisaged that the capacity of the proposed plants should be increased from 50 tonnes per annum to 125 tonnes per annum, mainly on the following considerations:

- (1) It was not desirable to allow this important drug to remain a monopoly of a private company; and
- (2) Indigenous process developed should be commercialised as an encouragement to the development of indigenous know-how.

2.142. Accordingly, sanction to the project report with an expanded capacity of 125 tonnes was accorded by Government in October, 1968. The order for indigenous machinery was placed in May, 1969.

2.143. The application for import licence was made in May, 1969 and the order for import of machinery was issued in April, 1970. Owing to the necessity to re-order certain equipment seized by Pakistan during December, 1971 hostilities and after obtaining permission from Government to use free foreign exchange instead of U.S. aid sources, machinery (both indigenous and imported) was received by December, 1972 and the plant was commissioned on 31st March, 1973. Commercial production in the plant had not commenced till March, 1975.

2.144. The project was originally expected to cost Rs. 118 lakhs with a foreign exchange component of Rs. 62 lakhs. This was revised to Rs. 163 lakhs (in February, 1972) with a foreign exchange component of Rs. 38.37 lakhs. The increase was attributed partly to reduction in the foreign exchange component of the project cost arising from indigenous substitution and partly to a general rise in the cost of materials and fabrication charges. The actual cost of the plant upto December 1974 was to the extent of Rs. 131.30 lakhs.

2.145. The revised cost of production of Vitamin 'C' bulk is expected to be Rs. 92.76 per kg. as against the estimated cost of Rs. 81.28 per kg. in 1966, while the fair selling price fixed under the Drug Prices Control Order (DPCO) 1970 is Rs. 72.70 per kg.

Assuming that half of the production of the plant (62.5 tonnes) is used for captive consumption of sub-divided products and the remaining half is sold in bulk form, the Company expects that the project may yield a return of 2.76 per cent (before tax) on the investment of Rs. 238 lakhs or Rs. 6.57 lakhs per annum.

2.146. In March, 1975 the Government have fixed the selling price of Rs. 116.34 per kg. for Vitamin C bulk manufactured by the undertaking which commenced production of this bulk drug for the first time after 31st March, 1973. However, the Company has not ascertained the cost of production against this selling price as the commercial production has not commenced till March, 1975.

2.147. On account of delay in the implementation of the project as originally sanctioned, substantial quantities of Vitamin C had to be imported to make up the gap between the indigenous production and the demand. A quantity of 676.35 tonnes of Vitamin 'C' was imported during the period from 1964-65 to 1971-72 involving a foreign exchange outgo of Rs. 192.80 lakhs. In the meantime, the production of Vitamin 'C' continued to remain entirely in the hands of a private company.

2.148. The delay in the commissioning of the plant, apart from the reasons already mentioned above, has been attributed to the following factors:—

(a) Shortage of cement.

(b) Shortage of steel necessitating the import thereof.

(c) Delay in the receipt of indigenously fabricated equipment.

In the Fifth Five Year Plan, the Company has a proposal to expand the capacity of the plant from 125 tonnes to 250 tonnes.

2.149. To end of August, 1975, 293.8 kgs of Vitamin 'C' bulk had been produced. The output of Vitamin 'C' was low due to malfunctioning of the refrigeration units, non-availability of acetone in the wake of oil crisis and problems connected with product quality and process in the last two stages as well as longer timecycles and lower efficiencies particularly at the sorbose recovery and final crystallization stages. It has been stated that the process problems were under review with the collaborators. On the basis of detailed discussions with the collaborators, National Chemical Laboratory, some modifications have been effected in the process wherever

necessary. As a result of this some stream of production had been established upto the final stage and over a ton of pharmaceutical grade Vitamin 'C' in addition to nearly 200 tonnes of sorbitol, an intermediate product in saleable form, had been produced so far. Efforts were in progress with a view to obtain the time cycles and efficiencies indicated in the project report, through plant trials and Research and Developments works. It has been stated that technology was obsolete since it gave only 34 per cent yield, while technology available abroad was stated to give 72 per cent yield.

2.150. Even if the process problems were resolved and efficiencies claimed by the collaborators were achieved, the cost of production would be much higher than the selling price fixed under Drug Price Control order. HAL has stated in a note that when full volume of production is achieved the cost of production would be approximately Rs. 500 per kg., on the basis of existing process efficiencies. In case the efficiencies claimed by the collaborators were obtained the cost would work out to Rs. 160 per kg. The selling price of Vitamin 'C' bulk fixed by Government in March, 1975 was Rs. 116.34 per kg.

2.151. Asked as to what was holding the commercial production of Vitamin 'C', the Managing Director informed the Committee during evidence as follows:—

“We have started commercial production. Lower efficiency and keeping the quality of the product consistent are holding up production. The Government of India appointed a task force....

As far as my assessment goes, it is like this. The technology was developed in 1960 or before it. In today context it is obsolete. Even if we get the various claims made by the collaborators, the cost of production will be much higher than the sales price fixed by the Government. Secondly, we are not getting the efficiencies anywhere near what is claimed by the collaborators. For that the task force suggested that the National Research Development Corporation, the National Chemical Laboratory and Hindustan Antibiotics should have a working group to review the entire technology, plant design, everything, and to suggest what should be done with this.

We are approaching this in two ways. One is to revamp the existing plant and technology to make it produce commercial quantities in an economical manner, and the second is, as suggested by the task force, to get better technology because that will ultimately be viable and because the present technology is not adequate."

2.152. In regard to cost of production *vis-a-vis* the price fixed under the Drug Price Control Order, the Managing Director stated that—

"As far as we know, the cost of production of Jayant is much higher than the sale price fixed by the Government. In fact, they approached the Government, and we also approached the Government, for a price revision, and we had discussions with them. The cost of Sarabhais is within the sale price. In fact, Government is pursuing a dual pricing policy. They have fixed Rs. 90.70 for Sarabhais and Rs. 116.70 for Jayant and Hindustan antibiotics because we entered the market later on. Jayant and we started recently and so, our investment was larger than Sarabhais.

We have also approached Indian parties, not only for parties, for know-how. We approached Sarabhais because we find that their know-how is the best available in India today and they are considering our request."

2.153. To an enquiry of the Committee whether it was wise to go in for expansion without the proper technology or collaboration, the Managing Director stated that—

"Today we find that 125 tonnes is too small a quantity. As you have correctly observed in the case of vitamin 'C', my own assessment is, particularly after the report of the task force, that this plant has to produce it. If it cannot produce it with the existing technology it has to produce it with the imported technology. There is no choice left before us. If we want to produce it and meet the requirement of the country a big way, then the public sector should go in for expansion."

2.154. In regard to stabilising the plant the Managing Director stated that "First, we concentrate on stabilising a plant and see

that it produces according to our satisfaction. That is what precisely we are doing. We are now making efforts to see how to produce Vitamin 'C' to the full capacity from the plant. With the help of assessment from other sources, we have made some adjustment with this plant, some adjustment in technology, minor changes in technology with the result we will be able to produce Vitamin 'C'. So as we are not investing any money.

2.155. Again you have to give some allowance for the indigenous technology which is developed and indigenous know-how and expertise. For example, in September, 1973, we did start commercial production. By that time, we did it in a small manner. This plant was not kept idle. It has produced one of the products called sorbitol about 150 tonnes in the first year and marketed it. We have earned profits from marketing this product. We are trying to do our best instead of resorting to certain methods followed by some other people. For obvious reasons, the public sector unit is not expected to follow certain methods. We have to work through our own collaborators, how best to improve the technology and become economically viable. We have made some progress in this direction."

2.156. In regard to the economics of working the plant to 125 tonnes capacity, the Managing Director stated that "If we can produce 125 tonnes according to the quality and standard laid down by the collaborators, the most will be around Rs. 143 per kg. as against the selling price of Rs. 116. We have made a study and a complete assessment of it. We will be losing Rs. 36 lakhs per year. What is the use of that? So, we must improve the technology or get it from outside so that this plant becomes economically viable. That is one of the constraints of production. We can produce more quantity. But the question is: At what cost?"

2.157. The Secretary of the Ministry also informed the Committee in this regard as follows:—

There are two main issues in regard to Vitamin 'C'. The first that has been raised by the Committee relates to delay in the commissioning of the project; and the second arising automatically is about the success or otherwise of the whole project. The second is more important and significant than the first. In regard to the first we would have to admit that this is one of the projects which went

through very slow. As far as we are concerned, the key date will have to be taken as October, 1968, viz., the date of the investment decision when the project was approved by the Government. There was one basic problem about the delay in commissioning. The technology was taken from the National Chemical Laboratory. But the word 'technology' would have to be understood in its perspective. The NCL gave the Company the process know-how. The term 'technology' really includes not only process know-how but also chemical engineering, which includes the drawings, basic engineering, detailed engineering and the whole up-scaling of the project. NCL did not give it. Therefore, it was for the company to decide the ways and means of providing this part of the technology. The decision was taken by the Board of Directors, that the Company would itself prepare the engineering part of it. In effect, therefore, the technology was not fully available on that date, viz., October, 1968 and during the period from October 1968 to January, 1970 when the civil engineering works started, the process of completing the drawing, engineering and upscaling went on. Civil engineering began in 1970 and the plant was commissioned 3 year later. One unfortunate incident which took place was that a critical piece of equipment was captured by the Pakistanis from our ship and taken to Karachi; and we had to make arrangements for replacing it. Undoubtedly, this plant could have been commissioned early. We have no brief for the delay; but the circumstances of upscaling the technology of the NCL would have to be kept in mind. It was not a very usual case. Perhaps the most important point is whether the project was successful thereafter, or not. We have no hesitation in admitting that it was not. The technology and the process knowhow got from the NCL do not seem to have clicked. The Board of Directors had appointed a Task Force. It has submitted its report this year.

- 2.157. They were to look into the causes, i.e., why had the plant not gone off; and to make suggestions as to what ought to be done. The Task Force has come to the basic conclusion that the technology, as given, is first of all obsolete, in the sense that it was given in 1960 and is no longer relevant today.

The second suggestion made by the Task Force, and also accepted by NCL, is that the best course is to discuss the matter with other people who have relevant technology and see how best we could solve the situation. Talks have therefore begun with other people who have technology. The best technology that is available in the world is that of Roche. The other is Merck, which has been adopted by Sarabhai. Jayant have adopted the Sarabhai technology. We have had discussions with Sarabhai and Jayant. They are willing to collaborate to put the plant on its feet. As things stand today, the NCL technology would result in uneconomic production. Even if the efficiency parameters suggested by the NCL are met, even assuming that all the efficiency parameters indicated in 1968 are met, the cost of production of Vitamin 'C' would be round about Rs. 160 per kg., as against the price of Rs. 116 which has been fixed by the Bureau of Industrial Prices and Costs and the price of Rs. 92 which has been allowed to Sarabhai."

2.158. About the existing cost of production, it was stated that it was totally unrealistic even to mention a cost of production when the production was so ridiculously low.

2.159. In regard to comparative cost of different technology the Secretary of Ministry stated—

"The Bureau of Industrial Costs and Prices has fixed the price for Sarabhai at Rs. 92. Of course, Sarabhai have been complaining that it is too low a price. But it gives an indication. Since BICP has fixed the price of Rs. 92, as against Rs. 160 on the basis of NCL technology on full efficiency parameter, it gives an idea of the difference in cost. We should evaluate these different technologies and considering the sad history of this plant. I think it would be advisable to get the very best technology available."

2.160. While discussing the question of delay in setting up the plant, the Committee pointed out the delay in taking the final decision for investment in 1968 whereas the idea of setting up the plant was first mooted in 1960, the Secretary stated that "I do not agree. In 1960 there was no firm proposal before the Government.

There was a suggestion that they should go in for Vitamin 'C'. There was a process know-how which had been developed by NCL, but Government took wise decision not to proceed with it till a pilot plant was put up and studies were made. That took this period."

2.161. In regard to the failure of the technology the Secretary stated "True, this we conceded right from the start. Even at the pilot plant stage doubts were expressed. There were problems even at the time of the pilot study, but there was a sense of confidence that the up-scaling would be possible. Even today I mentioned that we are receiving a number of proposals from the CSIR laboratories. Even the efficiency parameters which the NCL had said would be achieved have not been achieved. This is a fact which we must concede without hesitation."

2.162. On an enquiry of the Committee whether the failure of the project was entirely due to the wrong type of technology or due to inefficiency, the Secretary stated as follows:—

"As I mentioned, we had to choose between having either foreign technology or indigenous technology. It is quite evident that if we purchase foreign technology, the kind of problems which arise when we work in indigenous technology will not arise. There will be the question of transfer of technology and all that. We produce things on the basis of indigenously developed technology, we do run into difficulties. It is a price that we have to pay for development of indigenous technology and self-reliance. Quite often, we have succeeded. There are occasions when we have not succeeded. This is one of the occasions where we have failed. We have recently taken a decision, for instance, that the Hindustan Insecticides will go in for technology devised and developed by the NCL for endosulphan. This is a conscious decision we have taken although we had choice to import Hoechst technology. We have decided that technology developed by the NCL will be adopted by one of our public sector companies. This is a difficult decision to take. There is a considerable risk factor involved in adopting these technologies. The real question is: should we follow this policy, give it a fair trial and accept the fact that occasionally mistakes would be made

and failure would occur or straightway import foreign technology?

The Government appointed a Task Force which has given a clear opinion. This opinion has also been accepted and endorsed by Dr. Tialak the Head of the National Chemical Laboratory which gave the technology that the technology is obsolete and it has not given the necessary efficiency parameters. It is not really a question of my expressing an opinion. There is a technical opinion which is even accepted by the very Laboratory which gave the technology."

2.163. In regard to the recommendations of the Task Force, (See Appendix I) the Ministry stated as follows in a note:—

"This is an interim report. The Committee of Directors has appointed a sub-committee to go into the details of functioning of the existing plant and it will be possible to take further concrete action after the final report of the Committee is received. The interim report highlights the importance of seeking improved technology from elsewhere as the Committee feels that the existing technology will not lead to economic functioning of the plant even at the best efficiencies achievable as per the efficiencies indicated by the National Chemical Laboratory. In the context of this recommendation, Government have held discussions with M/s. Sarabhai M. Chemicals who have agreed to assist Hindustan Antibiotics Limited in establishing/modifying/altering the technology to make it operable on an economic basis. Similar discussions are also in hand with M/s. E. Merck and M/s. Roche. The Company has been apprised of the discussions taking place."

2.164. The Committee note that on the basis of a process developed by NCL for production of Vitamin C in 1960 a preliminary project report for a capacity of 50 tonnes per annum was prepared in June, 1960 for establishing the capacity in HAL after the management of HAL was satisfied about the successful trials of production in the NCL laboratory as well as in NCL pilot plant. In spite of the fact that the estimated cost of production worked out to Rs. 71/- per kg. against the imported cost of Rs. 33 per kg. and cost of Rs. 50 per

kg. by an indigenous firm, Government gave a go-ahead order in March, 1962 to take up the project. Since Vitamin C was already under production in the country, the Committee feel that Government should have made a thorough evaluation of the technology and cost of production before the go-ahead order was given. The Committee find that in February, 1963 in an inter-ministerial meeting it was decided that since HAL had no experience in the manufacture of Vitamin C, HAL should first establish pilot plant. This was again confirmed in an inter-ministerial meeting in July, 1963 where it was decided that the pilot plant should be established in about 4 months and a joint report with NCL about pilot plant runs should be submitted to Government by January, 1964. It was also decided that a decision regarding large scale production should be taken after a technical committee appointed by Government had examined the joint report by HAL and NCL. The Committee find that based on the joint report given in August, 1965 which concluded inter-alia that on the whole the efficiencies indicated in the original report (1960) have by and large been achieved and there was every justification to expect that this could be bettered in a properly designed and installed plant, it was envisaged that the capacity of the plant should be augmented from 50 tonnes to 125 tonnes per annum and sanction of Government was accorded in 1968. The Committee fail to understand as to why the techno-economic evaluation of the project based on the joint report of HAL and NCL was not undertaken as envisaged earlier and a decision was taken by Government without making sure of upscaling the technology or examining the cost. The Committee would like that this aspect should be investigated and responsibility fixed for the lapse.

2.165. The Committee note that the plant was commissioned in March, 1973 but commercial production was not started till March, 1975. It has been stated by the Managing Director that lower efficiency and keeping the quality of product consistent, were holding up production and the Government of India had appointed a Task Force to go into question. The technology which was developed in 1960 is stated to be obsolete in today's context. Even if the various claims made by NCL are met, the cost of production would be Rs. 160 per kilogram as against the selling price of Rs. 116 fixed by the Bureau of Industrial Costs and Prices, and the price of Rs. 93 allowed to Sarabhai. The Secretary of the Ministry during evidence has stated that "even at the pilot plant stage doubts were expressed". While it has been conceded that 'technology' should include besides process know-how, aspects like upscaling, detailed engineering, etc.

what was obtained from the NCL was only the 'process know' and it was for HAL to decide the ways and means of providing this part of the technology. While the Committee are all for affording every encouragement to indigenous know-how, the Committee need hardly stress that every prudent care should have been taken to have selected the appropriate technology and no efforts should have been spared to critically evaluate the same before taking the investment decision.

2.166. The Committee find from the interim report of the Task Force that "the loss on Vitamin C operations based on current efficiencies would be around Rs. 75 lakhs per annum. Even assuming that the efficiencies, claimed by the collaborators are achieved by HAL, the project would still continue to incur a loss of Rs. 34 lakhs per annum on the basis of the approved price for the bulk drug. The management also informed the Task Force that the yields at 2 stages serbos recovery and final crystallisation of Vitamin C are considerably lower than those claimed in the project report and this had resulted in significantly lower over-all efficiencies, and that they could obtain Vitamin C conform to Indian Pharmacopia only after making some modifications in the technology in the final stage." The Task Force has also recommended that the two problems require immediate attention for improving over-all efficiency and suggested that the management of HAL should immediately explore the possibility of obtaining better technology either locally or imported which will ensure better return on the investment already made with the minimal additional inputs and HAL should immediately explore the possibility of maximum utilisation of the plant already installed by constituting a joint working group comprising the scientists of HAL, NCL and also National Research Development Corporation to go into the details of the technology and the design of the plant in order to assess the techno-economic viability of the entire project afresh. The Committee feel that HAL should have evaluated in depth the NCL technology at the pilot plant stage in consultation with Indian Council of Medical Research, NRDC and other experts in the field especially when even at the pilot plant stage according to the Secretary doubts were expressed. The Committee feel that the pilot plant studies were not carefully done before setting up a plant for large scale production. The Committee recommend that HAL should without any further delay, take concerted measures to overcome the immediate problems affecting the production.

2.167. The Committee are informed that the opinion of the Task Force has been accepted and endorsed by the head of the NCL that

the technology is obsolete and it has not given the efficiency parameters. The Committee are also informed that in the context of the recommendation of Task Force, Government have held discussions with M/s. Sarabhai who have agreed to help HAL in establishing/modifying/altering the technology to make it operable in an economic basis. Similar discussions are also in hand with M/s. Merck and Co. and M/s. Roche. The Committee do not understand as to why, when IDPL another Public Sector Undertaking under the same Ministry is also producing Vitamin C, the assistance of that Public Undertaking could not be taken for revamping the plant. The Committee recommend that a careful evaluation of the available technologies should be made and the appropriate technology selected so that the plant is capable of operation on an economic basis. The Committee need hardly stress that it should be endeavour of the Public Sector Undertakings dealing with drugs to ensure that essential drugs of assured quality including those for prevention of diseases are made available at most competitive prices and in adequate quantities.

E. Aureofungin

2.168. The production of Aureofungin was taken up in 1966-67 by utilising the Penicillin and Hamycin plants and the pilot plant. The budgeted and the actual production upto 1971-72 were as under:

Year	Budgeted production	Actual production
	Kgs.	Kgs.
1966-67	658	733.62
1967-68	600	37.35
1968-69		..
1969-70	..	
1970-71	14 (later revised to 43)	43.22
1971-72	30	25.90 (reprocessed quantity)
		840.09

2.169. The total cost of production of the above quantity of 840.09 kgs amount to Rs. 17.06 lakhs (on the basis of respective year's cost). While a quantity of 143.51 kgs. was sold for Rs. 5.30 lakhs, 6.80 kgs were distributed as samples and 13.80 kgs. were treated as process loss. Out the balance quantity, 231.85 kgs. (valued at Rs. 3.67 lakhs were treated to have lost the potency and 444.13 kgs. valued at Rs. 4.48 lakhs were lying in stock as on 31-3-1972.

2.170. The budgeted and actual production during 1972-73 to 1974-75 are given below:—

Year	Budgeted Production Kgs.	Actual production Kgs.
1972-73	Nil	106.865 (reprocess quantity)
1973-74	50	44.950
1974-75	150	258.655

2.171. The total production upto 1974-75 works out to 1,249,776 Kgs. at a cost of Rs. 43.19 lakhs. In addition to the quantity sold upto 1971-72, the following quantities were further sold during 1972-73 to 1974-75:—

Year	Quantity (in Kgs.)	Value (Rs. in lakhs)
1972-73	31.080	0.64
1973-74	98.250	2.46
1974-75	264.690	3.96
Total sales upto		
1974-75	537.530	12.36

2.172. The total quantity produced upto 1974-75 works out to 1250.560 Kgs. at a cost of Rs. 38.98 lakhs (on the basis of respective year's cost). While quantity of 431.640 Kgs., was sold for Rs. 12.47 lakhs, a quantity of 10.215 kgs., was distributed as samples and 89.513 kgs., treated as process loss. Out of the balance quantity, 650.448 kgs. valued at Rs. 16.72 lakhs was treated to have lost the

potency and 68.744 kgs. valued at Rs. 1.53 lakhs were lying in stock as on 31st March, 1975.

2.173. The stock position during 1972-73 to 1974-75 was as follows:—

Year	Opening Balance	Production	Sales	Balance (in Kgs)
1972-73	675.98*	106.86	31	751.84
1973-74	751.84	44.95	98.25	698.54
1974-75	698.54	258.65	264.69	692.50

*including 231.85 Kgs. lost potency.

2.174. The production of this item which was developed as a result of Company's own research was undertaken on the basis of an indication given by the Ministry of Food and Agriculture in May, 1966 that a quantity of 5907 Kgs. (subject to firm indents being placed by the State Governments) might be required by the State Governments for the protection of crop against paddy blast. The Company however, took up the production, though on much lower scale of the anticipated demand, in anticipation of first indents from the State Governments as it was considered that blast attack being sudden and seasonal, it would not possible to produce the material immediately on receipt of firm indents which would have come only after the blast developed.

2.175. The reasons for which further production of this item was taken up during 1967-68, 1970-71 and 1973-74 when huge stock out of the quantity already produced in 1966-67 was in hand are, however, not clear.

2.176. During the course of evidence, the Secretary of the Ministry informed the Committee as follows:—

“Just as in the case of Hamycin, this was also a discovery. It must be said to the credit of the Company that they discovered this product. When the product was first brought to the notice of the Ministry of Agriculture, they were very enthusiase about it. They felt that it was an efficacious product, something new to the Indian market. They made an estimation of what the States' demands would be. As it happened, in practice, this demand did

not materialise. We cannot hold the Ministry of Agriculture responsible for this nor we can make any claim of compensation. The Ministry of Agriculture is a sister Ministry. They made *bona fide* assessment of what can be consumed. Even in the matter of fertiliser consumption and various other matters where the Ministry of Agriculture is concerned, they make estimations which, by and large, are correct."

2.177. Asked whether any market survey was conducted for aureofungin, the Secretary stated that—

"Aureofungin is an antibiotic meant for plants and it has the same market as pesticides have. Pesticides in India are consumed on a very small scale and it is the view of the Agriculture Ministry and also our view that there is need to stimulate the consumption of pesticides and plant protectants.

If we were to make a market survey, the existing level of offtake by the various plant protection agencies would be very relevant; therefore, their view is also taken. * * *

In the case of Aureofungin, the Directors of Agriculture, through their network in the cities and towns down to the village, taluk and the tahsil level etc., have knowledge of what is going on, and they report to the Ministry of Agriculture and the ICAR. These organisations have a fair knowledge of what is going down to the lower level. Therefore, we are guided to a great extent by the information of the Ministry."

2.178. On an enquiry of the Committee as to the justification for going into production regularly without the offtake being there resulting in dwindling of efficacy and loss to the undertaking, the Secretary stated there was a major production in the first year. The shelf life of this product was two years. When they found the sales were not doing well, they did not go in for any production in the next two years and in 1968-69 and 1969-70 there was no production at all. There was a small production in 1972-73. The shelf life of the drug being two years the shelf life of the drug made in the first year, that is in 1967-68, was over by 1969-70. When its shelf life was still valid, the company did not produce anything and when the shelf life was over, the Company tried to re-process some, but

scaled down the major production. Although there were stocks, they were not usable stocks.

2.179. The Committee note that HAL took up in 1966-67 the production of Aureofungin—a product developed by its own R & D efforts, on the basis of demand indications given by the Ministry of Agriculture in May, 1966 that a quantity of 5907 kgs. might be required by State Governments for protecting the crops against paddy blast. The Committee are informed that when the product was brought to the notice of the Ministry of Agriculture, they felt that it was an efficacious product something new to the market. The Committee feel that both the Ministry of Petroleum and Chemicals and HAL should have taken the assistance of the Ministry of Agriculture and the ICAR for testing the product in the field establishing its efficacy and popularising and standardising it as a pesticide before taking up production on a large scale. If it is established as a pesticide, or even as an antibiotic for agricultural products, the Committee feel that the undertaking should have passed on the know-how to another public undertaking dealing with the pesticide or to the Ministry concerned for further processing and development. The Committee regret to note that, instead, the Company went on manufacturing the product though on a moderate scale without obtaining any firm commitment of indents from the State Governments and produced 1250 kgs. till the end of March, 1975 at a cost of Rs. 39 lakhs out of which 432 kgs. were sold, 100 kgs. were stated to have been distributed as free samples or treated as process losses, 650 kgs. were stated to have lost potency and 69 kgs. were lying in stock. The Committee were informed that the shelf life of the product was two years and major production to the extent of 734 kgs. was in the first year 1966-67. When it was found that the sales were not doing well the Company did not go in for any production in the next two years namely 1968-69 and 1969-70. Subsequently there had been production continuously. It has been reported at the end of 1971-72 that a quantity of 232 kgs. were treated to have lost potency and 444 kgs. were in stock. The Committee see no justification for the company to have gone on with the production during 1972-73, 1973-74 and 1974-75 when there was already an accumulation of stock in 1971-72 and the shelf life of product was only two years especially when there were no firm indents/commitments from the State Governments.

2.180. The Committee find that the off-take of the product has not even been 50 per cent of the production to the end of 1974-75 and

even the stocks lying with the company are not usable with the result that the company has been put to a loss of over Rs. 20 lakhs calculated on the basis of total cost of production. The Committee would like that the entire matter should be thoroughly investigated with a view to fixing responsibility for the loss.

F. Other Items

2.181. The Company also took up, on an experimental scale the production of Chloro-tetracycline, Streptocycline, and Antiamoebin by using its own know-how and strain developed by its Research Division. No separate capacity for the production of these items was established. These items were produced by utilising the existing capacities in other plants or the pilot plant.

2.182. Chloro-tetracycline was produced in the pilot plant set up in 1959-60 at a cost of Rs. 6.62 lakhs for the production of Tetracycline. On account of lack of demand for Chloro-tetracycline and Aureofungin for which the pilot plant was proposed to be alternatively used, it was dismantled in 1970-71 (depreciated value being Rs. 1.31 lakhs) and the machinery was transferred to other plants for use.

2.183. In December, 1969, the Board of Directors approved the setting up of a plant for the manufacture of Semi-Synthetic Penicillin (5000 kgs. per annum) at an estimated cost of Rs. 50 lakhs (including foreign exchange component of Rs. 25 lakhs) during the Fourth Five Year Plan (1969-74). Government sanction to Semi-Synthetic Penicillin Project at a revised estimated cost of Rs. 62.25 lakhs including foreign exchange component of Rs. 13.75 lakhs, to be met under West German Credit, was received in May, 1972. Orders for indigenous machinery of the value of Rs. 8.14 lakhs for the Semi-Synthetic Penicillin Project have been placed (upto March, 1975) while import licence for other machinery was awaited. The Company is also having a plan of expansion of the project from 5 tonnes to 35 tonnes during the Fifth Five Year Plan. It is expected that the plant would be ready for commissioning in June, 1976.

2.184. In the meantime manufacture of Semi-Synthetic Penicillin capsules from imported Ampicillin bulk was started in November, 1971 and 200 kg. of Ampicillin bulk was imported in two lots of 100 kg. each in July, 1971 and October, 1972 at a cost of Rs. 2.25

lakhs. The entire stock was converted into 17.52 lakh capsules. Out of this, the company sold (at profit) 14.67 lakh capsules upto 31st March, 1975 and 0.80 lakh capsules were scrapped (produced in May, 1972) at cost price of Rs. 0.55 lakhs leaving a balance of 1.05 lakh capsules in stock.

2.185. The Management have stated (May, 1973) that the low volume of the sale of Ampicillin capsules was due to inherent difficulties in introducing a new formulation in the market.

2.186. The Board of Directors also approved in December, 1969 setting up of plant for manufacture of L. Lysin (500 tonnes per annum at an estimated cost of Rs. 200 lakhs including, foreign exchange component of Rs. 100 lakhs) during the Fourth Five Year Plan (1969—74) Government, however, informed the Company in April, 1973 that since L. Lysin had already been licensed for manufacture with Japanese collaboration in a State Government Project in Madras, its production need not be taken up.

2.187. The budgeted and the actual production of these items from 1966-67 onwards are as follows:—

(Figures in kg.)

		1966-67	1967-68	1968-69	1971-72	1972-73	1973-74	1974-75
1. Chlorotetracycline	Budgeted	420.00	59.50	400.00
	Actual	31.01	23.50
2. Strepto-cycline	Budgeted	6321.00	9020.00	1000.00	111	1160
	Actual	6440.00	3707.45	..	414	1256.71
3. Aniamocbin	Budgeted	..	180.00	500.00	2.9
	Actual	2.9
4. Tetracycline								
		Capsules filled from imported bulks						
5. Neomycin Sulphate	Budgeted	118.9
	Actual	(During December, 1970 to October, 1972)

Notes :—1. There was no production in 1969-70 and 1970-71.

2. Chlorotetracycline ceased to be produced since 1968-69 as this antibiotic was taken out of the United States Pharmacy.

3. Aniamocbin, chlorotetracycline, Tetracycline and Neomycin sulphate were not produced after 1971-72.

2.188. The entire quantity of Chlorotetracycline produced had been sold upto 31st March, 1972. "However the company had a closing stock of 758 kg. (in 3 gm. packets) of Streptocycline valuing Rs. 2.63 lakhs and 148 kg. (valued at Rs. 0.52 lakhs) including 14.10 kg. produced in the pilot plant of Antiamoebin, as on 31-3-1975.

2.189. No separate manufacturing capacity was established for the production of these items. These items were produced by utilising the existing capacities in other plants or the pilot plant set up for the production of Tetracycline. While the pilot plant (with a capacity of 1.5 tonnes) set up for the production of Tetracycline is being used for the production of other items like Chlorotetracycline, Streptocycline and Antiamoebin Tetracycline is being imported in bulk form to produce capsules.

2.190. The Company could not take up the production of Tetracycline in the pilot plant on account of objections raised by a private company alleging infringement on the patents held by them in India. According to H.A.L. "the process had been developed by HAL's R & D and not purchased from outside, no infringement was anticipated. Unfortunately the process developed by the R & D coincided with that of the private company process." A settlement was reached in 1962, whereby HAL agreed not to produce Tetracycline during the period of validity of the patents which has since expired in July, 1972. According to the Company, although there is no legal restraint now on the production of this item, it would not be possible for the Company to produce and sell it at competitive prices as the product has already been developed by other producers during the period when the Company was unable to undertake the production.

2.191. According to Management Neomycin Sulphate is still under trial production and, therefore, neither standard yield nor standard potency has been fixed. Against 30 batches seeded during December, 1970 to October, 1972, only 13 batches could be harvested and the remaining 17 were drained on account of heavy contamination. Even the final product (118.891 kgs.) could not be sold due to low potency. The entire expenditure of Rs. 33,906 representing the cost of material became a total loss (other expenses of production have not been worked out by the Management).

2.192. Besides expansion of its existing capacity for manufacture of penicillin, streptomycin and Vitamin C, the plans for which are

at different stages of consideration, the Company has planned manufacture of (i) Erythromycin (ii) Aminoglycosidic antibiotics like Xanamycin and Gentamycin and (iii) Industrial Enzymes. In fact the Company had submitted in 1973 nine schemes for inclusion in the Fifth Five Year Plan at an estimated total investment of Rs. 30 crores. According to study made by a Task Force appointed by the Government of India, the demand for Erythromycin, Aminoglycosidic antibiotics and Industrial Enzymes in the country by the end of the Fifth Plan would be 30 tonnes, 6 tonnes and 60 tonnes respectively, against the licenced capacity of 17 tonnes, 3.8 tonnes and nil tonnes respectively. The Company proposes to acquire technology for the manufacture of Erythromycin and Aminoglycosidic antibiotics from abroad, and negotiations were in progress. As regards Industrial Enzymes, the R&D wing of HAL developed a process for manufacture of the same, which had been tried out on a laboratory scale. Preliminary feasibility reports show that the projects for industrial enzymes and Aminoglycosidic antibiotics will be financially feasible. The project for Erythromycin would not however be financially feasible on the basis of the technology available with the Company at present. Efforts are stated to be being made to obtain improved technology before the project is processed further.

2.193. It has been stated that on the basis of profitability as worked out in the feasibility reports for the nine schemes proposed for inclusion in the Fifth Plan, a profit before tax of Rs. 7.65 crores approx. per annum is expected, when all the nine schemes proposed attain production to full capacity which would be in the year 1981-82. On the basis of the existing operation, the Company expects to make a loss of approx. Rs. 3 crores during 1975-76. Presuming that the same position would continue in respect of the existing plant, the overall profitability of the Company would, after all the proposed schemes have been commissioned and attain full production in 1981-82, be Rs. 4.65 crores before tax or about 2.09 crores after tax.

2.194. The Committee regret to not that though the undertaking set up in 1959-60 a pilot plant of 15 tonnes capacity at a cost of Rs. 6.62 lakhs for production of Tetracycline, the undertaking could not take up production of Tetracycline on account of objections raised by a private company alleging infringement of patents held by them in India as the process developed by the R&D

coincided with that of the private company process. The Committee are informed that a settlement was reached in 1962 by which the undertaking agreed not to produce Tetracycline till July, 1972 when the validity of the patent was to expire. The Committee regret to note that even though there is no legal ban on production, now, it would not be possible for the undertaking to produce Tetracycline at competitive prices as others are already in the field with the result that the plant could not be used for the purpose for which it was set up while Tetracycline itself is being imported in bulk form to produce capsules. The Committee find that this pilot plant was used for production of Chlorotetracycline again on the basis of know-how developed by research division and even this had to be abandoned on account of lack of demand. The Committee are informed that the plant was dismantled in 1970-71 and the machinery transferred to other plants for use and the entire Chlorotetracycline produced had been sold by 31st March, 1972. The Committee regret to observe that this is yet another instance of taking up experimental production without assessing the demand and developing the market for the product.

2.195. The Committee also note that the Board approved in December, 1969 setting up of a plant for the manufacture of 5,000 kgs. of semi-synthetic penicillin per annum at an estimated cost of Rs. 50 lakhs during the Fourth Five Year Plan and Government sanction was accorded to the project in May, 1972, for a revised cost of Rs. 62.25 lakhs. The Undertaking has also stated to have placed orders for indigenous machinery worth Rs. 8.14 lakhs and is awaiting import licences for other machinery. According to management, the plant would be commissioned by June, 1976. The Committee also note that in the mean time manufacture of semi-synthetic penicillin capsules was started in November, 1971, and out of 17.52 lakhs capsules manufactured, 14.67 lakhs were sold up to 31st March, 1975, 0.80 lakhs were scrapped (produced in May, 1972) leaving a balance of 1.05 lakhs in stock. The low volume of sale was stated to be due to inherent difficulties in introducing a new formulation in the market.

2.196. The Committee feel that the undertaking should have made intensive efforts for marketing this new drug. The Committee have given their recommendation on marketing organisation elsewhere in this report. Now that the plant would be commissioned by June, 1976, the Committee recommend that the undertaking should intensify its efforts to develop the market for the product

and also take steps to get the problems regarding efficacy and shelf life of the product resolved. The Committee would also like to reiterate that in sphere of drugs, particularly the new drugs, it is always advisable to take up production on a pilot basis before going in for production on a commercial scale.

2.197. The undertaking has also planned manufacture of Erythromycin and Aminoglycosidic and antibiotics like Xanamycin and Gentamycin etc. and Industrial Enzymes, and a provision of Rs. 30 crores was proposed for inclusion in the Fifth Five Year Plan. According to a study made by a Task Force, the demand for these products Erythromycin, Aminoglycosidic and Industrial Enzymes have been stated to be 30 tonnes, 6 tonnes and 60 tonnes respectively against the licensed capacity of 17 tonnes, 3.8 tonnes and nil tonnes respectively and negotiations for obtaining technology from abroad in respect of Erythromycin, Aminoglycosidic and Industrial Enzymes were stated to be in progress. As regards Industrial Enzymes, it is stated that they are being tried out on a laboratory scale out of a process developed by R. & D. wing of the HAL. The Committee are informed that the preliminary feasibility reports show that the projects for Industrial Enzymes and Aminoglycosidic antibiotics will be financially feasible while that of Erythromycin would not be financially feasible on the basis of the technology available with the undertaking at present and therefore efforts are being made to obtain improved technology before the project is processed further. The Committee would like that a thorough study of the technologies, if any, available, in India for the manufacture of these products should first be made before considering import of any foreign technology and the feasibility and economic viability of the projects should be critically examined before taking up the projects. In case selection of foreign technology is inevitable, the Committee would like that the undertaking should select the best technology capable of producing the drugs at most economic prices. The Committee also caution that the earlier mistakes of taking up manufacture of Hamycin, Aureofungin etc. should not be repeated while taking up manufacture of the new drugs and every care should be taken to ensure that the drugs produced will be efficacious, stable and have a viable market for them.

Cl. Rejections

2.198. The Quality Control Department tests all products from raw materials to the finishing stage. Besides, representative sam-

ples of each batch of finished products (bulk and sub-divided) leaving the factory are retained by the Company and are frequently tested to assert in their stability/potency. In the event of loss of stability, appearance, suspension, characteristics, etc., before the expiry period, the batches are withdrawn from the market. Rejects arising from the tests in the Quality Control Department and withdrawal from the market are reprocessed. No norms have, however, been fixed by the Company for rejections during different stages of production or thereafter and also for recovery/recrystallisation of the rejects. The Management have stated (March, 1972) as follows:—

“Rejects occur at several counts such as potency, sterility clarity, impurity, colour, etc..... In the type of manufacturing activity involving biochemical process for manufacture of life saving drugs, the quality of product is most essential. Under the circumstances it is difficult to fix norms for quality rejects. 10 per cent rejection is, however, expected on quality grounds.”

2.199. The following table indicates the percentage of quantity rejected to total production during 1966-67 to 1973-74:—

Bulk Production

	1966- 67	1967- 68	1968- 69	1969- 70	1970- 71	1971- 72	1972- 73	1973- 74
Penicillin	11.7	12.4	10.0	8.8	11.3	10.3	2.33	1.09
Streptomycin	22.3	21.3	26.5	18.3	11.7	10.9	0.54	3.43
VIALS								
Penicillin & Penicillin combination		4.2	6.0	9.0	18.5	12.3	3.93	8.49
Streptomycin	..	2.8	15.4	1.2	2.0	2.7	1.57	2.31
Streptopenicillin		1.0	5.8	1.6	2.9	5.5	0.88	2.76
PENICILLIN TABLETS	..	20.2	3.8	5.2	4.0	5.3	20.58	15.66

- Notes.—1. Separate figures of rejects reprocessed in respect of vials is not available.
 2. Figures of 1966-67 for vials and tablets are not available.
 3. Separate figures for rejections in respect of capsules are not available with the Company.
 4. Rejects of vials do not include with draws from the market as the product-wise details of such withdrawals have not been maintained by the Company.
 5. This also includes injections arising from tests in the Quality Control Department and withdrawals from the market.

2.200. The percentage of actual rejections to total production (bulk) in respect of Penicillin and Streptomycin ranged from 1.09 to 12.4 and from 0.54 to 26.5 respectively; the percentage of rejections to vialled tableted production was between 1.0 to 18.5 and 3.8 to 20.2. The cost of reprocessing the rejections (in bulk form) amounted to 23.22 lakhs in Penicillin and Rs. 22.7 lakhs in Streptomycin. The rejected tablets and vials are also reprocessed (capsules are not reprocessed) but the cost of reprocessing has not been worked out by the Company.

2.201. On an enquiry of the Committee HAL stated that broadly the reasons for rejection during the last seven to eight years had been high moisture content arising out of humidity, disintegration time and variation in potency. Rejections arise due to multiplicity of factors, amongst them being humidity, stability, potency, failure of equipment and personnel failures. The percentage of rejects in any year depends on a combination of these factors and this causes the percentage to vary from year to year.

2.202. To another query as to the reasons for the percentage of rejections in penicillin tablets during 1972-73 and 1973-74 being higher than earlier years, HAL stated that during these two years, production of penicillin tablets were largely of penicillin V in case of which there were large rejects on account disintegration and variation in potency. To overcome this, after July, 1973 a new process had been developed for manufacture of penicillin V tablets.

2.203. It has been stated by Audit that the percentage of rejected samples in the case of bulk products increased from 1.22 in 1967-68 to 6.93 in 1970-71; the rejects being mainly in Sodium Penicillin 'G'. However, in 1971-72 the percentage of rejected samples came down to 1.72 per cent which again increased to 3.63 per cent in 1973-74. The percentage of rejected samples in the case of formulations was the highest during 1966-67 and has been varying from year to year thereafter, the lowest being 1.38 in 1974-75. The Management have, however, not analysed the causes for the higher percentages of rejects and have stated (March, 1972) as follows:—

“Efforts are made to locate circumstances contributing to increase in rejects and corrective action taken in various directions.”

2.204. The Committee were, however, informed that the reasons for high percentage of rejection are analysed and corrective action taken, for example in the case of Penicillin V tablets, the percentage

of rejections improved for 35.58 per cent in 1973-74 to 7.5 per cent in 1974-75.

Withdrawals from the market

Particulars	1966-67	1967-68	1968-69	1969-70	1970-71	1971-72	1972-73	1973-74
1. No. of batches withdrawn	110	98	100	94	27	11	37	91
2. Quantity-vials (lakh numbers)	3.21	5.47	4.50	1.89	0.53	3.42	2.07	0.66
3. Quantity-tablets and capsules (lakh numbers)	0.27	0.20	0.46	3.40	0.58	0.18	0.27	0.03
4. % of returns to net sales .	0.48	0.78	1.66	0.24	0.52	0.26	0.26	0.07
5. Value of returns* (Rs. in lakhs)	3.45	5.06	10.53	1.75	3.08	1.90	1.12	0.38

NOTES :—*1. This includes adjustments, diversion and all returns not necessarily withdrawn on quality grounds.

2. No batches were withdrawn in the case of bulk products.

2.205. Besides, the investigation of complaints received from the consumers/institutions by the Quality Control Department, the Company conducts stability studies of the batches lying unsold in its sales section for more than six months from the date of manufacture. If the investigation/study confirms the fall in efficacy of the product or reveals any other defect, the complete batch is withdrawn from the market.

2.206. The maximum number of withdrawals pertained to the period October, 1965 to March, 1966; April, 1967 to September, 1967 and October, 1967 to March, 1968. The Management have stated that the batches withdrawn mainly pertained to Potassium Penicillin 'G' and its formulations; the withdrawal was mainly on account of non-conformity to specification at the time of complaint and its investigations.

2.207. On an enquiry of the Committee as to what were the reasons for which batches were withdrawn from market, particularly those manufactured during April, 1971 to March, 1972 and April,

1972 to March, 1973, which were withdrawn as early as 1972-73 and 1973-74, HAL stated in a note as follows:—

“Batches have been withdrawn following complaints from the market in regard to reactions, particularly fatal reactions, as also due to failure of stability which could be noticed as a result of tests carried by the Quality Control Department of the Company.”

2.208. During evidence Committee were informed by the representatives of the Ministry as follows:—

“So far as quality of penicillin and streptomycin manufactured by HAL is concerned, we have generally found that the quality is very satisfactory. The quality of streptomycin of HAL is in fact very good. We have not received any complaint from the formulators who have been buying penicillin and streptomycin from them.”

2.209. The Committee were also informed during evidence by the Secretary of the Ministry that pharmacopoeia ceutical standards in India were very high as compared to international standards.

2.210. The Committee find that the percentage of rejects to total production in the case of Penicillin bulk has come down from 12.4 per cent in 1967-68 to 8.8 per cent in 1969-70. Though it increased to 10.3 per cent in 1971-72, it again come down to 1.09 per cent in 1973-74. In the case of streptomycin, though the percentage of rejects to the total production was the maximum of 26.5 per cent in 1968-69, the percentage came down to 0.54 per cent in 1972-73. It, however, increased to 3.4 per cent in 1973-74. The Committee see no reason why the undertaking should not sustain the low percentage of rejections so far achieved. The Committee recommend that it should be the endeavour of the undertaking to ensure that the rejects are further brought down.

2.211. The Committee regard to note that while there is a record of the tablets and vials rejected out of the total production, no separate figures of rejections in respect of the capsules are available with the undertaking. The Committee feel that in the interests of assessing the quality of the finished capsules, it is desirable that a record of rejects in respect of capsules is also maintained separately.

2.212. The Committee also regret to note that the rejections of vials do not include withdrawals from the market and product-wise details of such withdrawals have not been maintained by the company. The Committee apprehend that if such withdrawals are also included, the percentage of rejections may perhaps be more.

2.213. The Committee would like that a record of withdrawals of vials from the market should be maintained and analysed in depth and deficiencies identified with a view to taking corrective measures. The Committee need hardly stress that such rejections on account of quality not only affect the image of the company but also involve risks to patients.

2.214. The Committee find that in the case of Penicillin tablets, the percentage of rejections varied between 3.8 per cent in 1968-69 to 20.5 per cent in 1972-73.

2.215. The Committee also note that the undertaking had to withdraw from the market as much as 65,000 to 5.47 lakhs of vials per year and 3,000 to 5,8000 tablets and capsules during the period 1966-67 to 1973-74. It has been stated that stability studies of batches lying unsold in the sales section for more than six months from the date of manufacture are conducted and if the investigation or study confirms fall in the efficacy of the product or reveals any other defect, the complete batch is withdrawn from the market. In the opinion of the Committee it should not be difficult for the undertaking to have a sample test check of batches if any lying unsold for more than six months to ensure that the efficacy of such batches remains in tact before they are actually sent to the market. The Committee feel that 'withdrawals from market' do not leave a good image of a public undertaking on the public mind. The Committee find that a maximum number of batches of potassium penicillin 'G' were withdrawn and they pertained to the period—October 1965 to March, 1966, April, 1967 to September, 1967 and October, 1967 to March, 1968, and the withdrawals were mainly on account of non-conformity to specifications. The Committee fail to understand how such batches which did not conform to specifications passed the quality control tests.

2.216. The Committee were also informed that during 1972-73 and 1973-74, batches have been withdrawn following complaints from the market in regard to reactions particularly fatal reactions and also due to failure of the stability which could be noticed as a result of test carried out by the Quality Control Department of the Company. The Committee view with concern how such batches were passed of Quality Control Department before they found their way into the market. The Committee would like that the deficiencies in the products which resulted in the fatal reaction should be thoroughly investigated without loss of time and deterrent action taken against all those responsible for the delinquency. The Committee also recommend that Board/Government should ensure a

conclusive action and also take suitable measures to avoid recurrence of such cases.

2.217. The Committee feel that these problems are not insurmountable and could have been controlled by the management by contemporaneous monitoring. The Committee would like that the undertaking should critically go into the reasons for the very high percentage of rejections and see how far they were avoidable. The Committee recommend that on the basis of the experience of working and with reference to norms obtaining in undertakings manufacturing similar drugs, the undertaking should fix appropriate norms for rejections and also tighten its quality control measures to see that the percentage of rejections does not exceed the norms.

H. Consumption of raw materials

2.218. A number of raw materials are consumed in different processes for different products. Most of these raw materials are indigenously purchased but some of them are imported from abroad. The following statement indicates the total value of raw materials consumed and the import content thereof during 1966-67 to 1974-75:

(Rupees in lakhs)

Year	Value of total consumption	Value of imported raw materials Consumed	Percentage of imported materials to total materials consumed
(1)	(2)	(3)	(4)
1966-67	267.84
1967-68	259.23
1968-69	270.22	68.09	25.2
1969-70	277.70	54.68	19.7
1970-71	269.51	60.42	22.4
1971-72	335.84	38.67	11.5
1972-73	336.73	50.94	15.13
1973-74	358.89	32.62	9.90
1974-75	426.30	26.30	6.20

2.219. The Company fixed the standard consumption of these raw materials on different occasions. These standards were subsequently revised in respect of certain raw materials based on the actual experience.

2.220. The budgets are prepared on the basis of standard quantity and quality of raw materials. The Company ascertains quantity/price variances in respect of important raw materials as compared with the standards adopted for the preparation of budgets. The standard consumption per unit as compared with the actual consumption of certain important raw materials is given below:

(Figures in kgs.)

Process/raw material	Unit	1967-68		1968-69		1969-70		1970-71		1971-72		
		Standard consumption	Actual consumption									
1	2	3	4	5	6	7	8	9	10	11	12	13
1. Fermentation (Streptomycin)												
(a) Soyabean meal	batch		3,800	3,679	3,800	3,900	3,800	3,411	3,800	3,640	3,800	3,449
(b) Dextrose	Do.		4,800	4,420	4,800	4,602	4,800	4,571	4,800	4,567	4,800	4,722
(c) White Oil	Do.		500	649	500	477	500	371	500	536	750	629
2. Fermentation (Penicillin)												
(a) Phenyl Acetic Acid	Do.		60	42	60	53	60	49	60	51	60	54
(b) Sugar	Do.		1,200	1,198	1,200	1,214	1,300	1,182	1,300	1,289	1,300	1,376
(c) Ground-nut-oil	Do.		250	221	250	313	300	283	300	279	300	187
(d) Peanut meal	Do.		650	601	650	556	650	633	650	641	650	644
1. Fermentation (Streptomycin)												
(a) Soyabean meal							batch		3,800	3,473	3,800	2,821

	1	2	3	4	5	6	7	8	9	10	11	12	13					
(b) Dextrose							Do.	48.00	4,910	4,800	5,343					
(c) White oil							Do.	750	437	750	274					
2. Fermentation																		
(Penicillin)																		
(a) Phenyl Acetic Acid							Do.	60	77	76	71	76	69					
(b) Sugar							Do.	1,300	1,397	1,200	1,237	1,200	1,171					
(c) Ground-nut-oil							Do.	300	317	360	354	360	327					
(d) Peanut meal							Do.	650	631	630	612	630	632					
3. Extraction :																		
(Streptomycin)																		
Phosphoric acid								Kg	2.20	1.72	2.20	0.81	1.50	0.98	1.50	0.74	2.00	0.89
4. Sterile Area																		
(Streptomycin)																		
Sulphuric acid								Kg.	3.00	2.97	3.00	4.27	4.50	3.82	4.50	4.34	4.50	4.60
5. Recrystallisation																		
(Penicillin)																		
(a) Butyl Alcohol								MMU	1,600	1,558	1,600	1,573	1,600	1,872	1,600	1,955	1,600	1,825
(b) Phosphoric acid							Do.	400	384	400	348	400	400	554	400	476	400	314
(c) Acetone							Do.	2,500	3,310	2,500	3,560	2,500	2,500	5,769	2,500	5,519	2,500	5,502

Process/raw material	Unit	1967-68		1968-69		1969-70		1970-71		1971-72	
		Standard consumption	Actual consumption								
6. Chemical products											
(Penicillin)											
Pro-hydrochloride .	Do.	600	576	575	562	575	596	575	503	575	662

Process/raw material	Unit	1972-73		1973-74		1974-75	
		Standard consumption	Actual consumption	Standard consumption	Actual consumption	Standard consumption	Actual consumption
3. Extraction (Streptomycin)							
Phosphoric acid	Kg.	2.00	0.91	1.50	0.93	1.50	0.99
4. Sterile Area (Streptomycin)							
Sulphuric acid	Kg.	3.00	4.50	4.12	4.50	4.89

Process/raw material	Unit	1972-73		1973-74		1974-75	
		Standard consumption	Actual consumption	Standard consumption	Actual consumption	Standard consumption	Actual consumption
5. Recrystallisation							
(Penicillin)							
(a) Butyl Alcohol	MMU	1,600	1,828	3,500	1,816	3,500	4,869
(b) Phosphoric acid	Do.	400	368	400	452	400	315
(c) Acetone	Do.	2,500	4,077	4,500	5,309	4,500	5,743
6. Chemical products							
(Penicillin) 6000							
Pro-hydrochloride	Do.	575	726	575	560	575	643

2.220. The actual consumption of raw materials per unit of production widely fluctuated from year to year. The fluctuations were more prominent in the case of Soyabean meal and White oil in case of fermentation of Streptomycin Phenyl acetic acid, Groundnut oil and Peanut meal in case of fermentation of penicillin, Phosphoric acid in case of extraction of Streptomycin, Sulphuric acid in case of Sterile area of Streptomycin and Butyl alcohol, Phosphoric acid and Acetone in case of Penicillin recrystallisation. The actual consumption does not also indicate any set pattern during a particular year in respect of all the items. In the case of Acetone used for recrystallisation process for the manufacture of Penicillin, the consumption per unit was always much higher than the standard consumption; it went up from 3,560 kgs. in 1968-69 to 5,769 kgs. per MMU in 1969-70 i.e. an increase of about 62 per cent over the consumption of 1968-69. Though it came down to 5502 in 1971-72 but again went up to 5743 in 1974-75, and 131 per cent over the standard consumption. The value of excess consumption of the above raw materials (calculated on the basis of the price adopted for the preparation of the annual budgets) was as follows from 1967-68 to 1974-75:—

1967-68	Rs. 1.99 lakhs
1968-69	Rs. 5.80 lakhs
1969-70	Rs. 2.90 lakhs
1970-71	Rs. 3.61 lakhs
1971-72	Rs. 7.42 lakhs
1972-73	Rs. 9.80 lakhs
1973-74	Rs. 6.09 lakhs
1974-75	Rs. 7.57 lakhs

2.221. Prior to May, 1970, monthly consumption statements and the variance analysis were prepared by Costing Section and sent to the Production-in-charge for corrective action. No records have, however, been maintained to indicate the action taken on these reports.

2.222. From May, 1970 onwards, the monthly accounts indicating the variation between the actual consumption of raw materials and the standard consumption adopted for the preparation of budgets are prepared and discussed in monthly production meetings for corrective action. However, the corrective action actually taken was not indicated in the statements appended to the monthly accounts.

2.223. On an enquiry of the Committee why the standard consumption norms for white oil were revised in 1971-72 from 500 kgs.

per batch to 750 kgs. per batch when in the previous years i.e., in 1968-69 and 1969-70 consumption was less than the standard consumption and in 1971-72 a little more, the Company stated in a note—

“The collaborators had originally given a standard of 750 kgs. per batch which had been reduced to 500 kgs. per batch subsequently. As the standard was fixed at 500 kgs. efforts were naturally made to work within it. It was however found that economy in use of white oil was not conducive to proper foam from control, which, in turn, affected production. As a result, it was decided to restore the standard to 750 kgs. per batch.”

2.224. On the other hand consumption of Soyabean meal had always been less (except in 1968-69), but the standard consumption had not been revised downwards. HAL explained it as follows—

“The standard of 3800 kg. of Soyabean Meal per batch was fixed with reference to the results obtained in previous years. Although the actual consumption has been lower than the standard, the difference has not been large and did not justify a change in the standard. During 1974-75 the new strain has been introduced for manufacture of Streptomycin and standards for all raw materials used in Streptomycin manufacture would be revised after the results of working with the new strain are stabilised.”

2.225. The Committee pointed out that standard consumption of sulphuric acid was revised from 4.50 kgs to 3.00 kgs during 1972-73 although the actual consumption had been much more than 3 kgs. On the other hand, the actual consumption of Butyl Alcohol has been constantly more than the standard consumption, but the standards have not been revised. Likewise the actual consumption of Phosphoric acid during 1969-70 and 1970-71 was less than the standard consumption, but the standard consumption, was still revised upward in 1971-72, HAL stated as follows:—

“The consumption of phosphoric acid and sulphuric acid is inter-connected. Attempts were made to replace phosphoric acid with the cheaper and more easily available sulphuric acid, and as a result the consumption of phosphoric acid has gone down below the standard while that of sulphuric acid has gone down above the standard. It

was however found later that sulphuric acid was not as efficient as phosphoric acid and therefore the standards were revised prescribing a lower standards of sulphuric acid and a higher standard for phosphoric acid."

2.226. To an enquiry of the Committee as to what was the criterion followed in deciding whether there was necessity for revision of standard consumption of a particular raw material, HAL stated in a note that the standard was fixed/revised keeping in view the optimum consumption best suited to suit efficient production.

2.227. The Committee find that the value of excess consumption of materials has risen from Rs. 2.9 lakhs in 1969-70 to Rs. 9.80 lakhs in 1972-73. Though it came down to Rs. 6.09 lakhs in 1973-74 it has again gone up to Rs. 7.57 lakhs in 1974-75. The Committee view with concern that in spite of such steep increases in the value of excess consumption of material which contribute to the increase in cost of production, no action seems to have been taken to investigate into the reasons for such excesses. The Committee also note that though prior to May, 1970 monthly consumption statements and variance analysis were prepared by costing section and sent to production in charge for corrective action, no records had been maintained to indicate the action taken on such reports. Even after May, 1970 although the monthly accounts showing the variances between standard consumption and actual consumption were prepared the corrective action taken was not indicated in the statements. The Committee feel that in the absence of information/records to indicate the corrective action taken in variance reports, it is neither possible to verify whether action has actually been taken nor to fix responsibility for any lapse in this regard. In the opinion of the Committee this only indicates casualness of approach and laxity on the part of the management. The Committee therefore recommend that the undertaking should not rest content with merely preparing a statement of variances between standards and actual consumption but also indicate and ensure corrective action.

2.228. A statement of variances along with action taken should be included in the monthly/quarterly financial review and placed before the Board of Directors who would no doubt examine in depth about the adequacy of remedial and other measures taken.

2.229. The Committee also note that the standard consumption in the case of white oil was revised in 1971-72 from 500 kgs. per batch to 750 kgs. per batch when in the earlier years the consumption

was less than the standard. On the other hand in the case of soyabean meal although the actual consumption has generally been less, the standard consumption had not been revised downwards. Similarly in the case of sulphuric acid, the standard was revised from 4.5 kgs. to 3 kgs. during 1972-73 although the consumption had been much more than 3 kgs. In the case of Butyl alcohol, though actual consumption has been more than the standard consumption, the standard has not been revised. Likewise, in the case of phosphoric acid, actual consumption was less than the standard consumption during 1969-70 and 1970-71, the standard was revised upwards in 1971-72. It has been stated that the criterion followed for revision of any standard in any particular raw material was that the standard was fixed or revised keeping in view the optimum consumption best suited to efficient production. Since improved strains have been introduced in the case of penicillin from 1971 and in the case of streptomycin during 1974-75, the undertaking should watch the performance of the new strains and take action to revise the standards after the production gets stabilised so that a realistic assessment of the consumption of raw materials with reference to such standards can be worked out.

2.230. The Committee recommend that any upward/downward revision of norms should be done only after a detailed objective analysis of the consumption of materials for a period, consistent with efficiency and quality of the product and with the specific approval of an officer not lower in rank than Managing Director and after consultation with Finance. Such revision of standards should also receive the special attention of Board of Directors.

I. Utilisation of services

2. 231 The following table indicates the installed capacity for the various services, the actual utilisation of these services for production and the percentage of utilisation of capacity:

Service Department	Unit	Installed capacity	1966-67	1967-68	1968-69	1969-70	1970-71	1971-72	1972-73	1973-74	1974-75
1. Power.	Million Kwh	748	528 (70.60)	508 (67.91)	550 (73.53)	615 (82.22)	630 (84.22)	640 (85.56)	642 (86.83)	649 (86.76)	591 (79.01)
2. Steam.	Lakh Kgs	4,122	1,566 (38.00)	1,496 (36.29)	1,533 (37.19)	1,680 (40.76)	1,983 (48.11)	1,989 (48.25)	2,066 (50.12)	2,200 (53.37)	2,033 (49.32)
3. Refrigeration	Tonnes	11,16,900	663,754 (59.43)	630,680 (56.47)	622,393 (55.73)	700,920 (62.76)	633,537 (56.72)	667,268 (59.74)	667,561 (59.77)	640,147 (57.31)	597,807 (53.52)
4. Compressed air	Lakh ⁷ cubic metres	3,908	2,969 (75.97)	2,808 (71.85)	3,030 (77.53)	3,471 (88.81)	3,869 (99.00)	3,382 (86.54)	3,654 (93.50)	3,750 (95.96)	3,687 (94.34)
5. Water	lakh gallons	3,942 and 8,322 from 1972-73	3,210 (81.43)	3,226 (81.84)	3,210 (81.43)	3,210 (81.43)	3,313 (84.04)	3,130 (79.40)	5,189 (62.35)	5,200 (62.48)	5,500 (66.69)

NOTES: 1. Figures in brackets indicates percentage utilisation of installed capacity.

2. The installed capacity has been indicated after providing 10% for maintenance and servicing as suggested by the Management.

2.232. The Company has a common supply system of services for various plants and there is no arrangement for recording actual consumption at different plants and/or for different process. Also, no yardsticks have been prescribed by which control can be exercised over actual consumption. The Management has stated (March, 1972) as follows:—

“It is very difficult to fix yardstick of consumption of various services for the processes/products. The most important point of consumption of services is at the fermentation stage; it is at this point that the Management roughly compares consumption of important services per fermenter batch to gauge the efficiencies in the absence of necessary instruments. . . . Increase have taken place during 1970-71 in the case of steam and air compared to 1967-68. It appears that steam product is on the higher side during 1970-71. The matter is under investigation.”

2.233. On an enquiry of the Committee that in the absence of arrangements for recording actual consumption at different plants/processes, how it was ensured that the consumption was not more than that it should be and whether a rough comparison of consumption of services at fermentation stage alone enabled the Management to exercise proper control, HAL stated that comparison of consumption of services at fermentation stage provided a rough guide and that meters were being gradually installed and until then control would have to be with reference to the estimates. The provision of meters was being speeded up.

2.234. The consumption of power, steam and compressed air has shown an increasing trend (except) compressed air during 1971-72). The consumption during 1970-71 was substantially higher as compared with 1966-67 although the production of Penicillin one of the major products, had declined, and that of Streptomycin was almost the same.

2.235. While the installed capacity of the services has not been fully utilised particularly in respect of steam and refrigeration, the production of Penicillin and Streptomycin suffered due to shortage of services. HAL explained that the shortage of services arose sporadically as a result of mechanical failures and was not related to capacity.

2.236. The Management stated (March, 1972) ha in any manufacturing industry, standby capacity for services is necessary. In the initial stage there was greater amount of standby which has been progressively utilised. In the case of refrigeration, under utilisation is due to the non-availability of the equipment on account of frequent breakdowns.

2.237. To an enquiry whether standby capacity to the extent of 50 per cent or so, as in the case of steam, was necessary, HAL stated in a note as follows:—

“No: so large a percentage of stand-by capacity is not necessary. This position has arisen as a result of reduction in some new plants like Vitamin C, Hamycin, Neomycin, and Aureofungin not having progressed as originally envisaged. Further some of the units such as boilers have become obsolete and will be disposed off. These give an exaggerated figure of available capacity.

A Centrychiller which was primarily responsible for the breakdowns in the Refrigeration unit has been completely overhauled in 1972.”

2.238. As regards frequent break-downs of refrigeration equipments it was stated that, “with a view to minimise break-downs in the refrigeration unit, planned preventive maintenance had been introduced after 1971, and was being gradually intensified. With the introduction of this breakdowns in refrigeration units were coming down progressively. These were 22 per cent in 1972-73, 18.3 per cent in 1973-74 and 3.7 per cent in 1974-75.”

2.239. The Committee regret to note that no yardsticks have been prescribed for exercising control over actual consumption of power steam and compressed air nor is there any arrangement for recording actual consumption at different plants and/or for different processes. The Committee find that the consumption of power steam and compressed air has shown an increasing trend (except compressed air during 1971-72) from 1966-67 to 1973-74. The consumption has slightly come down during 1974-75. The consumption during 1970-71 was substantially higher compared to 1966-67 although the production of Penicillin had declined and the production of streptomycin was almost the same. The Committee are informed that the most important point of consumption of services being at the for-

mentation stage, the Management roughly compared consumption of important services per fermentation batch in the absence of necessary instruments. The Committee cannot comprehend how a rough comparison of consumption of services, only at the fermentation stage could enable the management to exercise control over the consumption of services at the different stages|processes of production which is essential to control costs and cut out wastages at each stage|process. The Committee also fail to understand as to how in the absence of any meters or measuring instruments, the efficiencies in regard to consumption are at all gauged. The Committee are informed that meters are gradually being installed and till then the control would be with reference to estimates. The Committee feel that installation of meters or other measuring instruments should have been done along with the equipment themselves and recommend that the undertaking should lose no further time in fixing the meters and exercising proper control over consumption of services, which has a bearing on over-all cost of production.

2.240. The Committee recommend that Government|BPE should issue standing directions that measuring control instruments should invariably be provided along with the machines|equipment and should be fact from an integrate part of the machines.

2.241. The Committee also find that percentage of the consumption of steam has been the maximum—53.37 per cent in 1973-74 while consumption of compressed air has been the maximum 99 per cent in 1970-71 of installed capacity. The Committee would like that the reasons for abnormal increase should be critically examined with a view to taking suitable remedial action.

2.242. The Committee are also informed that although there had been stand-by capacity for other services, which had to be progressively utilised in the case of refrigeration the under utilisation of installed capacity was due to frequent breakdowns.

2.243. The Committee are informed that with the introduction of planned preventive maintenance introduced after 1971, the percentage of breakdown has come down from 22 per cent in 1972-73 to 3 per cent in 1974-75. The Committee feel that it is not so much the absence of stand-by but lack of preventive maintenance which had been responsible for such frequent break-downs. The Committee have given their comments elsewhere in this report about non-observance of preventive maintenance schedules.

2.244. The Committee also note that in the case of steam, 50 per cent of the capacity has been kept as a stand-by, although such high percentage for stand-by was not considered necessary. The Committee fail to understand as to why such large stand-by capacity was at all created. It has been stated that it was because of new plants of Vitamin 'C', Hamycin, Neomycin and Aureofungin not having progressed as originally envisaged and some of the boilers have become obsolete and would be disposed off. The Committee have already given their recommendations in regard to setting up of capacities for Vitamin C, Hamycin, Aureofungin etc. in the Performance chapter of this report.

J. Machine/Labour Utilisation

2.245. The Company works out the idle machine hours only in respect of fermentation (Penicillin and Streptomycin) and filling sections. No record is maintained indicating the idle labour hours and reasons therefor. HAL explained this in a note as follows:—

“H.A.L. is a continuous process plant, and in such a plant idle labour in respect of production and maintenance workers arises very rarely when a section is closed. In such cases the staff of the section are engaged for cleaning and house keeping or are diverted to other units. The time loss on account of idle labour is, therefore, insignificant and it has not been found necessary to maintain a separate record for this. From the different records available in the section, it is always possible to point out if and when necessary the extent and reason for idle labour.”

2.246. The table below brings out the idle machine hours in the fermentation and filling sections during the last eight years.

(a) Penicillin Plant

Annual overhaul	8,136	3,629	7,653	6,249	13,178	8,786	8,295	8,305
Filter renewal	2,124	2,557	5,567	4,154	5,033	3,619	3,276	4,528
Turnover time	9,723	11,153	16,065	16,218	14,095	12,836	14,014	13,297
Late seed growth	1,371	1,576	2,551	2,959	5,982	956	1,288	1,352
Planned seeding	12,562	8,511	7,838	13,185	11,921	9,344	3,169	3,300
Contamination	866	824	1,818	2,166	606	801	2,208	3,538
Break-downs	8,165	9,626	9,355	9,164	8,334	7,200	5,770	5,157
Miscellaneous	717	663	2,098	3,708	2,281	972	6,679	4,475
Total idle hours	43,664	38,538	52,945	57,803	61,430	44,514	44,699	44,252
Available machine hours	1,51,220	1,62,701	2,11,027	2,08,785	1,98,110	1,64,184	1,60,919	1,66,440
% of idle machine hrs. to available hours	28.87	23.68	25.09	27.68	31.01	27.11	27.78	26.59

(b) Streptomycin Plant:

Annual overhaul	1,434	383	570	2,410	1,435	3,635	3,656	5,684
Turnover time (including filter renewals)	5,640	5,480	6,200	6,060	4,248	6,372	6,977	2,380
Late seed growth	474	150	618	54	18
Planned gap for extraction	581	562	5,402

	1967-68	1968-69	1969-70	1970-71	1971-72	1972-73	1973-74	1974-75
Contamination	754	2,254	1,910	5,405	7,349	693	3,345	1,266
Break-downs	7,151	1,577	2,812	5,672	100	1,472	..	1,091
Shortage of raw material	707	12,468	1,602	2,433	360		5,472	7,795
Miscellaneous	340	2,070	4,700	5,438	3,559	15,070*
Total idle hours	16,267	23,198	13,442	24,060	18,342	18,228	22,863	38,706
Available machine hours	79,102	78,540	80,256	87,600	86,987	87,600	87,840	87,600
Percentage of idle machine hours to available hours	20.56	29.53	16.75	27.47	21.09	20.81	26.03	44.18
(c) Filling sections:								
Assembly adjustment	405	399	649	577	387	313	470	419
Weight adjustment	1,050	1,118	1,046	11,27	2,025	1,763	1,672	1,222
Rubber stopper unit adjustments	526	981	659	412	505	543	458	557
Sealing unit adjustments	878	720	622	670	1,245	1,392	1,382	1,256
Washing, cleaning and changing	43	692	754	685	52	533	839	382
High humidity		90	110	171	83	74	48	146

(1) Due to use of two fermenters for starch Hydrolyste test

	1967-68	1968-69	1969-70	1970-71	1971-72	1972-73	1973-74	1974-75
Break-downs	94	82	47	614
Miscellaneous	798	94	88	70	239	315	140	486
Total idle hours	4,097	4,189	4,010	3,759	5,150	4,933	5,009	4,461
Available machine hours	13,336	11,650	13,969	13,529	14,751	14,350	14,182	12,417
Percentage of idle machine hours to available hours	30.72	35.95	28.70	27.78	34.91	34.38	35.32	35.98

2.247. The Committee regret to note that the undertaking has not maintained any record to indicate the idle labour hours and only a record of idle machine hours is maintained and that too only in fermentation and filling section. The Committee see no reason why record of machine utilisation should not be maintained in the other sections and fail to understand how in the absence of such a record, allocation of costs is done and idle hours controlled. The Committee recommend that the undertaking should take steps to maintain suitable records to indicate the utilisation of machinery in the different sections and processes.

2.248. The Committee are informed that the production being on a continuous process system, idle labour in production or maintenance occurs very rarely and from the records already available, it is possible to know the extent and reasons for idle labour. The Committee feel that in the interest of assessing the efficiency and productivity of labour it is necessary that records of utilisation of labour and idle labour hours and the reasons therefor are maintained.

2.249. The Committee recommend that information regarding idle machine hours and man hours should be reflected in the monthly/quarterly reports to the Management and Board of Directors. The Committee also suggest that the internal audit should critically examine the records of idle machine/man hours and report to the Management/Board of Directors to enable them to take conclusive follow-up action. The Committee need hardly stress that high percentage of idle hours of men or machinery will only add to the cost of production, with the result the prices would cease to become competitive.

2.250. The Committee find that the percentage of idle machine hours to the total available hours in the Penicillin plant has been increasing from 23.68 per cent in 1968-69 to 31 per cent in 1971-72 and it has come down to 17.5 per cent in 1974-75. The Committee note that the bulk of the idle hours has been due to contamination turn-over time and breakdown of machinery. The Committee feel that these are areas which could be controlled by efficient management and the idle hours could be brought down. The Committee would like that the undertaking should take concerted measures to control idle hours on account of these factors in the best interest of production.

2.251. The Committee also note that in the case of Streptomycin, the percentage of idle machine hours to total available hours has shown varying trend. While it is lowest (16.75 per cent) in 1969-70

is shot up to 42.57 per cent in 1974-75. The Committee find that besides turnover time and shortage of raw materials contamination has also contributed to idle hours. The Committee see no reason why the undertaking should not have kept sufficient buffer stock of raw materials and obviated the necessity of keeping machines idle for want of raw materials. The Committee have already given their recommendation particularly in regard to the shortage of soyabeans because of which production has suffered. The Committee would like that the undertaking should take suitable steps to control idle hours due to contamination in the best interest of production.

2.252. The Committee would also recommend that the reasons for the very high percentage of idle machinery hours during 1974-75 should be investigated to see whether any of the reasons are avoidable.

III

FORMULATIONS

A. Vialling

The Company has 4 machines for vialling operations. On the basis of three shifts working, 12 shifts are available per day; 3 shifts required for cleaning and sterilising operations and 9 shifts are available for vialling operations. Assuming 300 working days in a year (excluding 52 Sundays and 13 other holidays) and after providing 10 per cent for overhauling and down time, 270 working days are available in a year. On this basis, total number of shifts available works out to 2430. The actual number of shifts worked vis-a-vis those budgeted during 1966-67 to 1974-75 are indicated below :—

Year	Budgeted	Actually worked
1966-67	2,475.6	2,065
1967-68	2,480.0	2,245
1968-69	2,547.2	1,833
1969-70	2,192.0	2,328
1970-71	2,232.0	2,254
1971-72	2,391.0	2,283
1972-73	2,160.0	2,442
1973-74	2,312.0	2,352
1974-75	2,228.0	2,084

3.2. The number of shifts actually worked was less than the available shifts (2430) on account of absenteeism, lack of trained operators, breakdown of machines, shortage of rubber stopper etc.; the shifts attributable to each of these reasons have not been analysed by the Company.

3.3. The vialling capacity of the Company works out to 48,000 vials per shifts (6,000 vials per hour into 8 hours for each shift). Assuming six effective running hours in a shift after allowing for make-ready and adjustment, lunch, and tea breaks, etc., and taking into account the fact that full speed cannot be maintained for all the running hours, the normal output per shift should, according to the Ministry, be 36,000 vials per shift as against 48,000 vials per shift stipulated by the manufacturers. But while budgeting the annual production, the Company has been assuming the vialling capacity as 25,000 vials per shift and on that basis the annual vialling capacity is reckoned at 600 lakh vials.

3.4 The Management stated in May, 1973 that the capacity of 48,000 vials per shift indicated by the manufacturers was based on continuous working of 3 hours without stoppage and is therefore, not practicable. The rated capacity of 36,000 vials per shift fixed by the Ministry is practicable, but it takes into account the use of raw materials like glass vials, rubber stoppers and sealing foil of a very rigid specification which it has not been found possible to obtain indigenously. As a result, the working capacity is assumed at 25,000 vials per shift.

3.5. The Managing Director informed the Committee during evidence in this regard as follows:—

“There are a number of groups in this. This is a completely automatic filling line in which a number of equipments are involved. Like the automobile assembly line, the weakest link determine the capacity of the line. On that basis, the company has formulated 25,000 vials per shift as the capacity. We are working on that basis, But I am not satisfied with it myself.”

3.6. On the Committee drawing attention of the Managing Director to the fact that Ministry regarded the capacity as 36,000 vials per shift as against 48,000 vials per shift of the manufacturers, whereas HAL had fixed it at 25,000 vials per shift, the Managing Director explained as follows:—

“I had the good fortune to visit all the units in different countries personally and I can tell you it depends upon the materials such as glass vials, rubber stoppers, the sense of responsibility of the operating personnel. We are our-

selves not happy with 25,000 vials. We are working on this problem. We have sent our people to private companies such as Sarabai, Hoechst, Alembics to show that they are doing a much better job than in our company. If under Indian conditions other companies are able to do more, why are we not able to do so? We are aligning our lines and we hope we would be able to increase this number. One snag here is that you are dealing with lives of people. If there is any negligence in respect of this each vial is so important that it will lead to very serious consequences. Secondly, we did force the pace and tried to increase the number but then the rejections also rose to 11—18 per cent compared to 4.5 or 4 per cent before. 25,000 is the average. In some formulations they have reached 40,000. If you go to sodium penicillin, it is only 20,000. As I said we are making constant efforts and in fact it has become a necessity to us; we must increase the vialing capacity and then only our profitability will improve. We want to instal a six crore plant and that will take three or four years. But even with the existing machine we want to increase the number per shift and we have given three or four alternatives: making the machine work all the time so that the machine does not stop in our case the machine works for five to six hours and then stops; then the people for the new shift come. If necessary we want to put in more people so that it is run and it does not stop so that you utilise the machine to the fullest capacity. But then there is the question of rejections."

3.7. In regard to rejections, the Managing Director stated that:

"Humidity is a very vital factor; it was not at the proper humidity, they used to stop the machine. We have taken some measures and we have long-term plans to see that humidity is maintained at the proper level."

3.8. The Secretary of the Ministry stated in this connection during evidence that:

"In case of vialing there was a serious difficulty. It was this. The vialing capacity was based on eight-hour shift. They are definitely losing two hours. We do not agree that the company should reduce the capacity because of this. They

have to find other ways and means of ensuring that machines are actually worked for eight hours.

* * * * *

There are certain technical problems in vialling, particularly in the size of the vials which are received. The most important question was the issue of shifts and this is a soluble problem. We are discussing with them how we can get a full eight hour shift so that vialling could go up."

3.9. The Committee note that as against the installed capacity of 48,000 vials per shift based on continuous working for 8 hours without stoppage, the Ministry considered a capacity of only 36,000 vials per shift as practicable. As against this, the management assumed the working capacity to be 25,000 vials per shift. The Managing Director has admitted during evidence that they are not happy with working capacity of only 25,000 vials. The Committee are informed that other companies in Indian conditions are able to achieve more. One of the reasons for reducing the capacity was stated to be loss of 2 hours in a shift of 8 hours. The Committee find that number of shifts actually worked was less than the available shifts, on account of absenteeism among workers, lack of trained operators, shortage of rubber stoppers, breakdown of machines, etc. The Committee regret to note HAL has not analysed the loss of shifts on account of each one of these reasons. The Committee agree with the Ministry that the undertaking should not have reduced the capacity because of the alleged loss of 2 hours in a shift but should find out ways and means of ensuring that the machines are actually worked for the full 8 hours so that vialling could go up. The Committee also see no reason why it should not be possible to increase the utilisation of installed capacity when other companies under Indian conditions are able to achieve this. The Committee are informed that the HAL is already aligning the lines and trying to maintain the humidity level to control rejections and also discussing with staff about the issue of shifts to get a full 8 hour shift so that vialling could go up. The Committee would like HAL should improve the utilisation of capacity and bring it to the level of 48,000 vials without further loss of time and money. The Committee would like to be informed of the concerted measures taken and the results achieved.

Capacity Utilisation

3.10 The vialling capacity of the company on the basis of the actual number of shifts worked during a year, original and revised

targets for vialling and vialling actually done during 1966-67 to operations would be as follows :—

(Figures in Lakhs Vials)

Year	Capacity (based on 36,000 vials per shift)	Targets		Actual production	Utilisation of capacity (col. 5 to 2) %
		Original	Revised		
		(Based on 25,000 vials per shift)			
1	2	3	4	5	6
1966-67	743.40	618.90	523.46	513.01	69.01
1967-68	808.29	620.00	586.66	558.43	69.09
1968-69	659.88	636.80	453.00	449.24	68.08
1969-70	838.35	548.00	551.18	544.94	65.00
1970-71	811.44	558.00	539.28	522.72	64.42
1971-72	821.88	597.74	535.03	549.73	66.89
1972-73	879.12	540.00	520.00	500.23	56.90
1973-74	846.72	578.00	578.00	528.27	62.39
1974-75	750.2	562.00	428.00	425.00	56.65

3.11. It is seen that actual production fell short of not only the capacity based on 36,000 vials per shift but also the reduced vialling capacity assumed by the Management. The number of vials actually produced per shift was also less than 25,000 vials per shift as indicated below:—

Year	No. of vials actually produced per shift
1966-67	24,844
1967-68	24,872
1968-69	24,508
1969-70	24,402
1970-71	23,191
1971-72	24,079
1972-73	20,484
1973-74	22,480
1974-75	20,393

3.12. Even if the actual vialling capacity is taken at 25,000 vials per shift as contended by the Management, the efficiency of vialling operations would be as follows:—

(Figures in lakh vials)

Year	Vialling capacity (25,000 vials actual shifts worked)	Actual number of vials produced
1966-67	516.25	513.01
1967-68	561.31	558.43
1968-69	458.25	449.24
1969-70	582.19	544.94
1970-71	563.50	522.72
1971-72	570.75	549.73
1972-73	610.50	500.23
1973-74	588.12	528.27
1974-75	521.00	425.00

3.13. Taking the number of available shifts as 2430 and the output per shift as 25,000 vials (the same as assumed by the Company for fixing annual targets of production although according to the manufacturers, it should be 48000 vials per shift) the existing capacity works to 607.50 lakh vials per annum.

3.14 The shortfall in vialling operations has been attributed by the Management in 1966-67 and 1967-68 to the fact that as against nine shift operations proposed from the four vialling lines, only seven shifts were operated partly due to lack of trained operators and partly due to deliberate policy of not going ahead with full production on account of heavy rejections and in subsequent years to absenteeism, shortage of vials, rubber stoppers and other packing materials and lack of orders due to non-finalisation of DGS&D contract.

3.15. The matter regarding the rubber stoppers was investigated by the Managing Director at the instance of the Board of Directors. It was found that there was no delay in initiating the procurement action or neglect of a nature sufficient to fix responsibility on a

person or persons concerned. However, the need to strengthen the inventory control procedures, build up of adequate buffer reserves and to keep close liaison with the suppliers was emphasised by the Board of Directors in March, 1970 so as to avoid recurrence of such a situation.

3.16. The problem of rubber stopper has since been resolved in the following manner:

“As regards rubber stoppers the company switched over to synthetic rubber stoppers in 1974. This had to be done as it was found that natural rubber stoppers did not afford adequate protection against seepage of moisture into the vial. The private viallers did not find use of synthetic rubber necessary as their product is mostly sold to the private trade where the turnover is very quick and does not involve prolonged storage. Synthetic rubber is imported and its availability is limited. We have now got adequate import licence and the problem of shortage of rubber stoppers due to shortage of synthetic rubber is not likely to recur.”

3.17. In regard to absenteeism the Management informed Audit in May, 1972 that separate statistics of absentees in respect of vialling operations were not available. It has been stated that this problem has since been attended to.

3.18. As regards shortage of vials HAL informed the Committee in a note that—

“There was only one supplier of glass vials viz. M/s. J. G. Glass Works who manufactured and supplied glass vials of the specifications required by HAL. This supplier had a virtual monopoly till the end of 1974 when an additional source of glass vials was established. Although tenders were invited on several occasions, no offer for the required specifications was received except from M/s. J. G. Glass. Until 1973-74, the firm did not however cause any interruption to supplies but in that year they started going slow in supplies. They raised the question that the price paid by HAL was uneconomic and they were not in a position to give adequate supplies unless a price increase was agreed to. The contract under which they were supplying was still in force, and they were contractually bound to supply at that rate. Increase in the rate was

therefore resisted but the firm insisted that contractual obligations notwithstanding they would not be in a position to ensure adequate supplies unless the rate was increased. Although legally the company had a right to enforce the contract, it could not be put into practice as this was the only firm and in the event of their not supplying, our production would be stopped. Moreover in the absence of an alternative source, it would not also be possible to procure vials from another source at the risk and cost of J. G. Glass. Taking into account the realities of the situation an increase in rate had to be conceded. But as stated above, in view of our contractual rights, it had to be resisted first. The increase was claimed and had to be allowed twice, ones towards the end of 1973 and again during 1974-75.

Apart from the unattractive rate, there was at that time, an overall shortage of glass vials in the country due to shortage of soda ash. The shortage of vials suffered by the company during 1973-74 and 1974-75 has been due to the above reasons.

In another note it was stated that M/s. J. G. Glass being situated on the land belonging the HAL, were ancillaries. The terms of lease of land provides that 50 per cent of requirements of vials would have to be supplied by J. G. Glass at the rate of the lowest tender obtained by HAL. As there was no other tender for the required glass vials during the last so many years, this provision had become redundant in practice. It would however, have afforded protection to HAL if some other offers lower than J. G. was received.

3.19. The Committee were also informed that HAL was using of BP 58 specifications, while other manufacturers were using U.S.P. Type III. Most of the HAL's sale was to Government institutions where the turn over was not so quick. The necessity for prolonged storage compelled HAL to be more rigid about the specifications of glass vials and rubber stoppers than private viallers and this limited the availability of supplies of the same.

3.20. During evidence the Managing Director also informed the Committee:

"Last year we had suffered very heavily because the company had supplied one crore less of vials than the required quantity".

3.21. In regard to a suggestion that HAL should acquire a captive plant for vials for their own use instead of depending on supply of vials from a private source, the Secretary of the Ministry stated:—

“We have decided against this both in the case of IDPL and HAL for the simple reasons that the technology of glass making is not within our competence. It is true that a couple of private firms like Sarabhai and Alembic have their own captive vials plants, because they have got a big glass empire. They produce bottles.

As it happens today, there is no public sector in the glass industry, do not say there ought not to be. But in the case of Sarabhai or Alembic they are in glass technology. It is a moot point whether we should concentrate in HAL and IDPL on the manufacture of glass, where the whole technology is entirely different. Now the capacity in the country for vialling is much better.”

3.22. On an enquiry from the Committee that when the private sector company failed to supply vials, as a result of which HAL suffered a loss, whether any penalty was received from them, the Secretary stated that:

“In fact, that company ultimately ran into considerable difficulty and they had to sell out. It was a badly managed concern.

There are two plants of JG Glass, one at Pimpri and another at Rishikesh. They are sick units. We did not want HAL, which is a partially sick unit, to have another sick unit. The moment they take over the JG Glass at Pimpri, the first thing they have to do is to bring up the scales of pay of workers in the vialling plant on par with HAL scales, which are considerably higher and straightway their vial cost would go up. We have given some thought to and we are wondering whether it would have an economic advantage, particularly in view of the fact that we have licensed in the last two years a large number of vial-making plants. We are in touch with DGTD for the supply of vials. About 60 to 70 per cent of the licensed capacity ultimately comes to fruition.”

3.23. Asked whether the Ministry were satisfied with the performance of the Company in the matter of vialling operations and whether any assistance was rendered by Government, it was stated that

the Government were anxious to assist the Company in improving their performance. However, the technical problems pertaining to operation of machines had to be rectified by the undertaking themselves with a view to improving the productivity of the vialling machines as they knew exactly where the shoe pinched. The Company was seized of the problems involved and therefore the question of extending any direct assistance at, this stage would not arise.

3.24. The Committee regret to note that the actual production fell short of not only capacity based on 36000 vials per shift but even the reduced vialling capacity of 25000 assumed by the Management, the lowest production being 20,393 in 1974-75. The Committee further note that, though on the basis of the number of available shifts at the output at 25,000 per annum, the capacity works out to 607.5 lakhs vials per annum, the Undertaking has fixed the capacity to 538 lakhs vials per annum. The Committee do not find any rationale for this reduction in capacity to 538 lakh vials. The Committee regret to note that even this reduced rate had not been achieved except during 1967-68, 1969-70 and 1971-72. The Committee recommend that the vialling capacity of each machine and the question of optimum number of working shifts should be gone into in depth with a view to identifying the constraints which affect the working of the plant at 48,000 vials and suitable measures taken to attain the full capacity under a time bound programme and the Committee informed.

3.25. The Committee are informed that the shortfall in vialling operations has been attributed to loss of two shifts in the vialling line due to lack of trained operators and partly due to deliberate policy of not going ahead with full production due to heavy rejections, shortage of vials, rubber stoppers, etc. The Committee are also informed that the Undertaking has also now taken some measures to see that the humidity is maintained at proper level to control rejections. This being a management function, the Committee fail to understand as to why this could not have been taken care of at the appropriate time and rejections controlled. The Committee recommend that the measures now taken should be kept under continuous watch so that humidity is maintained at the proper level.

3.26. In regard to rubber stoppers, though the problem is reported to have been solved by shifting to synthetic rubber, the Committee see no reason why this could not have been taken care of by proper planning. The Committee find that the need for strengthening the inventory control procedure, building up of adequate reserves and keeping close liaison with the suppliers was emphasised

by the Board as early as 1970. The Committee expect that the Management would keep their instructions in view and observe them so as to avoid recurrence of shortages of rubber stoppers and other vital accessories.

3.27. The Committee note that one of the reasons for the shortfall in vialling operations has been reported to be shortage of vials. The Committee find that HAL has been getting the vials of BP 58 specification produced by only one private sector firm situated as an ancillary unit on the land belonging to HAL. According to the terms of lease of land, 50 per cent of the HAL's requirements of vials would have to be supplied by it @ lowest tender obtained by HAL. Since there was no other tender for the required glass vials during the last so many years, this provision in the agreement became redundant in actual practice. The Committee feel that the agreement should have contained suitable provision for meeting the demand of the main undertaking in full and also the price to be paid for the cost of production and international price etc.

3.28. The Committee find that till the end of 1974 when the additional source of supply was established, this private sector company enjoyed a virtual monopoly and exploited that position by demanding a higher price which HAL first resisted but ultimately had to concede twice once towards the end of 1973 and secondly during 1974-75. The Committee were informed by the Managing Director during evidence that the undertaking suffered very heavily because it had supplied one crore less of vials than the required quantity during 1973-74. The Committee are of the opinion that the private firm which was nurtured as an ancillary unit with all the attendant facilities, should have given priority of supplies to the main undertaking HAL according to the terms of the agreement and even if there had been any dispute about rates these could have been resolved by arbitration etc. at a later stage. The Committee fail to understand as to why no legal action was taken against the private firm by the undertaking to enforce the terms of the contract. The Committee are constrained to observe that HAL allowed a situation to develop in which the private sector company was able to hold it to ransom by interrupting supplies of glass vials and forcing it to agree to price increase just to avoid stoppage of production. The Committee are led to conclude that the agreement with the Company either did not adequately safeguard the public interest or the provisions thereof were not effectively and promptly invoked. The Committee would like that the agreement and the role of HAL in

drawing and implementing it should be thoroughly investigated with a view to fixing responsibility for the lapses. The Committee would like to be informed of the precise action taken in pursuance of this recommendation.

3.29. The Committee recommend that Government/BPE should on the basis of experience of the working of the agreement define the role and obligation of the ancillary industries vis-a-vis the main industry. They should draw up a model agreement for such ancillary industries making it obligatory for them to meet the requirements of Public Undertakings in full and supplies made by them to the Public Undertaking should be most competitive with reference to the price charged by other units/international price/cost of production.

3.30. The Committee note that private companies like Sarabhai and Alemic are having their own captive vialling plants and there is no such plant in the public sector to meet the needs of the industry. The Committee recommend that, since the public sector drug companies-HAL and IDPL are reported to be facing considerable difficulties in obtaining the requisite quality and quantity of vials, Government should consider the feasibility of setting up captive vial making capacity with the public sector units after carefully examining the technical and financial implications thereof.

Percentage of quantity formulated

3.31. The quantities of viallable antibiotics (Penicillin 'G' and Streptomycin) produced, the quantities vialled and the percentage of vialled quantities to total production during 1966-67 to 1974-75 are given in the following table:—

Year	Quantity produced	Quantity issued for vialling	Percentage of issues to total production
1	2	3	4
Penicillin G (MMU)			
1966-67	58·38	23·93	40·99
1967-68	45·16	17·81	39·44
1968-69	47·15	15·31	32·47
1969-70	51·04	21·53	42·81

1	2	3	4
1970-71	50.70	19.96	39.37
1971-72	56.35	20.40	36.20
1972-73	66.97	24.18	36.11
1973-74	66.31	24.40	36.80
1974-75	58.10	12.57	21.63
Streptomycin (Kgs)			
1966-67	60,670	22,231	36.64
1967-68	66,393	36,241	54.59
1968-69	70,253	30,301	43.13
1969-70	83,138	31,024	37.32
1970-71	60,971	31,840	52.22
1971-72	62,038	27,869	44.92
1972-73	72,350	27,339	37.79
1973-74	64,027	27,469	42.90
1974-75	63,370	33,733	53.28
Balance quantity has been sold to private viallers			

3.32. As already pointed out, the Company has not been fully utilising its available vialling capacity. Despite this, the quantity of viallable antibiotics issued for vialling was much less than the total quantity produced. In June, 1971, it was stated by the Management that no specific directive was issued by Government to restrict the vialling of antibiotics to any particular level and it was left to the discretion of the Company as to which product was to be vialled and in what proportion. The present vialling capacity was gradually established from inception to November, 1963. Although the production capacity of Penicillin and Streptomycin was substantially expanded thereafter the Company appears to have considered the question regarding further expansion of its vialling capacity only in June, 1971 when it was decided that the capacity should be increased from 538 lakh vials to 838 lakh vials at a cost of Rs. 71.5 lakhs. Pursuant to discussions with the Government, Management had agreed (November 1973) to review this project on obtaining improved strain and technology in respect of Streptomy-

cin. The project has now been included in the fifth Five Year Plan and its feasibility report is under process (May 1975).

3.33. The Management stated in May, 1973 that the expansion of vialling capacity is primarily intended to cater to the increased production of Streptomycin. As Government have deferred the consideration of sanction to the expansion of Streptomycin plant, the sanction for the expansion of vialling capacity would be automatically deferred.

3.34. The Committee on Drugs and Pharmaceutical Industry (Hathi Committee) recommended in April, 1975 that atleast 60 per cent of bulk drugs produced by the public sector units should be formulated by the public sector industry itself. In the disposal of remaining 40 per cent, first preference should be given to meet the needs of the Indian Sector particularly the small scale units. On an enquiry of the Committee as to what was the percentage of formulations of bulk drugs in HAL and whether it was in conformity with recommendations of the Hathi Committee, HAL stated in a note as follows:—

“The percentage of formulations to the total bulk produced during the 3 years 1972-73, 1973-74 and 1974-75 in the case of two bulk drugs produced by HAL, viz. Penicillin and Streptomycin has been as follows:—

	1972-73	1973-74	1974-75
Penicillin	26%	27%	18%
Streptomycin	48%	57%	62%

It has not been possible to formulate 60 per cent of the production of bulk drugs except in the case of Streptomycin during 1974-75. In the case of Penicillin particularly only a small proportion of the bulk produced could be formulated because Penicillin 'G'. Sodium which is one of the major constituents of Penicillin formulations is hygroscopic and requires special type of synthetic rubber stoppers to avoid seepage of moisture and the availability of butyl rubber and imported material is limited. The availability of glass vials of the required specifications for Sodium Penicillin is also limited, as till recently there was only one supplier in the country. An alternative source of supply of glass vials has since been established. Efforts have also been made to procure adequate quantity of synthetic rubber stoppers and with this, the production of

Penicillin vials would increase substantially. In the budget for 1975-76, 44 per cent of the production of Penicillin bulk, and 33 per cent of the Streptomycin bulk production is planned to be vialled."

3.35. The following table brings out the number of vials filled, quality rejections and the percentage of rejections to the number filled during 1966-67 to 1974-75.

(Figures in lakhs)

Year	Number vialled	Number rejected on quality	Percentage of rejection
1966-67	513.01	76.68	14.95
1967-68	558.60*	15.88	2.84
1968-69	449.24	39.27	8.74
1969-70	544.94	23.00	4.22
1970-71	522.72	39.67	7.59
1971-72	549.73	36.71	6.68
1972-73	500.27	13.70	2.74
1973-74	528.27	27.30	5.17
1974-75	425.00	19.64	4.62

*Includes 0.17 lakhs vials rejected and returned by labelling section.

3.36. The rejections were due to problem of sterility, clarity, appearance of foreign particles and presence of varying quantity of soluble silicon in water, shortage of rubber stoppers and contamination. The heavy rejections in 73-74 were also attributed to the fact that the supplies of glass vials were not strictly in accordance with the specifications and consequently the rubber stoppers not adhering to the vials. This problem was solved by changing specifications of rubber stoppers suitably.

3.37. In regard to 1974-75, the high percentage of rejection has been due to variations in manufacturing conditions particularly humidity. A committee has been set up to investigate into the conditions of manufacture and suggest remedial measures.

3-38. The percentage of rejections of vialled formulations by the Quality Control Section of the Company during 1967-68 to 1974-75 is given below product-wise:

Product	1967-68	1968-69	1969-70	1970-71	1971-72	1972-73	1973-74	1974-75
1. Penicillin G.								
Benzathene Penicillin 6 lacs				27.74	3.41	3.00	3.27	24.34
Pen. G Sodium 5 lacs	7.65	12.48	9.94	23.22	19.25	4.76	6.64	11.97
Pen. G. Sodium 10 lacs		2.72	5.47	34.78	43.45	5.48	5.41	7.45
Pen. G. Pot. 10 lacs	2.65	18.17						
Procaine Aq. 15 lacs	5.06		9.83	5.45	3.98	4.62		
P. oc. Fortified with Sodium 4 lacs	2.86	7.14	7.90	14.25	6.88	3.43	12.05	5.12
Proc. Fortified with Sodium 20 lacs			1.90	13.94	13.47	1.94	2.73	3.72
2. Streptomycin								
Streptomycin half gram	1.10	8.38	1.47	2.98	6.05	0.84	2.78	4.81
Streptomycin 1 gram	0.60	1.00	1.28	2.68	2.83	0.88	2.16	2.53
Streptomycin 1 gram	2.91	10.62	1.38	1.78	2.94	1.91	2.22	..

3.39. It will be seen that the percentage of rejections varied widely from year to year and product to product. It ranged between 2.72 per cent and 43.45 per cent in respect of Pen. 'G' Sodium 10 lacs. In other products also the percentage of rejections was comparatively higher in some years than in other years. The Management stated in May, 1973 as follows:

"The percentage of rejections had been high in earlier years, particularly with Sodium Formulations due to problems of humidity due to the hygroscopic nature of the product. The process of formulation of Sodium products has been changed in 1970-71 to sterile handling and with constant efforts, it has been possible to effect an appreciable reduction in the percentage of rejections. The figure for 1972-73 is 3.37 per cent against 12.26 per cent for the year 1971-72."

3.40. To an enquiry of the Committee whether reasons for abnormal rejections were analysed and remedial action taken to bring down the rejections, HAL stated in a note as follows:—

"Rejections of formulated vialled products are mainly due to product being non-sterile after vialling. Sterility of product depends upon sterility of (a) bulk used (b) equipment used, (c) personnel factors (d) conditions of temperature and humidity of the place. It is also effected by the break-down of equipment due to various reasons thereby increasing handling and also increasing microbial population in sterile areas, short power failures during vialling when outside air is likely to enter in the sterile area."

There are some products which are easier to fill due to the crystal structure and non-hygroscopic nature while others which are hygroscopic need more stringent conditions. These products due to their hygroscopic nature jam the machine parts or make them not run smoothly.

Percentage of rejections therefore vary from product to product. Conditions of manufacture of bulks also play very important role in the success of vialling.

Since sterility is measured by taking a certain quantity of bulk and testing, any marginally sterile bulk is likely to escape initial testing and may get revealed in subsequent sub-divisions.

Similarly if rejections are calculated merely on percentage, these are likely to show deviations although costwise there may not be such great variations.

It can be said that though such variations are existing in rejections from product to product still overall a rejection rates both due to sterility and other reasons have come down during the last three years as compared to earlier years as can be seen from the table below with an exception of 1972.

1968	5.4%
1969	4.2%
1970	7.4%
1971	6.5%
1972	2.9%
1973	4.8%
1974	4.2%

3.41. In this connection HAL further stated in a note as follows:—

“A Committee consisting of SQC, SR, SP, CE and Dy. SFP went into great details with regard to sterility rejects of various products and have recommended certain short term and long term measures to overcome these. Some of these short term measures implemented are given below:—

- (1) Vialling is carried out with controlled relative humidity. No vialling is done if relative humidity is more than 30 per cent.
- (2) Sodium bulks for vialling are heat sterilised.
- (3) Ultra violet tubes are checked periodically and replaced.
- (4) Formal fumigation of air ducts leading to sterile area done regularly.
- (5) Regular checking and changing of absolute Cambridge air filter.
- (6) Use of butyle rubber stoppers for speci Sodium Pencillin 'G' and formulations.
- (7) Changing of rubber stoppers specifications to suit vials available.

In case of long term measures such as relative humidity of 15 per cent to 20 per cent in filling cubicles; sterile air cooling zone on two machines to be modified, Laminar flow system for sterile area stricter control over the rubber stoppers and vials specifications, improved maintenance of machines and equipments are being followed. It is expected that with the introduction of these controls, rejection rates will come down considerably."

3.42. The norms of quality rejection were fixed in November, 1973 as follows:—

Penicillin G Sodium	5 lakhs	8%
Penicillin G Sodium	10 lakhs	2%
Fortified proc. Pen	4 lakhs	3%
Streptomycin Sulphate	1 gm	5%
S:reptopenicillin	1/2 gm & 1 gm	1%

3.43. The Committee note that the percentage of rejections to the number of vials filled was the highest in 1966-67 (14.95 per cent) and lowest in 1972-73 (2.74 per cent). The norms of rejections, product-wise, were fixed only in 1973. Product-wise the percentage of rejections of vialled formulations by the Quality Control Section of the company varied from year to year. It ranged between 2.72 per cent and 43.45 per cent in respect of Penicillin 'G' Sodium 10 lakhs, as against a norm of 2 per cent, between 4.76 per cent and 23.22 per cent in respect of Penicillin 'G' Sodium 5 lakhs, as against a norm of 8 per cent between 2.86 per cent and 14.25 per cent in the case of Proc. Fortified with Sodium 4 lakhs as against a norm of 3 per cent and between 0.84 per cent and 8.38 per cent in the case of Streptopenicillin 1/2 gm as against a norm of 1 per cent. In other products also the percentage of rejections has been high. The Committee regret to observe that in spite of the heavy percentage of rejections no norms were fixed prior to 1973 and there was no system of controlling the rejections. The Committee are informed that rejections are mainly due to product being non-sterile after vialling. The higher rate of rejections has been attributed inter-alia, to the problem of humidity, break-down of equipment and short power failures during vialling when outside air is likely to enter in the sterile area. It has been claimed by the company that overall rejection rates both due to sterility and other reasons have come down during the last three years (2.9 per cent in 1972, 4.8 per cent in 1973 and 4.2 per cent in 1974) as compared to earlier years. They note that a technical Committee appointed by the Company went into the question of sterility rejects of various products and this Committee

has recommended certain short term and long term measures which are expected to bring down the rates of rejection considerably and the management has taken certain measures already. They strongly recommend that all the long term and short term measures recommended by the technical Committee of the Corporation should be implemented scrupulously without avoidable delay so as to ensure that the rejections are minimised and in any case kept within the norms. The Committee would also like that a report about the rejections compared to the norms together with the remedial measures taken should be included as a standing item in the agenda for the Board meeting so that the Board of Directors may have an opportunity of reviewing them.

3.44. The Committee are further informed that during 1973-74 one of the likely causes of the higher rejections was that the supplies of glass vials were not strictly according to specifications and the rubber stoppers did not adhere properly to the vials. They are surprised to learn that instead of compelling the supplier to adhere rigidly to the specifications, the glass vials deviating from the prescribed specifications were accepted and the specifications of the rubber stoppers changed to match those of the glass vials received. They are unhappy to find that HAL agreed to compromise on standard laid down for glass vials and accepted below-specification vials to avert cessation of production in view of the monopoly of the supplier in this field. The Committee fail to understand as to why HAL could not have enforced the technical specifications laid down in the contract. The Committee deprecate the lack of foresight on the part of HAL in allowing such a situation to develop in which it found itself completely at the mercy of a private sector company for glass vials and recommend that the matter should be investigated with a view to fixing responsibility.

3.45. The Committee are informed that a large number of vials making plants have been licenced in the last two years and if 60 to 70 per cent of that licenced capacity comes to fruition, the shortage of vials will no longer be there. The Committee recommend that Government should ensure that the plants which have been licenced are really set up and commissioned on schedule and that scarcity conditions in the matter of availability of vials are not allowed to develop.

Spillages & Overseas

3.46. The vialling operations involve some spillage and certain amount of overage to retain the potency of the vialled products.

While no information regarding the norms generally observed by the industry for spillage is available with the Management, an excess of 5 per cent over the actual requirement has been accepted by the Company as standard both for spillage and overage separately. These standards are stated to have been fixed in the initial stages and have not been reviewed on account of the fact that the actual spillage and overage was always in excess of the standards.

3.47. The standard requirement of Penicillin and Streptomycin for vialling done, standard spillage and overage and actual consumption during 1966-67 to 1974-75 are given in Appendix-II.

3.48. It will be seen that the percentage of actual spillage ranged from 5.46 per cent to 9.95 per cent while the percentage of actual overage ranged from 8.85 per cent to 22.15 per cent. Cumulative loss on this account during the last eight years was Rs. 50.33 lakhs.

3.49. During evidence it was stated that the variations were analysed and efforts made to have control over these. Asked as to why such huge variations were not controlled the Managing Director stated that:

"We had put a group of people on this job and wanted them to suggest straightway as to what can be done. From out of the equipments in the Company, they have made some additional equipments and they have also fixed the minimum humidity required.

* * * * *

Between 1973 and 1975 we have taken certain measures to ensure a certain amount of humidity.

Today the position is much better than before."

3.50. The Ministry stated in a note that:

"By adoption of more rigorous controls losses due to spillage have been brought down. Besides the above, changes in process have also been effected so as to improve the overages and spillage and to reduce losses due to spillage. As a consequence of all the measures taken, the losses arising on account of overage and spillage have been brought down from an average of approximately Rs. 8 lakhs during 1966-67 to 1971-72 to Rs. 3 lakhs on an average from 1971-72 to 1974-75."

3.51. The Committee note that the vialling operations involve some spillage and certain amount of overage to retain the potency of the vialied products. An excess of 5 per cent over and above the actual requirement has been accepted by the undertaking as standard both for spillage and overage separately. The Committee are not sure about the basis on which the standard for spillage and overage has been fixed at 5 per cent above the requirement and whether this is in accordance with the standards in the collaborator's works or in the industry elsewhere. The Committee are concerned to note that the spillages and overages have always been in excess of standard and the cumulative loss on this account during the last 8 years was of the order of Rs. 50.33 lakhs. The Committee stress that the reasons for such spillages and overages should have been critically analysed and timely action taken to arrest such excess spillages and overages. The Committee also recommend that the standards which were fixed in the initial stages should be reviewed by the R&D wing of the company in the context of the present stage of equipments and processes and stricter standards evolved for the purpose of assessment of the efficiency of the vialling operations.

3.52. The Committee are informed that by adopting more rigorous controls and changes in processes, the losses on account of spillages and overages have been brought down from an average of Rs. 8 lakhs during 1966-67 to 1971-72 to Rs. 3 lakhs on an average during 1971-72 to 1974-75. The Committee feel that the improvements made during the last three years should not create a sense of complacency in the Management and the Management should continue to keep the percentage of spillage and overage under review so that suitable remedial steps may be taken in time to keep them within the norms fixed for the purpose.

B. TABLETING AND CAPSULATION

3.53 (i) *Determination of capacity*:—Tablets are made from Penicillin 'V' and Hamycin. Capsules are manufactured from Tetracycline imported from abroad. The Company has two tableting machines and one capsulation machine. As certain sections of the equipment are common to both and due to restrictions placed by the Drugs Control Act, 1940, the tableting and capsuling operations cannot be undertaken simultaneously. The rated capacity of the tableting machines (based on single shift working of 6½ hours for 300 days in year and 350 tablets per minute) is 800 lakh tablets per year if there is no capsulation; similarly, the rated capacity of the capsulation machine is 140 lakh capsules (300 days × 6½ hours × 120 capsules per minute) per year if there is no tableting. As the production programme for tableting and capsulation has to be adjusted

to the demand pattern and as the production of the two items had to be undertaken alternatively, an attenuated operable installed capacity of 120 lakh tablets and 60 lakh capsules per year was fixed by the Management in 1968-69. The production of these two items is theoretically expected to utilise only 58 per cent of installed capacity. In the absence of details for fixing the attenuated operable installed capacity it cannot be stated whether this ensured full utilisation of the installed capacity both for tableting and capsulation.

3.54. In regard to the details about fixing the attenuated operable installed capacity, HAL stated in a note as follows:—

“The Audit have worked out the capacity of 800 lack tablets per annum and 140 lac capsules per annum assuming 300 working days in a year, single shift working, each shift being of 6½ hrs., 350 tablets and 120 capsules per minute. The figure of 350 tablets per minute and 120 capsules per minute represents the capacity of each punching and filling machine respectively. There were 2 punching and 1 filling machine. The capacity of tableting and capsulation does not however depend only on the capacity of filling/punching machines but is determined by the capacity of the ancillary facilities like drying equipment, granulation equipment, even the space available plays a part. The capacity of 120 lakh tablets per annum and 60 lakhs capsules per annum was fixed on the basis of actual trials. The capacity thus arrived at correspondants to an out-turn of 50 tablets/capsules per minute and is much lower than the mechanical capacity of the punching/filling machines on account of the limited facilities available in respect of other ancillary equipment like drying machines, granulating machines, available space etc. Since their adequate ancillary facilities have been provided in the tableting-Section, which enables proper utilisation of the punching capacity. With this and with the addition of one punching and one filling machine, the capacity of tableting and capsuling is now rated at 1248 lakhs and 137 lakhs respectively per annum.”

3.55. In this connection the Ministry stated that:

“The Company has explained that in so far as tableting is concerned, the capacity is not dependent upon the last stage i.e. the punching operations only, but it has a direct linkage to the facilities available for the earlier stage like granulations, drying and mixing etc. Therefore, the

capacity has necessarily to be fixed on the basis of such constraints in the production operations. Since the company has identified the points of bottlenecks and hold-ups, they have installed balancing equipments at respective positions and they have now worked out the capacity for tableting at 1248 lakhs."

3.56. *Actual Production*:—The following tables brings out the original and revised targets of production, actual production and the percentage utilisation of capacity during 1966-67 to 1974-75.

(Figures in lakh numbers)

Year	Operable capacity as fixed by the Company	Targeted Production		Actual production	Percentage utilisation of capacity (Col. 5 to 2)
		Original	Revised		
1	2	3	4	5	6
1966-67	Tablets .	6.50	48.95	49.77	
	Capsules .	15.00	19.61	9.53	..
1967-68	Tablets .	101.20	81.03	83.99	..
	Capsules .	50.00	54.94	47.65	..
1968-69	Tablets 120	109.80	107.60	119.78	99.82
	Capsules 60 . .	60.00	30.01	28.01	46.68
1969-70	Tablets 120	128.40	143.20	137.49	114.58
	Capsules 60 . .	48.00	31.87	37.52	62.53
1970-71	Tablets 120	157.00	129.02	140.69	117.24
	Capsules 60 . .	60.00	48.53	42.49	70.82
1971-72	Tablets 120	156.00	134.65	147.06	122.55
	Capsules 60 . .	48.00	38.97	35.73	59.55
1972-73	Tablets 1800 .	180.00	155.00	120.49	6.7
	Capsules 144 .	124.00	90.00	58.39	40.54
1973-74	Tablets 1800	360.00	143.77	196.23	10.90
	Capsules 144 .	192.00	46.20	72.57	50.40
1974-75	Tablets 1800 . .	360.00	192.00	149.62	8.31
	Capsules 144 . .	66.00	57.00	75.73	52.59

Note:—The above figures exclude other formulation, the production of which is negligible.

3.57. On an enquiry of the Committee why the original targets for tablets and capsules were fixed low (except during 1973-74 in respect of capsules) as compared to installed capacity and the reasons for scaling down the target, HAL stated in a note:—

“The production programme is sale oriented. The market for tablets and capsules is being developed gradually and is at present much below the installed capacity.”

3.58. HAL informed that the full capacity in tableting could be achieved after airconditioning facilities would be commissioned by November, 1975.

3.59. *Quantity issued for tableting*: The quantity of Penicillin ‘V’ produced and issued for tableting during 1966-67 to 1974-75 is given below:—

(Figures in MMU)

Year	Quantity produced	Quantity issued for tableting	Percentage of quantity issued to Production
1966-67	7.35	0.75	10.20
1967-68	8.01	1.00	12.48
1968-69	8.63	1.68	19.47
1969-70	9.30	2.08	22.37
1970-71	7.53	1.99	26.43
1971-72	9.97	1.99	19.96
1972-73	14.90	2.16	14.50
1973-74	8.81	3.70	42.00
1974-75	4.73	3.01	63.64

3.60. The percentage of quantity issued for tableting to quantity produced in bulk form increased during 1973-74 to 1974-75 partly due to lesser production in bulk form and partly due to increased production of tablets.

3.61. The remaining quantity of Penicillin ‘V’ was sold in bulk form. The sale of Penicillin ‘V’ in the form of tablets is more profitable to the Company as it yields a higher margin of profit, as compared with the sale in bulk form and amounted to 22 paise per mega unit in 1969-70 and 14 paise per mega unit in 1971-72. In the absence of information regarding the Company’s capacity to sell Penicillin

'V' in tablets, it is not possible to work out the gain that would have been made by not selling the major portion of Penicillin 'V' in bulk form.

3.62. To this the Ministry further added in a note that:—

"The Company has been formulating 40—45 per cent of its main products *viz.*, Penicillin and Streptomycin. Of the above, 97 per cent have been sold to the Government agencies. The sales to Government institutions were given priority by the Company in accordance with the policy of Government.

As far as tableting is concerned, the products to be tableted/capsuled are Vitamin 'C', Ampicillin, Tetracycline and Penicillin V in tablet form. The company has plans to increase the tableting and capsuling capacity and steps have already been taken in this direction. Additional capacity of 77 lakhs capsules and 1128 lakhs tablets had been established during 1974-75.

The company did not need to push its sales in the market as almost its entire production was geared to meet the institutional requirements from Governmental agencies. The Government had also an obligation to supply the bulk drug to private viallers who were not licensed to manufacture the bulk drugs."

3.63. As earlier stated Government has not imposed any restriction on the vialling of antibiotics by the Company. While on the one hand HAL was not utilising its vialling and capsulation/tableting capacity in full, on the other hand it was not in a position to meet all the orders for vials, tablets and capsules. The details of orders received and cancelled during 1966-67 to 1974-75 are given below:—

(Figures in lakhs numbers)

		Orders received	Orders cancelled	Percentage of orders cancelled to orders received
	1	2	3	4
1966-67				
Vials	543.42	252.72	46.5
Tablets	3.12	0.70	22.5
Capsules	1.35	0.13	9.6

1	2	3	4
1967-68			
Vials	562.12	30.48	5.4
Tablets	3.33	0.64	19.2
Capsules	1.22	0.23	19.0
1968-69			
Vials	527.01	36.47	6.9
Tablets	2.23	0.36	16.1
Capsules	0.92	0.05	5.4
1969-70			
Vials	613.70	169.10	27.5
Tablets	2.25	0.41	18.4
Capsules	0.53	0.21	39.6
1970-71			
Vials	536.19	74.51	13.9
Tablets	2.24	0.89	39.5
Capsules	0.40	0.08	20.0
1971-72			
Vials	681.16	134.27	19.7
Tablets	2.66	0.31	11.7
Capsules	0.55	0.12	21.8
1972-73			
Vials	593.13	56.30	9.5
Tablets	2.59	0.73	28.2
Capsules	1.30	0.04	3.1
1973-74			
Vials	602.06	34.88	5.8
Tablets	2.42	0.69	28.5
Capsules	2.88	0.25	8.7
1974-75			
Vials	566.16	115.16	20.3
Tablets	2.85	0.40	14.0
Capsules	1.30	1.10	84.6

3.64. HAL informed the Committee that an additional capacity for 1338 lakh tablets and 72 lakh capsules per annum had been commissioned recently. In the Fifth Five Year Plan further expansion of formulations capacity was proposed as follows:—

Vials	1208	lakh Nos.
Capsules	1592	„ „
Tablets	9095	„ „
Ampules	488	„ „
Ointment	1013	„ „
Oral Syrup	5	„ „

3.65. The Committee note that though HAL had two tableting machines and one capsulation machine, tableting and capsulation operations could not be undertaken simultaneously due to certain restrictions which are stated to have been placed under the Drug Control Act. While the installed capacity of the machines is 800 lakhs tablets per annum or 350 tablets per minute, if there was no capsulation and 140 lakhs capsules per annum or 120 capsules per minute if there was no tableting based on the capacity of punching and filling, the management fixed the attenuated operable installed capacity as 120 lakhs tablets and 60 lakhs capsules per year corresponding to 50 tablets|capsules per minute.

3.66. According to Management, the production of these two items is theoretically expected to utilise only 58 per cent of installed capacity. The Committee were informed that these were fixed on the basis of actual trials and were lower than mechanical capacity of machines on account of lack of ancillary equipment since the capacity of tableting and capsulation does not depend only on punching and filling but also on ancillary facilities.

3.67. The Committee see no reason as to why such ancillary facilities could not have been provided along with the machines so as to utilise the full capacity and why only 58 per cent of the capacity was put to effective use. The Committee are informed that these facilities have since been provided in tableting section and new machines have been added and the installed capacity has been increased to 1800 lakh tablets and 144 lakh capsules per annum. The operable capacity is now rated as 1248 lakhs and 137 lakhs per annum respectively. The Committee do not see the rationale behind fixing the operable capacity at a reduced figure even after addition of new machines and facilities and stress that concerted measures should be taken to ensure full utilisation of the installed capacity for tableting and capsulation.

3.68. The Committee regret to note that even after the installed capacity of tableting has been increased, the percentage of utilisation of operable capacity has been of the order of 9.6 per cent in 1972-73, 15.7 per cent in 1973-74 and 12 per cent in 1974-75. In the case of capsules, the percentage of utilisation varied from 42 per cent to 55 per cent although earlier it varied from 47 per cent in 1968-69 to 71 per cent in 1970-71. The Committee are informed that production programme is sale-oriented and market for tablets and capsules is being developed gradually and is at present much below installed capacity. The full capacity of tableting could be achieved after air-conditioning facilities could be commissioned in November, 1975. The Committee see no reason why these facilities could not have been provided along with the installation of ancillary equipments and additional punching machines and capacity utilisation augmented and why the undertaking could not have developed the market for tablets and capsules. The Committee would like that the undertaking/Government should critically examine the constraints, if any, in the marketing of tablets and capsules and the reasons for the underutilisation of capacities when there is larger margin of profit in sale of tablets and capsules which would be of direct service to the common man.

3.69. The Committee regret to note that in spite of the fact that vialling, tableting and capsuling capacities had been underutilised, the quantities issued for vialling and tableting have been less than the quantities produced. In the case of Penicillin 'G' the percentage of quantity issued for vialling to the quantity produced varied from 21 per cent to 42 per cent and in the case of streptomycin the percentage varied from 36 per cent to 55 per cent and the rest was sold in bulk form, though no specific directive was issued by Government to restrict the vialling of antibiotics to any particular level and it was left to the discretion of the Company as to which product was vialled and in what proportion. The percentage of quantity issued for formulations. The Committee are doubtful whether this under-1966-67 to 63 per cent in 1974-75, and the remaining quantity was sold in bulk form although sale of Penicillin V in tablets was more profitable.

3.70. The Committee regret to note that while on the one hand the undertaking was not utilising its vialling and capsulation/tableting capacity in full, on the other hand it had been cancelling orders in various years due to inability of the Company to meet the demand for formulations. The Committee are doubtful whether this under-received varied from 5 per cent to 47 per cent in the case of vials while it ranged from 8 per cent to 42 per cent in tablets and 5 per

cent to 69 per cent in the case of capsules. The Committee regret to observe that in spite of formulations being a profitable proposition, the undertaking did not make any attempt to increase the capacity for formulations. The Committee are doubtful whether this under-utilisation of capacity was deliberate and they would like that this matter should be critically gone into. In this connection the Hathi Committee on Drugs and Pharmaceutical Industry have recommended in April 1975 that at least 60 per cent of bulk drugs produced by the Public sector industry should be formulated by itself and in the disposal of the remaining 40 per cent first preference should be given to meet the needs of the Indian sector particularly the small scale/units.

3.71. The Committee are informed that the Government have accepted these recommendations of Hathi Committee. At the present moment, the Company has the capacity to formulate 45 per cent but it is operating this capacity either for Penicillin or for Streptomycin, depending on which is more advantageous to formulate. They are also informed that additional capacity for 1338 lakhs tablets and 72 lakhs capsules per annum has been commissioned recently and further expansion of formulations capacity during Fifth Five Year Plan is proposed to be undertaken. The Secretary, Department of Chemicals and Fertilizers, stated during evidence that "it is only with the new formulations units that they will be able to achieve the target of 60 per cent". They would like HAL to investigate the constraints on the optimum utilisation of the existing formulation capacity, take conclusive measures to remove these constraints and ensure that not less than 60 per cent of production is utilised for formulations.

C. Bulk vis-a-vis Formulations

3.72. A major portion of the total production of different products is sold by HAL in bulk form to private viallers in spite of the fact that HAL was not able to utilise its vialling/capsulation/tableting capacity. However, it has not made so far any study for comparative profitability of the sale of its products in bulk form *vis-a-vis* formulation.

3.73. It has been noticed from a study made by Audit that the sale in vialled formulations was more profitable than sale in bulk form up to 1969-70.

3.74. The analysis of the customer composition brings out clearly that the Company's sales have almost entirely been confined to the Government/Semi-Government and charitable institutions. No effort was made by the Company to build up a suitable marketing organisation in order to take a share in the sale of antibiotics to the public in general. In spite of the lower price charged by the Company in some cases and the investment in augmenting the capacity of formulations being not an important constraint, the policy of the Company not to increase the production of formulations appears to be a deliberate decision flowing from the constraint of marketability. The absence of an effective sales organisation has not only hampered the Company in entering the general consumer market but also led to its inability to develop market for new products developed by the Company.

3.75. The Management stated in May, 1973 as follows:—

“In the earlier stages, the Company had to encounter serious competition from private viallers particularly of foreign origin who had established themselves in the business over crores of years. The production was also limited and in the circumstances it was considered prudent to concentrate on the institutional consumers in which field the Company expected to have some advantage over others. By the time the Company had established itself in the field of institutional consumers and was poised for a meaningful entry in the field of general market, the profitability on vialling has undergone a serious erosion.....In view of this, the Company would have to proceed cautiously in expanding its vialling capacity and strengthening its marketing organisation. The Company does, however, have plans for expansion of its vialling capacity.....It has also plans to expand its market organisation.”

3.76. In 1970-71, the Penicillin products in vialled form became a losing proposition (except in one case) while the Streptomycin formulations continued to be more profitable than sale in bulk form. In 1972-73 also a similar trend was maintained except in one or two cases. The profit on formulations showed decreasing trend from 1970-71 onwards due to the following reasons:—

- (i) Increase in the cost of filling and packing materials.
- (ii) High percentage of quality rejects which were 7.59 per cent in 1970-71 compared to 4.22 per cent in 1969-70.
- (iii) Spillage and overage which ranged from 16.82 per cent to 19.08 per cent in Penicillin and 14.78 per cent in Strepto-

mycin during 1970-71 and 1971-72 as compared with the standard of 10 per cent (5 per cent spillage and 5 per cent overage).

- (iv) High cost of production of bulk products, particularly Penicillin Sodium and Streptomycin.

3.77. The Company's retail sale price of its vialled products is almost the same as that of private viallers who purchase a major portion of the Company's products in bulk form. The selling price for Government supplies, although equal in both the cases, is less than the open market price available to both the private suppliers and the Hindustan Antibiotics Limited. As, however, bulk of the supplies of formulations is made by the Company to the Government, its total net back on formulations is comparatively less than the private viallers. The cost of vialling in the Company is also high. The main causes for the high cost of production of formulations are heavy rejections, overages and spillages and increasing rate of wages and raw materials (vials, rubber stoppers, silicon, etc.).

3.78. A comparative study of profitability of the sale of products in bulk form *vis-a-vis* formulations for the years 1972-73 and 1973-74 indicate that the sale in formulations was more profitable in certain cases while it was a losing proposition in others, particularly streptomycin formulations. According to HAL the continuous loss sustained in some formulations had been the result of increase in the cost of inputs

3.79. On another enquiry of the Committee as to how it was that the private viallers found it an attractive proposition to make formulations out of bulk products purchased from the Company, whereas same formulations made out of its own bulk products prove unprofitable to the Company, HAL stated:—

“The cost of production of bulk in most cases, exceeds the selling price. As this company can sell the bulk only at the selling price the bulk cost to the private viallers is much less than it is to this Company, and this gives them a better margin. The Government have been requested to fix fair selling prices for streptomycin and penicillin expeditiously.”

3.80. Explaining the background of supply of bulk to private viallers, the Managing Director informed the Committee during evidence as follows:—

“When the Government started, for example, Hindustan Antibiotics Ltd. in 1954, at that time all these bulk products

were being imported and the people had capacities to formulate them. So, when the factory at Pimpri started manufacturing bulk, naturally this factory started supplying bulk to those people. That is how the supply of bulk started. Those people had the formulation capacity installed even before we started manufacturing of bulk. So, today as we see, the situation is that they are producing streptomycin and we produce bulk and we lose. So the question of supplying bulk to others has to be viewed in retrospect. But today the situation is that when the prices are controlled on bulk, the basic manufacturer continues to lose but those who do the formulations are not affected. A man who buys bulk from the basic manufacturer stands to gain. If you buy bulk at 'X' price per kg. then 'X' plus Rs. 50 or some percentage is added to this price to fix the price of the formulation. That includes return on the investments also. In other words, a man who does not manufacture bulk, who only buys bulk from us but manufactures the vials and does the formulations stands to gain. He does not lose. This is the anachronism which has set in. Now, we want to improve our viability. First we have to increase our productivity, then we have to do more and more formulations instead of giving the bulk to somebody. Third is diversification. Production of some of the products where there is no price control and where there is a good profit margin is to be taken up....

They have a very big range of products where they can distribute their overheads. Secondly, to utilise the capacity, they sell 90 per cent at the market rate and dump 10 per cent against Government tenders at lower prices. In fact, the people who buy bulk from us are the people who compete with us in Government tenders by quoting lower prices..... Most of our loss is due to supply of bulk."

3.81. In this connection, the Secretary to the Ministry stated as follows during evidence:—

"We have accepted the recommendation of the Hathi Committee that the public sector drug plants will formulate 60 per cent at least of the bulk drug production they have. This has been accepted by the Government and the consequential decisions are being taken—setting up of formulation units both in the HAL and in IDPL. At the present moment, the company has a capacity to formulate 45 per

cent, but they are operating this either for streptomycin or for penicillin depending on which is more advantageous to them. At the moment they find it more advantageous to formulate streptomycin. They have taken up streptomycin and dropped penicillin production. It is only with the new formulation units that they will be able to achieve the target of 60 per cent.****We have definitely accepted this recommendation of the Hathi Committee and in fact it has been put into practice even before the committee made its recommendation. We will give you some figures which will be revealing.

In the case of penicillin in 1972-73 the proportion of the bulk sold to foreign companies and Indian companies was, 76 per cent and 23 per cent. In the next year it got reduced to 50 per cent to foreign companies and 49.5 per cent to Indian companies. It further dropped in the case of foreign companies to 49 per cent and went upto 50 per cent in the case of Indian companies.

I must bring to your notice that in regard to anti-biotics vialling there is no small scale sector. It can only be sold to the organized sector.

So far as HAL is concerned, it does not gain or lose by selling to X or Y or Z. To whomsoever they sell the price is the same and if there is any Indian formulator, if he approaches us, invariably he will get the preference. I give that categorical assurance."

3.82. On an enquiry of the Committee to whom the bulk was being sold, the Secretary informed the Committee as follows:

"I must make one submission to the Committee. So far as the public sector drug companies are concerned, they can only sell to parties who are officially licensed to produce. Whether these parties are multinationals or national firms or not is a different issue. Obviously they were importing these drugs. Instead of importing we have saved foreign exchange by producing the bulk drugs ourselves. Initially it was the Government's policy that public sector drug companies should be in bulk business. Now this policy has been changed."

The Committee were also informed by Secretary that "there are some other companies who have for a long time been in bulk production. Secondly, the drug industry was al-

most non-existent in 1947. We used to import the finished drugs. The starting point of the Drug Industry in this country was formulations as in most parts of the world. A decision was taken by the Government of India not only in the Drug Industry but in so many other sectors of Indian economy that the public sector would go into the infrastructure in intermediate area. I do not want to offer comments on the validity of this policy. It was the policy that the public enterprise in his country would move into infra-structural areas of the economy and would not move into consumer areas of the economy. When they defined commanding height of the economy, this is what was meant by the infrastructure of the economy. They felt that this infrastructure should be controlled by the public sector and let others depend upon public sector rather than depend upon the imports. This policy is being modified and the public sector is moving into the consumer sector.

In our licencing policy, we insist that the formulators will move into bulk."

3.83. On an enquiry of the Committee as to when it would be possible for us to make our own bulk, make our own formulations and do away with multi-national firms, the Secretary stated as follows:—

"The Hathi Committee has made some recommendations in respect of the future drug production in this country. They have made a recommendation that if the multi-nationals are to continue, they should continue under certain disciplines and they made certain suggestion—certain conditions. They have said that we might regularise their production provided they go into the bulk production and provided also they give at least fifty per cent of their bulk production to associated formulators. These matters are under consideration of Government and Government will no doubt announce their policy which will affect these companies. One thing is very clear that over a period of years a policy has been evolved and we are expecting that with the growth of the drug industry, firstly, the public sector will definitely now assume a leadership role. We are poised for it. After entering a most difficult area, we will find it not difficult to move into the easier areas; in our Indian sector, we encourage them and we are liberally giving licences to the Indian sector to come up and there is a lot of entrepreneurship which is now coming into the

Indian sector. We hope that this will come up. We cannot of course prejudice the interests of the consumers because we want drug availability in the country and, as the public sector grows up, it would be possible that the foreign sector can exist within the bounds of the kind of discipline suggested by the Hathi Committee that is, so long as the laws of the land are observed, it is all right. After all that is made by Parliament and by Government."

3.84. The Committee note that major portion of the total production of different products of HAL is sold in bulk form to private viallers. Although sale in vialled formulations was more profitable than sale in bulk. The Committee have earlier observed that though the undertaking has not utilised the full formulation capacity, there was cancellation of orders due to inability of the Company to meet the demand, and the undertaking did not make any attempt to increase the formulation capacity.

3.85 The Committee are informed that prior to 1971, increase in the sale of formulations was not even considered though investment in augmenting the formulation capacity was not an important constraint. They are unable to appreciate why the Company has not been fully utilising its vialling capacity and why it cancelled orders for formulations and why the Government thought that they "had also an obligation to supply the bulk drug to private viallers" even though the bulk sales has been a substantial factor contributing toward losses which the Company has been sustaining currently.

3.86. The Committee are constrained to conclude that by showing excessive concern for the requirements of private viallers and by keeping HAL's formulation capacity under-utilised all through this period, the administrative Ministry as well as HAL have not acted as the guardian and promoter of the interests of the public sector but has rather helped the private firms, particularly the foreign firms to earn huge profits at the expense of the public sector and national interest. They recommend that Government should thoroughly investigate into the reasons for the under-utilisation of formulation capacity, indifference to the need to augment the formulation capacity and develop markets for HAL's products, the so-called "obligation" to supply bulk drugs to private viallers and cancellation of orders for formulations in spite of having unutilised capacity, with a view to fixing responsibility and inform the Committee of the precise action taken in the matter.

3.87. The Committee are informed the profit on formulation showed a decreasing trend from 1970-71 onwards due to increase in the cost of filling and packing material, high percentage of quality rejects, high percentage of spillage and overage, high cost of production of bulk product and increasing rate of wages and raw materials.

3.88. A comparative study of profitability of the sale of products in bulk vis-a-vis formulations for the years 1972-73 and 1973-74 indicates that the sale in formulations was more profitable in certain cases while it was a losing proposition in others, particularly streptomycin formulations.

3.89. The Committee recommend that the company should identify such of the formulations which are a losing proposition and critically go into all the factors which have been affecting the profitability on formulations so as to take suitable remedial action without further delay. Since the cost of formulation also depends on the cost of bulk drugs, the Committee recommend that the undertaking should take concerted measures to bring down the cost of bulk production, the cost of vialling and elimination of all wastages and heavy rejections by stricter management controls. They would like this matter to be included as a regular item of the agenda at the meetings of the Board of Directors so that it receives contemporaneous attention and effective measures are taken to bring down the cost of production of bulk and formulations.

3.90. The Committee note that the cost of production of bulk in most cases exceeds the selling price which is fixed for them with the result that the private viallers find it an attractive proposition to purchase bulk from HAL and to make formulations therefrom and this gives them a better margin of profit. The Committee are informed that so far as public sector drug companies are concerned they can only sell to parties who are officially licensed to produce whether these parties are multinationals or otherwise. The Committee are also informed that the proportion of bulk drugs sold to foreign companies and Indian companies was 76 per cent and 23 per cent in 1972-73 it got reduced to 50 per cent to 49 per cent in 1973-74 and further dropped to 49 per cent and 51 per cent in 1974-75.

3.91. In this connection the Hathi Committee have recommended that if the multinationals are to continue in the field of drug production, they should continue under certain disciplines and should be required to go into bulk production and to give at least

50 per cent of their bulk production to associated formulators. These recommendations are stated to be under the consideration of the Government. The Committee would like the Government to take an early decision in the matter so as to ensure that the public sector does not have to continue to supply bulk products to formulators, more particularly foreign drug Companies, at a loss to itself and the Committee be informed of the decision taken in the matter within three months of the presentation of this report.

IV

PRICING POLICY AND SELLING PRICES

4.1. The first price control order in respect of drugs was promulgated by Government in 1962 requiring manufacturers, importers and distributors of drugs to publish price lists of their products and the dealers to display such price lists in their premises. The Order did not link the prices of various drugs and formulations to actual cost of manufacture. This was followed by the Drugs (Control and Prices) Order, 1963 which pegged the selling prices of drugs at the levels obtaining on 1st April, 1963 and prevented manufacturers and others from increasing the prices without prior approval of Government. Thereafter, a comprehensive measure called the "Drugs Prices" (Display and Control) Order, 1966 was issued under the Essential Commodities Act, which in addition to the earlier order of 1963, required the manufacturers to obtain Government's approval in respect of prices of new drugs. In August, 1966, Government entrusted to the Tariff Commission the examination of the cost structure of 18 major drugs inclusive of Penicillin, Streptomycin and Vitamin 'C' and to recommend the prices at which these should be sold. The Tariff Commission submitted its report in August, 1968 which was followed by the Drugs (Prices Control) Order of May, 1970.

4.2. The Drugs (Prices Control) Order of May, 1970 enables Government to fix the maximum prices at which essential (bulk) drugs shall be sold and also the manner of working out the retail prices of formulations derived from the former and other bulk drugs. So far as the Company is concerned, its main bulk products viz. Penicillin and Streptomycin (comprising 99 per cent of the total value of production) fall within the purview of this Order. In the case of these products, the prices notified by Government were those at which these were marketed by the Company prior to the issue of the Order, i.e. Penicillin potassium—

—Re. 0.50 per MU Sodium Penicillin

—Re. 0.50 per MU, Procaine Penicillin

- Re. 0.50 per MU; Potassium penicillin 'V'.
- Re. 0.80 per MU and Streptomycin.
- Rs. 295 per kg.

4.3. In this connection, HAL informed the Committee in a note as follows:—

“The selling price of bulk drugs is fixed by the Government under the Drugs Prices Control Order. The price fixed takes into account cost of production. The drugs prices control order was enacted in 1970. At that time, the selling prices of essential bulk drugs were fixed by the Government at the rates prevailing at the time. In the case of HAL, the selling prices of these two bulk products, viz., Penicillin and Streptomycin, prevailing in 1970 had been in vogue since 1959 in the case of Penicillin and 1967 in the case of Streptomycin. The prices notified by the Government under the Drugs Prices Control Order were fixed at the same level, viz. 1959 in the case of Penicillin bulk and 1967 in the case of Streptomycin bulk. The same prices continued until August, 1974 in the case of Streptomycin when a 15 per cent increase was allowed, and November, 1974 in the case of Penicillin when a 15 per cent to 20 per cent increase was allowed in the case of different Penicillin 'G' bulks; no increase being allowed for Penicillin V. In the case of new products, the selling prices are fixed by the Government under the Drugs Prices Control Order on an application by the manufacturer. If there is more than one manufacturer, the price applied for by different manufacturers is taken into account. The Drugs Prices Control Order does not prescribe how the selling prices of drugs are to be fixed. Recently, the Hathi Committee has recommended that the selling prices of bulk drugs should be fixed at the cost price plus 15 per cent of the capital employed.

As regards the selling price of formulations, the same is derived from the selling price of bulk drugs fixed by the Government under the DPCO according to the formula prescribed in that order. The cost of the bulk, the cost of formulation and packing plus a certain 'mark-up' is allowed under the DPCO. The mark-up allowed at present in

respect of the formulations marketed by HAL has been 75 per cent. Thus both in the case of bulk drugs as well as formulations, the selling price is fixed by the Government. The selling price so fixed by the Government for formulations is the retail price at which the drug is available to the consumer. In view of market competition, a trade discount has to be allowed over the retail price to enable the distributor to earn his margin of profit. The discount generally varies from 10 to 15 per cent of the retail price.

In the case of Government/Semi-Government customers also to whom most of the sale of HAL is affected, a discount has to be offered depending upon the competition from other tenderers. A price preference of 10 per cent. is allowed in favour of the Public Sector Companies, viz. HAL and IDPL over the prices offered by the other competitors. In practice, however, this preference does not help HAL, as the contracting Agencies, viz. the DGS&D and the concerned authorities at State levels enter into parallel rate contracts with private vendors leaving it to the indenters to order from HAL or the other tenders, and in cases where a price preference exists, the indenter normally obtains his supplies from the other tenderer whose rate is lower. HAL has, therefore, to match the quotations offered by competitors notwithstanding the 10 per cent price preference. Certain States like Tamil Nadu, Andhra Pradesh, Gujarat, Rajasthan do not invite tenders but obtain their supplies by direct negotiations with HAL and IDPL."

4.4. In regard to the selling price of HAL's formulations *vis-a-vis* selling price of other pharmaceutical companies. HAL stated in a note as follows:—

"The retail price of drugs and the price to the retailers has to be notified, by every company. The price so notified is related to the price of the bulk drug which is fixed by the Government under the Drugs Price Control Order. The notified retail price to the consumer and price of retailer of all companies is therefore the same with marginal differences. The Company allows a discount of 10 per cent to its distributors. The corresponding discount allowed by other companies varies considerably.

As regards sale to Government/Semi-Government institutions, the rates quoted by this Company are competitive with those quoted by other pharmaceutical companies."

4.5. Further explaining the basis on which the prices of drugs are fixed, the Ministry of Petroleum and Chemicals stated in a note as follows:—

“In the case of bulk drugs, prices have so far been determined taking into account the actual cost of production and allowing a return of 15 per cent on the capital employed. This has been done in respect of 41 bulk drugs costed by Tariff Commission and Working Group of BICP and several other bulk drugs costed by BICP. The prices of other bulk drugs were frozen at pre-May 1970 level on the enforcement of Drugs (Prices Control) Order, 1970. However, these other drugs are also costed as and when applications are submitted by the parties concerned to secure price revision consequent upon increases in the costs or outputs, or otherwise where Government *suo motu* directs the BICP to take up such cost examination. Actual investigation into the cost structure is made by the BICP. The cost of production of major producers of the respective items are taken into account.

In the case of formulations, the prices are fixed on the basis of the provisions contained in the DPCO 1970 as amended from time to time, and the interim guidelines issued by the Government on the subject.

4.6. The selling price of Penicillin, Streptomycin and Vitamin C on various dates are given below:—

	Price	Date	Price	Date
Penicillin Potassium (per mu)	0.40	18-5-70	0.57	15-11-74
Sodium Penicillin (per mu)	0.50	18-5-70	0.60	15-11-74
Procaine Penicillin (per mu)	0.50	18-5-70	0.58	15-11-74
Streptomycin (per kg.)	295.00	18-5-70	343.00	8-8-74
Vitamin C	72.70 116.34	18-5-70 21-3-75*	90.72	8-8-74

*If production is commenced first time after 21-3-1975.

Increases earlier given on various dates were only to the extent of increase in the cost of raw materials as a temporary measure as detailed cost investigation takes considerable time. Simultaneously the Bureau also undertakes

detailed cost examination. Presently investigation into the cost structure of Penicillin and Streptomycin has been completed by the BICP and their report on Streptomycin has been received, and considered by Government. The revised prices are expected to be notified shortly.

4.7. The Chairman, Bureau of Industrial Costs and Prices also explained during evidence to the Committee that some form of price control on bulk and formulations had been in operation for the last 12 years. First there was freeze of price and in case of a very few items price increase was allowed partly to compensate the manufacturer to make extra money on less essential drugs in order to keep prices of essential drugs low. In determining the price, the Tariff commission or the Wanchoo Group adopted the criteria that the bulk drug manufacturer working reasonably efficiently should make a gross profit of about 15 per cent on the capital employed. With increase in costs all over today the 15 per cent would have meant a lower return. That was why the Hathi Committee suggested (i) that profitability in respect of bulk drugs ought to be higher than the profitability in respect of formulations and (ii) that the level of profitability should be adequate in today's circumstances. The Hathi Committee had suggested that in respect of bulk drugs, the profitability should be around 12/14 per cent on share holders money, after making all payments, taxes etc. which was significantly higher than was earlier permitted by the Tariff Commission. He stated that in principle Government had accepted the proposition that a rate of return post-tax on equity is a suitable basis for determining profitability.

4.8. He further stated that in the Bureau, while arriving at a price which would give adequate profits to an efficient unit, they made a thorough technical investigation of the production processes and determined the attainable production capacity. Secondly they determined what were the attainable norms. He stated that as long as inefficiency was to be condoned, the prices to the consumer could never be low and unless efficiency was rewarded there would never be an incentive to go forward and do everything possible to increase efficiency.

4.9. To an enquiry of the Committee that this might put the public sector at a disadvantage, the Chairman of the Bureau stated that it was not true that the public sector efficiency was uniformly lower than in the private sector. For instance, in the case of streptomycin, so long as they had older technology, they were losing, but since acquiring the new strain, there was considerable improve-

ment and there was margin for further improvement. This scope of further improvement had taken into consideration while recommending the revised price of streptomycin, which was under the consideration of Government. The Chairman of the Bureau admitted that in spite of accent on efficiency the price of bulk drugs as compared to international prices continued to be high. One of the main reasons for the prices being high was the scale of production was too small in terms of modern technology. Besides emphasis was on maximum use of indigenous raw materials, which were costlier in some cases than imported chemicals and whatever little was imported had a very high custom duty. Though the indigenous labour was cheap, it had relatively a small role in the drug industry.

4.10. In regard to fixation of prices for formulations, the Chairman of the Bureau stated that the policy evolved in 1970 under the Drugs (Price Control) Order was that there was a deliberate decision by Government not to allow the prices of essential drugs to increase. This policy has worked to the detriment of those units like HAL and IDPL who were producing a much larger proportion of essential drugs, than other units who were producing less of essential drugs. In order to remove this disadvantage the Hathi Committee recommended that the pricing policy should make a distinction between firms on the basis of socially desirable criteria. That is to say, if "a firm engaged in bulk drug manufacture is undertaking basic research and is also engaged in formulations, then the pricing policy for its formulations should be a little more liberal than that for the formulations of a firm engaged only in formulations and nothing else."

4.11. The cost of production of bulk products during 1966-67 to 1974-75 expressed as indices (taking 1966-67 as the base year) are given below:—

	Cost of Production								
	1966-67	1967-68	1968-69	1969-70	1970-71	1971-72	1972-73	1973-74	1974-75
1. Penicillin (G) 1st crystals (per MU)	100	111	100	116	126	132	106	148	209
2. Penicillin (G)									
(i) Potassium (Per MU)	100	132	120	152	156	148	132	144	253
(ii) Procaine (Per MU)	100	112	116	124	140	136	129	154	222
(iii) Sodium (Per MU) ■	100	167	139	145	161	145	117	153	206
3. Penicillin (V) (Per MU)	100	98	89	111	134	138	113	164	228
4. Streptomycin (Per kg.)	100	103	112	105	133	139	141	174	203

4.12. The cost of production has been gradually increasing. It, however, did not exceed the selling price except in the case of streptomycin from 1970-71 onwards and Penicillin 'G' Sodium in 1967-68 and 1970-71.

4.13. The cost of production of formulations is shown in Appendix III. As in the case of bulk products, the cost of production of different items of formulations has gradually increased year after year. It however, did not exceed the selling price except in certain cases. Benzyl Penicillin Sodium (5 lakhs and 10 lakh vials) which were profitable items initially became losing ones from 1970-71 on account of increase in cost of production. On the other hand, Hamycin tablets which were a losing item became profitable in 1970-71 while the cost of production of 'Hamycin Glycerin Suspension bottle' has been widely varying from year to year.

4.14. During the year 1972-73 cost of production of streptomycin sulphate (bulk) exceeded the selling price. In 1973-74 cost of Sodium Penicillin bulk and streptomycin sulphate bulk exceeded the selling price. In 1973-74 in the case of following formulations also, the cost of production was higher than the selling price:

1. Strepto-Penicillin $\frac{1}{2}$ gm. vial
2. Strepto-Penicillin 1 gm. vial
3. Streptomycin 1 gm.
4. Sodium 5 lakh vial

4.15. During 1974-75, the cost of production of the following bulks exceeded the selling price:

1. Potassium Penicillin G
2. Sodium Penicillin G
3. Potassium Penicillin V
4. Streptomycin Sulphate

4.16. The production of following formulations also exceeded the selling prices in 1974-75:

1. Strepto-Penicillin 1 gm. vial
2. Strepto-Penicillin $\frac{1}{2}$ gm. vial
3. Streptomycin Sulphate 1 gm. vial
4. Sodium 5 lakh and 10 lakh.

4.17. The increase in cost of production is stated to be due to increase in the price of furnace oil, power tariff and raw materials in the course of time. There has also been increase in wages as a result of increase in Dearness Allowance. The increase in expenditure in 1974-75 compared to that of 1970-71 on account of above factors is as follows:

	Rs. Lakhs
Furnance Oil	83.73
Power	37.44
Raw materials	88.37
Wages	36.00
	245.54

4.18. HAL stated in a note that as a result of technological improvement a reduction has been achieved in the cost of production as follows:

“Penicillin Bulk: 8 per cent due to increase in the average fermentor activity from 6928 u/ml (1970-71) to 8015 u/ml (1974-75)

Streptomycin Bulk: 15 per cent due to increase in the average fermentor activity from 5335 u/ml (1970-71) to 14549 u/ml (1974-75).

The increase in cost of production due to increase in the cost of inputs is however, 103 per cent and has outstripped the reduction in the cost of production due to improved technology.”

4.19. In this regard, the Secretary of the Ministry informed the Committee during evidence that the Bureau of Industrial Costs and Prices as charged with the duty of fixing prices. One of the parameters for fixing prices was to fix efficiency norms, because the Bureau would not accept the position that the consumer would pay for the inefficiency in any plant, in either public or private sector. The Ministry were getting reports including the one on streptomycin, and the price would be fixed, based on assumed norms. Therefore, the Company would not be allowed to charge prices based on anything less than what was considered a reasonable norm, taking into consideration the parameters of the Indian situation.

4.20. The Secretary also informed the Committee that HAL had asked for increase in price of Streptomycin and Penicillin. The

Bureau of Industrial Costs and Prices examined the issue and recommended substantial rise in prices which if accepted will enable the Company which has been making losses to start making profits. The recommendations were under the consideration of the Government, which was in dilemma since increase in the price of an essential drug would not be in keeping with the policy of Government to provide drugs at lower prices to the common man. There was also the question of getting fair return on the money invested in reduction of essential drugs. The Secretary added during evidence "it is true we are not entirely happy about profits by purely price rise. There should be better strains and better productivity and greater efficiency which will give more profits."

4.21. The Secretary, however, stated that HAL should formulate and sell more and this should be backed by an efficient market organisation.

4.22. He went on to say that public sector had pioneered bulk drug production and that Hathi Committee had reported that investment in bulk drug production should be encouraged by giving investment incentive; but many of the multi-national firms hesitated to go in for bulk production. Any increase in the price of bulk drugs must reflect itself in the prices of formulations before mark-up. He further pointed out that there had been liberal mark-ups in the past in the case of non-essential items, the mark-ups were very low, sometimes negative, in the case of essential items. The Hathi Committee had recommended that there should be control of mark-ups and that the range should be between 60 to 70 per cent and this will result in the prices of essential drugs, which had a limited mark-ups to go up. The Bureau of Industrial Cost and Price had made sample studies as to the impact of direct acceptance of the recommendations of the Hathi Committee on the range of drugs.

4.23. In this connection, the Committee on Drugs and Pharmaceutical Industry (Hathi Committee) have *inter alia* recommended as follows:

"While the operation of price control so far has certainly helped in preventing the emergence of very large or excessive profits by the drug and pharmaceutical industry, it does not appear to have contributed materially to the emergence of a product or price pattern which is more in consonance with social needs or national objectives.

The administrative regulation and licensing should be geared to ensure that greater emphasis is laid on the pro-

duction of the 117 essential medicines identified by the Committee. In this area, the policy objective should ensure that prices are fair and reasonable to the producer and to the consumer.

In the case of bulk drugs in which production is already established and in which imports are no longer necessary, greater attention should be paid to ensure that the cost of production is kept to the minimum. It would also be desirable to exempt from Price Control items in which there are no imports and which in terms of total sales of the basic drug do not exceed Rs. 25 lakhs annually.

In respect of other bulk drugs, a system of price regulation based on detailed cost investigation should continue, subject, however, to the price being so fixed that an efficient manufacturer is able to get a return on his capital employed which is a little higher than is available on formulations for the industry as a whole.

The Committee after taking into consideration the question of the rate of return on investment required for production of bulk drugs, made by the Tariff Commission and also the Working Group headed by Shri N. N. Wanchoo recommends that a return post-tax between 12 to 14 per cent on equity i.e. paid up capital plus reserves may be adopted as the basis for price fixation, depending on the importance and complexity of the bulk drug.

The Committee feels that the recommendation of the Working Group on Drugs and Pharmaceuticals under the Chairmanship of Shri N. N. Wanchoo, on formulation activity, under the alternative scheme of pricing, may be adopted with the revised rates of ceiling on profits, as 8 per cent to 13 per cent on sales turnover, by adding 2 per cent to 6 to 11 per cent, to cover the recent increase in the cost of inputs, bank rates etc., following the category of firms having the activities listed under the large, medium and small groups. Marginal adjustments would need to be made when an unit shifts from one class to another. In order to ensure that the profitability ceilings as above do not work to the disadvantage of manufacturing units, particularly the Indian Sector, the Committee would further suggest that, as an alternative criterion, the ceiling of profit may also be specified as between 10 to 12.5 per cent, post tax, on net worth i.e., paid up capital and reserves.

In order to ensure that the Drug and Pharmaceutical Industry acquires adequate social content, the extension of the public sector to acquire a dominant role in this industry is very important. In addition, however, the Committee feels that it is essential to evolve an effective and continuing system of monitoring in respect of this industry if social objectives are to be achieved.

4.24. On an enquiry whether this recommendation had been accepted by Government, the Secretary of the Ministry stated that Government was in a dilemma, because acceptance would in effect mean that practically prices of all the essential drugs would have to go up substantially. Some alternatives which could be just to the producers just to the consumers, not allowing prices of essential drugs going up and not allowing manufacturers of non-essential drugs huge margin of profit, were under the consideration of the Government. He also stated that if, the price of bulk was to be increased, the price of formulations out of that would also increase.

4.25. During the discussions on the Report of the Committee on Drug and Pharmaceutical Industry (Hathi Committee) in Lok Sabha on the 22nd January, 1976 members also pleaded for Government taking over multinational firms as they were repatriating huge profits to their principals by taking to formulations by purchasing bulk drugs from Indian public sector firms and sale of essential and non-essential formulations. Their profits should be checked. Multinational firms should not be allowed to import bulk or spread over in areas where they are not existing now. Government should help bringing down the prices of essential drugs and making them available to people during necessity and that Public Sector should go in for more formulations.

4.26. The Minister of Chemicals and Fertilisers (Shri P. C. Sethi) informed Lok Sabha on the 22nd January, 1976 in this connection that the broad principles which should govern the future approach to drug industry would be followed and stated as follows:

“We would also like to make the drugs available both to the hospitals and the common man at a reasonable price and for this purpose, continuance of price control upto a point is inevitable.

While keeping a careful watch on the prices, it would also be our duty to ensure that producers get a fair deal and they get a reasonable return on the capital invested so that the incentive for a further investment remains.

In working out returns to investors, we would like to encourage investment in bulk production rather than purely on formulations.

We would give the public sector a leadership role in the industry.

Hathi Committee's recommendation with regard to the pricing policy is that in the case of basic drugs the return should be 12-14 per cent and in the case of formulations 8-13 per cent. We have worked it out in terms of mark-ups; this would give us a range of 60 mark-up to 75 mark-up. Unfortunately the position at present is that most of the non-essential drugs like tonics or vitamins and other things have a mark-up of 100 to 150 per cent or 200 per cent and they are essentially consumed by elite population. According to the recommendations of the Hathi Committee there is scope for reduction of the price in these categories where the markings are high*** There are many essential and household drugs where the existing mark-up is 5, 6, 10, 20 or 25 and if we apply Hathi Committee's formula, their prices would go up. The recommendation of the Hathi Committee is: if you want companies to invest in basic drugs and other drugs, that much margin should be given. This is the biggest dilemma. We do not want that the price of essential drugs should go up."

4.27. The Committee note that the maximum prices of HAL's main bulk products viz. Penicillin and Streptomycin are fixed by the Government under the Drugs (Prices Control) Order of May, 1970. In case of these bulk products, the prices notified by Government at that time were those at which these were marketed by the Company prior to the issue of the order. The selling prices of Penicillin and Streptomycin prevailing in 1970 had been in vogue since 1959 in the case of Penicillin and since 1967 in the case of Streptomycin. The Committee further note that these prices continued until August, 1974 in the case of streptomycin when a 15 per cent increase was allowed and November, 1974 in the case of Penicillin when a 15 per cent to 20 per cent increase was allowed in the case of different Penicillin 'G' bulks. No increase was, however, allowed for Penicillin 'V'.

4.28. As regards the selling price of formulations, the Committee note that the same is derived from the selling price of bulk drugs fixed by the Government and it is the retail price at which the drug is available to the consumer. In view of market competition, a

trade discount of 10 to 15 per cent is allowed over the retail price to the distributor.

4.29. The Committee note that the cost of production of various bulk drugs and formulations by HAL has more than doubled since 1966-67 in most cases and the cost of production of many items has been higher than the selling prices fixed by the Government. The increase in cost of production is stated to be due to increase in the price of furnace oil, power tariff and raw materials and increase in wages due to upward revision of Dearness Allowance which have outstripped the reduction in cost of production brought about as a result of technological improvements. The slight increase granted in the selling prices of Penicillin and Streptomycin in 1974 is stated to be insignificant as compared to the enormous increase in the cost of inputs since 1959. In this connection, the Committee have already pointed out in the earlier chapters of this report about the inefficiencies in production, under-utilisation of capacity, excessive rejections, spillages and overages which have a bearing on the cost of production and have given their recommendations in this regard. The Committee recommend that the Undertaking should take concerted measures to reduce its cost of production by better utilisation of the capacity, improving its efficiency and controlling rejections and eliminating all wastages.

4.30. The Committee note that HAL has since approached the Government for revision of prices. It is stated that the price structure of Penicillin and Streptomycin has been studied by the Bureau of Industrial Costs and Prices, who have recommended substantial increase in prices which, if accepted, will enable the Undertaking, which has been making losses, to start earning profits. These recommendations are stated to be under consideration of Government. It has, however, been stated that increase in price of essential drugs would not be in keeping with the policy of Government to provide drugs at lower prices to common man.

4.31. The Committee are informed that under the Drugs (Prices Control) Order there was a deliberate decision by Government not to allow the prices of essential drugs to increase and this policy has worked to the detriment of public sector units like HAL and IDPL who are producing a much larger proportion of essential drugs than other units while many of the multinational firms, for example, have hesitated in going in for bulk production. It was also stated that in the past there had been liberal mark-ups in the case of non-essential items while the mark-ups were very low or even negative in the case of essential items.

4.32. The Hathi Committee have made a recommendation that the pricing policy should make a distinction between firms on the basis of socially desirable criteria, that is to say that if a firm engaged in bulk drug manufacture is undertaking basic research and is also engaged in formulations, then the pricing policy for its formulations should be a little more liberal than that for the formulations of a firm engaged only in formulations and nothing else. It has recommended that there should be a control on mark-ups and the range should be between 60 per cent and 70 per cent while the return on investments should be 12 per cent to 14 per cent of the capital invested in the case of bulk drugs and 8 per cent to 13 per cent in the case of formulations. As any increase in the price of essential drugs would not be in consonance with the policy of Government, Government are reported to be considering certain other alternatives which could be beneficial both to producers and consumers and not allowing huge margin of profits to manufacturers of non-essential drugs. During discussion in the Lok Sabha on 22nd January, 1976, the Minister also stated that "there are many essential and household drugs where the existing mark-up is 5, 6, 10, 20 and 25 and if you apply the formula, the expectation is that the prices would go up..... If you want companies to invest in basic and other drugs that much margin should be given. This is the biggest dilemma. We do not want prices of essential drugs to go up. Out of 117 drugs, Government should try to find out which are essential drugs so that in so far as these are concerned, the prices would not go up." The Committee hope that the work of identification of the essential drugs would be completed soon so that priority may be given to fixation of prices of those drugs. The Minister also assured that "we would give the public sector a leadership role in the drug industry.....would like to make drugs available both to the hospitals and common man at a reasonable price and for this purpose, continuance of price control upto a point is inevitable. While keeping a careful watch on the prices, it would also be our duty to ensure that producers get a fair deal and they get a reasonable return on the capital invested so that the incentive for a further investment remains."

4.33. The Committee are further informed that in spite of accent on efficiency the prices of bulk drugs as compared to international prices continued to be high on account of low scale of production, maximum use of indigenous raw materials which are costlier and high customs duty.

4.34. The Committee recommend that the Government may expeditiously examine the various aspects of the pricing of bulk

drugs and formulations in the light of the Reports of the Bureau of Industrial Costs and Prices and the assurance given by the Minister in the House about Hathi Committee's recommendations and evolve a pricing policy by which the public sector should play a dominant role in drug industry by making essential drugs available both to the hospitals and the common man at most competitive prices. The public sector should also have appropriate blend of bulk and formulations so as not to make losses, but generate adequate margins on capital invested to make it self-reliant and growth oriented.

4.35. The Committee note the assurance given by the Minister on the floor of the House in regard to price of essential drugs and stress that in so far as essential drugs are concerned, their prices should not go up. In order to keep the prices of essential drugs lower and within the reach of the commonman, the Committee would also like Government to consider the feasibility of introducing a dual taxation structure so that essential bulk drugs may be given concessions in the rates of customs and excise duties and the resultant loss in tax receipt off-set by increasing the duties on non-essential drugs.

MARKETING

A. Market participation

HAL's participation in the trade on the basis of licensed capacities and actual production of bulk antibiotics during the period 1967 to 1970 is indicated below:

Actual production

Name of the producer/product	Licensed Capacity (% to total capacity)	1967 (% to total production)	1968 (% to total production)	1969 (% to total production)	1970 (% to total production)
Penicillin (MMU)					
Hindustan Antibiotics Limited, Pimpri	84 (31.3)	64.1 (52.45)	54.9 (45.41)	57.2 (35.59)	61.01 (35.57)
Alembic Chemicals, Baroda	20 (7.6)	22.1 (18.9)	29.2 (24.15)	51.01 (31.74)	49.2 (27.08)
Standard Pharmaceuticals Limited, Calcutta	20 (7.6)	36.00 (29.46)	36.8 (30.44)	39.8 (24.77)	41.6 (22.90)
I.D.P.L. N. Delhi	140 (53.0)	Negligible	Neg.	12.7 (7.0)	29.9 (16.45)
Total (MMU)	264	122.2	120.9	160.7	181.7
Streptomycin (Tonnes)					
Hindustan Antibiotics Limited, Pimpri	80 (39.0)	64.8 (51.27)	65.9 (49.66)	85.3 (49.88)	65.6 (41.76)
Synibiotics	40 (19.5)	61.6 (48.73)	63.5 (47.85)	79.2 (46.32)	76.5 (48.70)
*Indian Drugs & Pharmaceuticals Ltd. New Delhi	85 (41.5)	..	3.3 (2.49)	6.5 (3.80)	15.01 (9.54)
	205	16.4	132.7	171.0	157.1

*Production commenced in September, 1968.

5.2. It may be seen that the private manufacturers have always produced more than their licensed capacities and, therefore, they had a major share of the market in Penicillin and Streptomycin. It will also be seen that Company's production always fell short of its capacity.

5.3. The licensed capacities of the private producers were increased during 1971 to 1974. The Company's participation in the production of Penicillin and Streptomycin during these years, on the basis of the figures furnished by the Ministry, is indicated below:

Name of the producer/product	Licensed capacity (% to total capacity)	1971 (% to total production)	1972 (% to total production)	1973 (% to total production)	1974 (% to total production)
1	2	3	4	5	6
PENICILLIN (MMU)					
Hindustan Antibiotics Pimpri	84 (26.8)	55.47 (27.9)	84.28 (37.8)	78.85 (32.1)	64.82 (25.3)
Alembic Chemicals Baroda	50 (from Sep. 71) (15.9)	48.23 (24.3)	46.71 (20.9)	57.71	67.85
Standard Pharmaceuticals Calcutta	40 (from Sep. 71) (12.7)	53.46 (26.9)	47.92 (21.5)	52.93	60.37
Indian Drugs & Pharmaceuticals Ltd. New Delhi	140 (44.6)	41.65 (20.9)	44.22 (19.8)	56.23	62.72
Total	314	198.81	223.13	245.72	255.76
STREPTOMYCIN (TONNES)					
Hindustan Antibiotics Limited, Pimpri	80 (32.4)	63.10 (35.3)	71.90 (37.5)	69.72 (39)	57.71 (30.4)

1	2	3	4	5	6
Alembic Chemicals, Baroda	20 (8.1)	0.75 (0.4)	1.40 (0.7)	1.66	2.51
Synbiotics	62 (from June 72) (25.1)	92.89 (53.5)	94.73 (49.5)	82.46	88.16
Indian Drugs & Pharmaceuticals Limited, New Delhi	85 (34.4)	17.10 (9.8)	23.58 (12.3)	24.50	58.79
	247	173.84	191.61	178.34	126.97

5.4. It will be seen that the Company's production during 1971, both of Penicillin and Streptomycin, came down but improved in 1972. In the case of Streptomycin, its production continued to be less than its licensed capacity although the production of Penicillin during 1972 was slightly more than the licensed capacity. However, one of the two private producers, both in Penicillin and Streptomycin continued to produce more than the licensed capacity.

5.5. It is seen that Company's production of Penicillin and Streptomycin further declined during the years 1973 and 1974, whereas one of the two private producers continued to produce more than the licensed capacity.

5.6. The Secretary of the Ministry explained during evidence that:—

"I would like to draw the attention of the Members to the essential difference between licensed capacity and installed capacity. If one is looking for efficiency parameters, then one has obviously to compare the actual production with installed capacity, rather than compare the production to licensed capacity. I am saying this advisedly, because the Hathi Committee Report has itself brought to our notice that a larger number of plants in the private sector in fact have installed capacities very much more than their licensed capacities. In a recent report which we have received on streptomycin prices from the Bureau of Industrial Costs and Prices, they have pointed out that even in the case of streptomycin it is quite evident that the private sector has installed a larger capacity than for which it had been licensed."

5.7. The Committee regret to note that the share of HAL in the trade on the basis of licensed capacity and actual production, instead of going up with the passage of time has decreased from 52.45 per cent in 1967 to 25.3 per cent in 1974, in the case of Penicillin, while in the case of streptomycin from 51.27 per cent in 1967 to 30 per cent in 1974. While the private manufacturers have produced more than their licensed capacities, the Undertaking has not even been able to fully utilise its own installed capacity. The Committee are surprised to note that private sector units have been allowed to have installed capacity more than their licensed capacities. The Committee would recommend HAL should take concerted measures to improve its performance so as to have a significant if not a dominant role in the market.

B. Marketing

5.8. At present HAL does not have a Marketing Organisation either to meet its present requirements or to undertake further plans of marketing the bulk as well as the formulations. The marketing operations can however be grouped in the following three categories:—

- (i) **Bulk Sales:** Supplies of bulk penicillin are affected mainly to private viallers on the basis of the firm orders procured from various parties. Till 1966, the supplies of bulk antibiotics (Penicillin and Streptomycin) were made by the Company as per allocations made by the Ministry of Petroleum and Chemicals in two half yearly periods, viz. April to September and October to March. The allotment of bulk Penicillin was discontinued from April, 1966 and the Company was allowed to sell the product to private viallers depending upon their requirements and the availability of stocks.

Supplies of streptomycin are restricted to the quota allocations done by the Ministry of Petroleum and Chemicals (now by Indian Drugs and Pharmaceuticals Ltd.) to big viallers while allocations to small scale viallers is made by DGTD.

So far no bulk sales have been effected in case of Vitamin C by HAL. Vitamin C is however a canalised item and would be distributed in accordance with the directions of the State Trading Corporation of India Ltd.

(ii) **Formulations:** Most of the supplies are affected to institutional buyers like Government/Semi-Government and charitable hospitals. All supplies are effected directly from Pimpri, except local supplies effected from Delhi and Bombay Depots to parties situated in these cities. Market-sale is very meagre, though it is aimed that atleast 10 per cent formulation should find way in the general market through the normal channel of distribution.

(iii) **Agricultural Products:** Streptocycline and Auerofungine Sol are useful for bacterial and fungal diseases of plants and recent trials conducted on a few crops have shown potential for these products. Detailed plans about their marketing are being worked out.

5.9. Thus the marketing activities of the Company are solely governed by the Demands of Government institutions and supplies in bulk to a few private viallers, which does not require any significant marketing effort. The demand for products has generally been more than the product availability (except during the period 1966-67 to 1967-68 and 1970-71 in respect of Penicillin bulk). Only in the case of new products like Hamycin and other agricultural antibiotics, vigorous sales effort is required.

5.10. The gross sales after return and breakages for the last three years are given below:—

	(Rs. in lakhs)		
	1972-73	1973-74	1974-75
(1) Sale of bulk antibiotics	429.28	370.38	288.01
(2) Sale of agricultural products	5.67	9.41	11.79
(3) Sale of vialled antibiotics			
(a) To trade	0.34	0.30	0.29
(b) To Govt/Semi-Government Institutions	426.07	491.65	444.33
	<u>861.36</u>	<u>871.74</u>	<u>744.42</u>

5.11. The table below gives the sales expenses, total sales and percentage of sales expenses to total sales during the last eight

years:—

Year	(Rupees in lakhs)		
	Sales expenses	Total Sales	Percentage of sales expenses to total sales
1967—68	19·08	712·97	2·68
1968—69	19·91	683·17	2·91
1969—70	25·60	788·68	3·25
1970—71	22·80	685·47	3·33
1971—72	25·65	803·99	3·19
1972—73	27·98	865·37	3·23
1973—74	30·76	878·02	3·50
1974—75	33·20	748·90	4·43

(The selling expenses for all the eight years include packing and forwarding charges).

5.12. It will be seen that the percentage of sales expenses to total sales has been the maximum of 4.43 per cent in 1974-75, whereas the average in the private sector of the industry appears to be around 10 per cent as stated in a study made in 1971 by the Bureau of Public Enterprises of the marketing organisation of the Company.

5.13. As a major portion of the Company's total sales is made to Government/Semi-Government institutions, the Company is apparently not required to undertake vigorous sales efforts. As a result, its selling expenses are comparatively low.

5.14. In regard to expansion of marketing activities, HAL informed the Committee in a note as follows:—

“The Company has plans to expand its activity in the private market and aims to increase its participation in the private market to 10 per cent by the end of the Fifth Plan. For this purpose, it would be necessary for the Company to strengthen the Marketing Organisation. This would mean considerable extra expenditure and therefore company has to move cautiously in the matter. Before expanding

its own marketing organisation, the Company has explored the possibility of utilising the services of distributors to increase its participation in the private market. This has not however been found feasible, as the established distributors who are in the business at present undertake only the distribution work and require the pharmaceuticals companies to do their own sales promotional work. The possibility of utilising the marketing organisation of IDPL, a sister concern and Smith Strainstreet in the Public Sector, has also been explored, but not pursued further as it is considered that it would not be practicable for the marketing organisation of one company to promote the products of another company having similar and competing lines of manufacture, even though both companies have the same ownership, i.e. by the Government. The Company would, therefore, have to fall back on its own marketing organisation and would have to augment the same, but this would have to be developed gradually."

5.15. On an enquiry of the Committee as to the reasons for HAL's inability to push its formulations in the open market, HAL stated in a note that:—

"Due to stiff competition from other pharmaceutical companies who are established in field for the last several years, sale of the Company's formulations in the open market requires considerable promotional efforts. At present, the company is not able to undertake this on account of its limited marketing organisation. The company has plans to increase its marketing organisation gradually and enter the private market for formulations. This will be developed gradually. Admittedly sufficient attention has not been paid in the past to the private market and to the need for strengthening the Company's marketing organisation. Efforts are also being made to entrust some of the marketing to other established organisations preferably in the Public Sector pending expansion of the company's marketing set up."

5.16. HAL also informed the Committee that with the limited marketing organisation it had not been possible to arrange a regular feed back of market intelligence for planning future operations of the Company.

5.17. In this connection, the Ministry informed the Committee as follows:—

“The need to strengthen the marketing organisation has been accepted by the Company. The question of having a common marketing organisation for IDPL and HAL has also been under consideration. The Committee on Public Undertakings have recommended [Para 5.7 of Fortieth Report CPU (1973-74)] that Government should evolve, if possible, a centralised sales and marketing set up for each type of industries and, if that is not possible, this type of set up should be evolved at least for some specific products which are manufactured by more than one public undertaking.

The two public sector undertakings have a challenging task before them as their share of sale of formulations has to increase from the present level of 6 to 8 per cent to about 20 per cent by 1978-79. Considering the fact that the turnover of drug industry will also increase from Rs. 300 crores to Rs. 600 crores by the end of the Fifth Plan, a formidable task of increasing the marketing share from the present level of about Rs. 18—Rs. 20 crores to about Rs. 100 crores would pose a challenge of both the organisations. The range of products of the two companies are also likely to be different and therefore all the skills at the command of the two organisations would be required to stand in competition with the multi-national and big Indian companies. The aspects concerning creation of one more marketing organisation in a big way will therefore have to be gone in greater depth.”

5.18. The Committee note that a major portion of its production is sold either in bulk to private viallers or in formulations to Government/Semi-Government and charitable institutions neither of which requires any significant marketing effort. The Committee also note that even the total sales has only increased marginally from Rs. 712.97 lakhs in 1967-68 to 748.90 lakhs in 1974-75. The Committee are surprised that in spite of these the sale expenses have nearly doubled from Rs. 19 lakhs in 1967-68 to 33 lakhs in 1974-75. In 1968-69 while the sales were less than the previous year, the sale expenses were more. Similar was the position in 1974-75. The Committee cannot appreciate the phenomenon of rising sale expenses vis-a-vis declining sales and why strict watch was not kept on this aspect. They would like HAL/Government to analyse the various factors comprising the sales expenses and the reasons

for the increase under any or all the items so that suitable action may be taken to effect economies in sales expenses.

5.19. The Committee also note that the sale of formulations to general consumers which has constituted an insignificant proportion of the total sales has declined from Rs. 34,000 in 1972-73 to Rs. 29,000 in 1974-75 and this has been attributed to the stiff competition in the field and to the limited marketing organisation of the Company. The Company has admitted that sufficient attention has not been paid in the past to the private market and the need for strengthening the Company's marketing organisation. The Committee are informed that the Company has explored the possibility of utilising the services of distributors to increase its participation in private market but this has not worked as the distributors undertake only distribution work and require the pharmaceutical companies to do their own sales promotional work. The possibility of utilising the marketing organisation of IDPL and Smith Staintreet in the public sector is also stated to have been explored but not pursued further as it was considered that it would not be practicable for the marketing organisation of one company to promote the products of another company having similar and competing lines of manufacture.

5.20. In this connection, the Committee had in paragraph 5.79 of their 40th Report on 'Role and Achievements of Public Undertakings' presented to Parliament in September, 1973, recommended that Government should evolve, if possible, a centralised sales and marketing set-up for each type of industries and, if that is not possible, at least for specified products which are manufactured by more than one public undertaking. The Ministry has stated that the two public undertakings (HAL and IDPL) have a challenging task before them to raise the sales of their formulations from the present level of Rs. 18—20 crores to Rs. 100 crores by 1978-79 and the range of their products is also likely to be different and all their skills would be required to compete with multi-national and big Indian companies. The Ministry has further stated that the aspects concerning creation of one more marketing organisation in a big way will therefore have to be gone into in greater depths. The Committee feel that the Government have already taken over 2 years to take a final decision about the shape and size of the centralised marketing set up for HAL and IDPL even though the need to strengthen the marketing organisation has been accepted in principle. They would like the Government not to lose any more time to decide about the set up of a central marketing organisation which would not only be economical but would also lead to greater co-ordination, evolution of effective sales strategies and development of expertise in the field of sales and management. The Committee

also stress that there should also be a regular feed back of market intelligence so that the undertaking may plan/regulate its production/sales operations accordingly.

C. Discount on sales

5.21. The Company does not offer any discount on sale of products in bulk form to private viallers. In respect of formulations, a discount of 10 per cent on list price is allowed to the distributors through whom these products are sold to the general trade while Government, Semi-Government and charitable institutions ordering supplies direct from the Company get a discount of 15 per cent on the list price (23 per cent on Tetracycline capsules).

5.22. As a result of a circular issued by the Government of India in 1956, most of the Government and Semi-Government institutions were placing orders direct on the Company. However, certain State Governments as well as DGS&D started calling open tenders from 1969-70 onwards. The Company, therefore, decided in March, 1970 to adopt a flexible policy, i.e. offering uniform discount for those institutional buyers who buy exclusively from the Company and giving different competitive quotations to others depending on the competitors' prices. In 1970-71, the Company quoted against eight tenders invited by the State Governments of Maharashtra, Madhya Pradesh, West Bengal, Delhi Administration and the DGS&D; it secured full orders in seven cases and partial order in one case and made supplies to the tune of Rs. 166.07 lakhs. Similarly in 1971-72, the Company quoted against eight main tenders; it secured full orders in four cases and partial orders in the remaining cases and made supplies to the tune of Rs. 250.43 lakhs. In 1972-73 and 1973-74 the Company secured nine and ten orders valuing Rs. 391.53 lakhs and Rs. 485.32 lakhs respectively. The following table indicates average discount offered against tenders during 1970-71 to 1973-74:—

Year	Discount offered			Total additional discount allowed over and above the normal discount (Rs. in lakhs)
	Formulations %	Tablets %	Capsules %	
1970—71	17.94	15.27	30.96	4.95
1971—72	16.54	12.16	40.04	5.72
1972—73	9.71	4.87	38.17	5.02
1973—74	12.24	7.45	38.25	15.38

5.23. On an enquiry from the Ministry whether they could persuade the Delhi Administration and the Director General, Supplies and Disposals to obtain their requirements direct from the Company without inviting tenders, the Secretary informed the Committee as follows:—

“We as Ministry are very much in favour of it. We have been pursuing this. Our Minister has also been discussing this with the Department of Supply. But, I must in fairness to them, explain also what their point of view is. They say that under the conditions existing in the hospitals today and taking into account the constraints on finance, if they could get more drugs within the same budget, they would like to buy them cheap and they tell us ‘please compete’. Of course, they are giving a price preference to the public sector. But, they are not willing to go away from the tendering system.”

5.24. In regard to offering higher discount against tenders, HAL informed the Committee as follows:—

“The Company is not now offering higher discounts against tenders. Even when higher discounts were offered in certain cases, parties who used to place direct orders were in a more advantageous position as they were entitled to a uniform discount on all products.”

5.25. The Committee note that the Company does not offer any discount on sale of products in bulk-form to private viallers. In respect of formulations, a discount of 10 per cent is allowed to the distributors through whom these products are sold to the general public, while Government and semi-Government and charitable institutions ordering supplies from the Company direct get a discount of 15 per cent on the list price (23 per cent on Tetracyclin Capsules). Certain State Governments, most of whom were previously placing orders for formulations on the company direct, as well as DGS&D started calling tenders from 1969-70 onwards. The Company adopted a flexible policy from March 1970 i.e. offering uniform discount for these institutional buyers who buy exclusively from the company and giving different competitive quotations to others depending on the competitor's prices.

5.26. The Committee would like that the system of giving discounts should be placed on a sound and rational basis to avoid any complaints in this regard and would like that Government Departments/Hospitals etc. place their orders directly on the Public Undertakings on regular basis and the price of the drugs should be settled well in advance by DGS&D on behalf of the customers.

5.27. The Committee are informed that the Company has given a discount of approximately 31 per cent, 40 per cent, 38 per cent and 38 per cent on capsules supplied against tenders during the years 1970-71, 1971-72, 1972-73 and 1973-74, respectively. On comparing these rates of discount given against tenders with the uniform discount of 15 per cent. (23 per cent on Tetracycline capsules) given to Government/Semi-Government and charitable institutions who place direct orders on the Company without inviting tenders, the Committee apprehend that the policy of offering higher discount against tenders would only discourage the public and charitable institutions who have been the permanent customers from placing direct orders on the Company and getting a lower discount. The Committee are informed that the Company is now not offering higher discount against tenders and even when higher discounts were offered in certain cases, parties who used to place direct orders were in a more advantageous position as they were entitled to a uniform discount on all products. The Committee would like that the new arrangements are kept under continuous and constant review and modified if necessary in the best interest of undertaking and Government institutions.

D. Appointment of Distributors

5.28. For the first time the Company appointed regional distributors for the sale of its products from October, 1967. The minimum limit of sales for a distributor was also fixed and the discount payable was related to total sales. In case, a distributor failed to lift the minimum quantity, the Company was entitled to recover a refund upto 2-1/2 per cent of the list price of the quantity actually purchased. The table below indicates the minimum level of sales fixed by the Company for all the groups of products and sales actually

effected by each distributor during 1968-69 and 1969-70:

Name of the Distributor	Territory	(Rs. in lakhs)			
		1968-69		1969-70	
		Mini- mum off take	Actual off take	Mini- mum off take	Actual off take
1. M/s. Godbole Joshi, Poona	& (Maharashtra & Goa)	5.00	0.50	5.00	1.95
2. M/s. Sidhomal Sons,, Bombay	& (Bombay City)	5.00	0.02	5.00	..
3. M/s. Sivavam Swamy, Madras	& (Madras, Pondicheri)	5.00	0.09	5.00	0.20
4 M/s. Fairfield (P) Limited	(Delhi, Punjab etc.)	5.00	0.14	5.00	0.07
5 M/s. Magadh Pharma	(Bihar, West Bengal)	5.00	1.23	5.00	2.33
6. M/s Martin & Harris(P) Limited	(Calcutta City)	5.00	1.06	5.00	0.73
		<u>30.00</u>	<u>3.04</u>	<u>30.00</u>	<u>5.28</u>

5.29. Although the sales effected by each distributor fell much short of the minimum stipulated off-take, the Company did not enforce the refund clause in the agreement on account of the following reasons, as stated by the Management in May, 1972:—

- (i) Till 30th September, 1970, the discount allowed to the distributors was 10 per cent as against 15 per cent allowed to Government/Semi-Government/Institutional buyers.
- (ii) This clause was incorporated in the agreement so that the distributor would make maximum efforts to achieve the minimum business. There was no intention to enforce the clause.
- (iii) HAL's share in the market was very low till 1970 and the minimum quantity was decided on ideal share that HAL should have in the market. It was not decided on any past performance and even at the time of finalising terms of agreement, it was decided not to enforce this particular clause unless it is absolutely necessary, i.e. only when a particular distributor works against interest of H.A.L.

- (iv) Had this clause been enforced, the distributor who has procured business for the largest quantities, but still failed to lift the minimum guaranteed quantities would have been penalised more and this would have spoiled relation of HAL with the distributor."

5.30. The distribution arrangements were reviewed by the Company in September, 1970 when it was decided to give up the practice of existing arrangements from October, 1970 except in Bihar and Maharashtra and to appoint new distributors or stockists in other territories on the basis of periodical contacts after personal approach and assessment. It was also decided that while the distributors would continue to get a discount of 10 per cent, the stockists would be granted a lower discount between 5 per cent to 7-1/2 per cent. The Company has engaged 13 sales representatives on whom it spent Rs. 0.76 lakh and Rs. 1.14 lakhs during 1972-73 and 1973-74 in the form of pay and allowances (excluding travel expenses) and other benefits. They could however effect sale of Rs. 82 and Rs. 1,852 only during these years. No stockists have however been appointed. The sales representatives were appointed with the primary object of contacting and keeping liaison with company's institutional customers such as Government hospitals, institutions and departments and hence the sales representative could not effect the sales effectively as the number of sales representative is limited and the market to be covered is wide enough.

5.31. The existing distributors in Maharashtra and Bihar could effect sales of the following value for 1970-71 to 1973-74:

	(Rs. in lakhs)	
	Maharashtra	Bihar
	Rs.	Rs.
1970-71	1.38	1.00
1971-72	1.61	0.15
1972-73	0.47	0.60
1973-74	0.50	0.10

This was much less than the minimum level.

5.32. HAL informed the Committee in a note that "With the limited number of representatives available at present, it has not been possible to make any significant dent in the private market.

The existing sales representatives are doing good work and their continuance in service is justified."

5.33. On an enquiry of the Committee whether in view of the performance of distributors in Maharashtra and Bihar, whether HAL was thinking of any other arrangement, HAL stated in a note as follows:—

"The poor performance is due to lack of detailing of its products by the Company to the medical profession on account of its limited market organisation. Change of distributors is not called for. The Company is considering augmentation of its marketing organisation."

5.34. The Committee find that the company has in addition to the distributors appointed thirteen sales representatives. The Committee note that these representatives could effect sales of Rs. 82 and Rs. 1852 only during the years 1972-73 and 1973-74 as against an expenditure of Rs. 0.76 lakh and Rs. 1.14 lakhs incurred during these years on their pay and allowance (excluding travel expenses) and other benefits.

5.35. Considering the performance of sales representatives, the Committee feel that they have hardly been able to justify their existence, although it is understood that the Sales Representatives are one of the media for promotion of sales. The Committee would like that the undertaking should go into the reasons for the poor performance of sales representatives with a view to draw lessons therefrom.

5.36. The Committee also feel that such stray attempts at sales promotion as have been made by the Company so far are not likely to make any worthwhile dent in the highly competitive market which is at present dominated by multinational and big private companies. unless the products of the Company are detailed to the medical profession, unless the medical profession is convinced of the high quality, easy availability and competitive prices of the Company's products, and unless the net work of distributors, stockists and also of the sales representatives are made result oriented no sales promotion campaign can hope to achieve the desired success. The Committee would like HAL to undertake a study in depth as to how leading pharmaceutical firms in the country have built up their sales organisation for efficient sale service and distribution of drugs to consumers, so that the Company can take advantage of such studies in planning its sales and distribution mechanism.

5.37. The Committee also recommend that pending the setting up of the central Marketing Organisation the undertaking should review the working of the existing marketing agencies and functionaries, spell out their roles and targets, introduce schemes of incentives and take positive measures to ensure that all of them put in all possible efforts to promote the sales of the Company's products.

5.38. The Committee note that the Company appointed distributors for the sale of its product from October, 1967 fixing a minimum limit of sales for a distributor and relating the discount payable to the total sales. In case a distributor failed to lift the minimum quantity (Rs. 5 lakhs in terms of money), the Company was entitled to recover a refund upto 2½ per cent of the list price of the quantity actually purchased. The Committee regret to find that even though none of the six distributors appointed all over the country fitted even half of the stipulated minimum during 1968-69 and 1969-70 the Company did not enforce the refund clause in the agreement. The Company has stated that the refund clause was incorporated in the agreement in the hope that the distributor would make the maximum efforts to achieve the prescribed volume of business and that there was no intention of enforcing it except when a particular distributor worked against the interest of the Company.

5.39. The Committee are not satisfied with the justification for not enforcing the recovery clause for no lifting of minimum quantity especially when according to Management the minimum quantity it was decided on ideal share that HAL should have in market.

5.40. The Committee note that distribution arrangements were reviewed in September, 1970 after a period of 3 years and it was decided to give up the then existing arrangements from October, 1970 except in Bihar and Maharashtra and to appoint new distributors or stockists, who will get a discount of 10 per cent or 5 per cent to 7½ per cent respectively. The Committee are not convinced as to why in spite of the earlier poor performance of Maharashtra and Bihar, the distribution arrangement in these two States were continued. The Committee find that even during the years 1970-71 to 1973-74, sales effected by the distributors in Maharashtra and Bihar have been much below the stipulated minimum, the sales during 1973-74 being of the value of Rs. 50,000 and Rs. 10,000 in Maharashtra and Bihar respectively. In the opinion of the Committee penal clauses which are incorporated in agreements but are not enforced encourage the trade not to take the company seriously and instead

of providing incentive to effecting greater sales of the company's products embolden them to ignore HAL's interests and pay greater heed to the products of other companies which seriously enforce such clauses. The Committee would like Government to take immediate steps to enforce the penal provision and effect the recovery of dues. The Committee would also like Government to go into the causes of the poor off-take of distributors. The Committee recommend that HAL should impress upon the distributors the need to take serious interests in promoting the sales of its products and to make it known to them that if they do not discharge their obligations under the agreements, not only the penal clauses will be enforced but the award of distributorships to them may also have to be reviewed. This is all the more necessary now when HAL is poised for entry in the open market at a much bigger scale. The Committee are not sure whether proper distributors were selected by the undertaking to promote the sales of its products. They would like the undertaking to select established distributors who have standing and experience in the field for marketing its products.

EXPORTS

5.42. The Company entered the export market for the first time in 1965-66 when a quantity of 3.6 kgs. of Hamycin in bulk was exported realising a sum of Rs. 0.72 lakh. The details of exports of Hamycin (bulk) and vialled antibiotics by the Company from 1968-69 to 1974-75 are given in the following table :—

	1968-69		1969-70		1970-71		1971-72	
	Bulk	Vialled	Bulk	Vialled	Bulk	Vialled	Bulk	Vialled
1. Quantity Exported (Bulk in Kgs and vialled in Nos.)	0.500	..	4.361	7,07,005	3,350	5,50,487	2.662	2,62,887
2. Cost of production (Rs.)	11,250	..	133,023	3,49,795	22,614	2,36,828	23,520	1,08,660
3. Export value (Rs.)	11,250	..	75,735	1,72,603	67,500	1,04,397	29,948	48,722
4. Profit (+) Loss (-) (Rs.)	(-) 57,288	(-) 1,77,192	(+) 44,886	(=) 1,32,431	(+) 6,428	59,938

Note : — There were no exports of Hamycin/vialled antibiotics during 1966-67 and 1967-68. Hamycin was exported to U.S.A. while vialled products were exported to East African countries.

No.	1972-73	1973-74	1974-75
1	47,628	144	3,00,414
2	19,330	416	1,76,945
3	8,795	216	1,55,756
4	(—)10,535	(—)200	(—)21,189

5.43. No efforts were made to export other bulk products (*viz.*, penicillin and streptomycin) due to limited availability. The value of products exported by the Company upto the end of 1974-75 amounted to Rs. 10.82 lakhs on which it suffered a loss of Rs. 4.07 lakhs.

5.44. HAL has given following justification for these exports:—

“With an eye on the future development of the Company particularly in view of its big expansion programme, it is necessary for it to enter the export market in a small way to start with. The Company has plans for expansion and during the course of the next few years, it would be in a position to make a meaningful entry in the export market. It may be added that in the later contracts for exports, a better price has been obtained which does not result in a loss if the variable expenditure only is taken into account. In earlier stages a low price had to be offered as we were beginning to enter the export market.”

5.45. As against the exports made by HAL, the imports of penicillin and streptomycin in the country since 1966-67 has been as follows:—

Year	Item	Installed capacity	Penicillin—MMU StreptomycinKgs.		
			Actual production	Imports during the year	Foreign exchange out go
1	2	3	4	5	6
(Rs. in lakhs)					
1966—67	Penicillin 'G'	84	69.40	64.43	65.51
	Streptomycin	80,000	60,670	17,690	10.06
1967—68	Penicillin G	84	57.17	52.46	58.56
	Streptomycin	80,000	66,393	89,226	82.96

1	2	3	4	5	6
1968—69	Penicillin G	84	60·10	1·98	2·64
	Streptomycin	80,000	70,253	35,688	73,73
1969—70	Penicillin G	84	64·99	1·53*	2·78*
	Streptomycin	80,000	83,138	35,697	65,47
1970—71	Penicillin G	84	62·00	NIL	..
	Streptomycin	80,000	60·971	12,531	22·45
1971—72	Penicillin G	84	71·30	41·18*	62·61*
	Streptomycin	80,000	62·038	83,703	170·10

*Also includes import of Procaine Penicillin 'B' Oil.

5.46. During 1972-73 to 1974-75 Penicillin|Streptomycin bulk has not been imported by the Company.

5.47. In this connection, the Secretary of the Ministry informed the Committee that "HAL had certain export obligations placed on them because of the import of some capital goods. So, in discharge of that, they had to export." On an enquiry whether it was necessary to do so, the Secretary stated as follows:—

"We have, in fact, suggested that if they do not find it favourable to export, we can get a waiver. As it happened, they tried to fulfil the legal obligations placed on them. As I mentioned earlier, the price of penicillin itself in the domestic market was not favourable. Therefore, while they lost Rs. 3-4 lakhs in exports, we have asked them to calculate how much they would have lost, had they sold the same in the domestic market. I have the provisional figures. The difference might have been round-about Rs. 5,000. That is all. I have this right now. In point of fact, they were losing, whether they were exporting or they were selling in India. Here, they were earning foreign exchange. But, in principle we are against the export of items which are simultaneously being imported, and in fact, these export obligations sometime do land us in peculiar situations. Firms, both in the public and in the private sector, have been forced to export items which are simultaneously being imported."

5.48. The vialled products have been exported by the Company through an indigenous firm (Unichem Laboratories Ltd.) in terms of arrangements made in February, 1969 for exporting the Company's

products to certain countries, mainly in Africa, together with the firms' own products. The terms of the agreement are as follows:—

- (i) The vials would be supplied in packed corrugated card board boxes. Further packing would be to M/s. Unichem's account.
- (ii) Printing of lables would done by Unichem Laboratories. However, the Company would be paying printing charges.
- (iii) The consignments would be delivered at Bombay at Unichem's godowns.
- (iv) 60 per cent of the import entitlements obtained by M/s. Unichem from Government will be passed on to the Company.

5.49. It has been stated that the exports were made through a private company as HAL did not have its own facilities which would enable it to sell in the private overseas market. Assistance from the State Trading Corporation was also not available in this regard.

5.50. In this connection the Secretary of Ministry stated that—

“Quite obviously, when they do not have a marketing organisation in India, it follows that they do not have a marketing organisation abroad as well. There are a number of firms which are in the international market. They were a small business.”

5.51. On an enquiry whether this could not be done through the STC, the Secretary stated that this year, STC was entering into the market.”

5.52. The Ministry submitted the following note on difference in value of export of drugs by HAL and value of sale of that quantity within the country:—

“During 1974-75, HAL exported 3 lakhs vials of Streptomycin 1 gm. and small quantities of Streptomycin and Aureofungin, Streptomycin sulphate 1 gm. vials were exported at £2.75 per hundred vials being the price for institution consumers. On the FOB value of exports, HAL are also entitled to 20 per cent cash incentive. The resultant loss

may be seen from the following statements:—

	Rs.
If sold in the internal market	
Exported quantity (cif)	1,86,990
Rs. 153,540(fob)	1,38,190
Difference	48,800
Less 20 percent cash incentive	27,638
Net loss to HAL on the quantity exported based on FOB value	21,162

5.53. Under a commitment made in 1962 to Government in consideration of release of free foreign exchange amounting to Rs. 34 lakhs for the streptomycin expansion project, the Company is obliged to export products worth Rs. 34 lakhs. The Company has not been able to fulfil the export obligation fully due to scarcity of bulk material in India and severe competition for formulations abroad.

5.54. The Committee note that the Company entered the export market from 1965-66 under a commitment made to Government in 1962 in consideration of release of free foreign exchange amounting to Rs. 34 lakhs for streptomycin expansion project. Though it was obliged to export products worth Rs. 34 lakhs, the Committee regret to observe that the undertaking had not been able to fulfil the commitment and till 1974-75 it had exported products worth only Rs. 11.14 lakhs and that too resulted in a loss of Rs. 3.66 lakhs. The Committee are informed that it had to offer low prices in the beginning to enter the export market "with an eye on the future development of company particularly in view of its big expansion programme" and in the later contracts a better price had been obtained which did not result in loss if the variable expenditure only was taken into account. The Committee need hardly stress that profit or loss should be reckoned on the total price and not separately on fixed or variable costs. The Committee also do not appreciate the justification sought to be given viz. that domestic market was also not favourable and the Company was to lose either in exports or in domestic sales. If so, the Committee fail to understand as to why the offer of the Ministry to get a waiver of the legal obligation to export was not availed of. The Committee are surprised to note that while, on the one hand, Penicillin 'G' and Streptomycin are being imported in bulk for being converted into vials to meet the internal demand, on the other hand, HAL has been exporting its vialled products at a loss. The Secretary,

Department of Chemicals and Fertilisers stated during evidence that "..... in principle, we are against the export of items which are simultaneously being imported."

5.55. The Committee recommend that Government should review its orders of 1962 and consider revising them suitably so as not to put the undertaking into losses in the fulfilment of its export obligations. The Committee also stress that so long as the country is dependent on imports for the essential drugs, the company would do well to concentrate all its marketing efforts on sales in the domestic market and after establishing a name in domestic market for formulations consider extending its sales activities in foreign markets.

5.56. The Committee find that, at present, exports are being made through a private drug company M/s Unichem in terms of an arrangement with them in February, 1969 according to which inter alia HAL would be entitled to 60 per cent of import entitlements obtained by M/s Unichem from Government. The Committee are informed that arrangements had to be made through a private firm because assistance from STC was not available nor was there any marketing organisation of HAL abroad. The Committee are not aware as to how M/s Unichem were selected for exporting the products of the company and whether any offers of other companies in this regard and their terms and conditions were examined. The Committee would like that this matter should be investigated by Government to see how far the terms and conditions and arrangements with M/s Unichem have subserved the interest of the undertaking and whether HAL products are not being sold under the Unichem's brand names.

RESEARCH AND DEVELOPMENT

One of the objectives of setting up the Company, as enunciated in the Joint Plan of Operations between the Government of India, UNICEF and WHO, was the establishment of an important centre of research and training in the field of antibiotics. The Research and Development Organisation of the Company was established in 1955 and its activities fall in two divisions (i) development research and (ii) basic research. Development research is a part of an overall business strategy which requires a systematic and deliberate effort to achieve the objectives of the Company through improved technology. It has been stated that planning in research both developmental and basic is integrated not only with a view to achieve higher productivity and discovery of newer antibiotics, but also to ensure that the tasks undertaken fit in with the Company's objectives about its expansion and new ventures, as also its resources. Broadly, the work allotment of research staff in the laboratory consists of about 40 per cent of work with reference to problems of the plant, 30 per cent on the new antibiotics development and about 20 per cent on the basic research.

6.2. The following table brings out the number of personnel in the Research and Development Organisation and the expenditure incurred on research and development by the Company during 1966-67 to 1973-74 :—

	1966-67	1967-68	1968-69	1969-70	1970-71	1971-72	1972-73	1973-74
I	2	3	4	5	6	7	8	9
1. Personnel employed (No.s)	110	112	112	112	112	112	112	112
2. Research & Development expenditure (Rs. in lakhs)								
(i) Within Company's laboratory	12.15	27.73	22.94	22.75	20.21	26.01	24.13	27.07
(ii) Out-side	0.45	0.72	0.76	0.98	0.73	0.30	0.07	0.95
TOTAL	12.60	28.45	21.70	23.73	20.94	26.31	24.20	28.02
3. Sales turnover (Rs. lakhs)	716.60	646.62	632.55	723.50	619.98	728.01	789.29	785.30
4. Percentage of research expenditure to sales	1.76	4.40	3.43	3.28	3.38	3.61	3.07	3.57

6.3. According to the Management (October, 1971) the research activities of the Company have to be viewed in relation to their (i) contribution to the plant, (ii) efforts at import substitution and (iii) discovery of new antibiotics.

(i) As regards contribution to the plant, it is claimed that the research laboratory is continuously rendering technical advice and assistance for improving the quality of products and in suggesting improvements to achieve higher productivity. This is being done by selecting improved strains, keeping properties of the penicillin salts and study of metabolism, enzyme make up, biosynthesis etc. of penicillin production. The research laboratory also renders service in the adoption of better fermentation and extraction techniques.

(ii) Import substitution of raw materials is being given high priority since the commencement of trial operations on Penicillin production in 1954. It is stated that the Company has wholly or partially replaced extensive and bulk imported raw materials like Lactose, Cornsteep concentrate, corn oil, Lard oil with indigenous substitutes like Sugar, Peanut meal, Ground nut oil, etc. Considerable efforts are also being made to either replace or develop indigenous production capacity for the essential imported raw materials needed for Penicillin, Streptomycin, Tetracycline, and Hamycin. Originally the requirement of foreign exchange involved annually was estimated at Rs. 14 crores for the Company's production. The value of imported raw materials during the seven years was as follows:—

	(Rs. in lakhs)
1968—69	41·28
1969—70	25·18
1970—71	28·26
1971—72	24·45
1972—73	50·94
1973—74	32·62
1974—75	26·37

6.4. The percentage of imported materials total materials consumed has come down from 25.2 per cent in 1968-69 to 6.20 per cent in 1974-75:—

6.5. On an enquiry by the Committee as to the outcome of work done by the R&D Wing so far, HAL submitted in a note as under:—

“(i) HAL was established in 1954 for the production of Penicillin. The strain employed at that time had an activity

of less than 2000 units per ML and depended mostly on imported raw materials. Through constant research and development efforts, new strains have been introduced over the last two decades. The average activity obtained at present from the strain is about 8,000 to 10,000 units per ML with the use of indigenous raw materials only, except for a very small percentage of imported materials which constitute about 10.48 per cent of the total raw materials employed in the manufacture of Penicillin.

- (ii) Streptomycin, A new strain has been acquired in 1974 for the manufacture of streptomycin from company's collaborators. The R&D Wing has been engaged on stabilisation of the fermentation parameters and strain improvement programmes, which have contributed to the stabilisation of the activity of the strain which is at present 14,549 units per ML against the average of 7,000 units obtained from the old strain in use before 1974. The R&D Wing has evolved a process for conversion of starch to Dextrose using Enzymes which has been adopted in the plant and has resulted in reduction of the cost of manufacture.
- (iii) Semi-synthetic Penicillin: The Company has acquired technology for the manufacture of Ampicillin—a semi-synthetic Penicillin—from 6 APA, an intermediate compound in the process of manufacture of Ampicillin from Penicillin. The technology for the first stage of the process viz., conversion of Penicillin 1st crystals into 6 APA has been developed entirely by the R&D wing of HAL. The plant for manufacture of 6 APA from Penicillin 1st crystals is based on this technology.
- (iv) Antifungal antibiotics: The R&D wing has discovered or developed two plant protection antibiotics viz. Aureofungin and Streptocycline which have been successfully marketed. The R&D wing has also developed an antifungal antibiotic called Hamycin, and a veterinary product called Autiamoebin. The work on both these is being reviewed due to some process difficulties and for standardization and stabilization.

The following new antibiotics have also been developed by the Company:—

- (i) Dermostatin—An antifungal antibiotics active against skin infection. Commercial production has not yet started.

- (ii) Neomycin—A preparation used for skin and eye infection.
- (iii) Antiameobin—An antiprotzoal and antelminite antibiotics used against worm infections in the animals. The production of this antibiotics is still in the pilot plant stage.
- (iv) Formulations—Penicillin V and streptocycline.

The R&D Wing has also evolved processes for the manufacture of the following industrial Enzymes.

- (a) Penicillin Acylase.
- (b) Amylolucosidase.
- (c) Penicillinase.
- (d) Lipase.
- (e) Glucose Oxidase.

The projects based on these processes have been included in the company's Fifth Five Year Plan submitted to the Government."

6.6. The Management have stated that no specific projects undertaken by the Research and Development Organisation have been abandoned, although there are a number of items which may not come to successful commercial exploitation but add to the development of technical skills and scientific coordination between institutions all over the world engaged in similar endeavour.

6.7. In this connection, it may be stated that the Standing Technical Sub-Committee of Directors in a meeting held in March, 1970 to, *inter alia*, examine the various projects that were being tackled in research laboratory observed *inter alia* that "most of the schemes placed for consideration...had been under investigation for more than one year, but the report did not give sufficient data for the work done in the past, year by year, as a base for comparison of the progress of work done during the year 1969-70 and there was also no statistical analysis of 1969-70 data for comparing with the previous year."

6.8. On being asked whether research in same or similar fields was being done both at HAL and IDPL and, if so, how duplication is avoided and coordination ensured, HAL stated in a note as follows:—

"This company has no authentic information in regard to the activities pursued by the R&D wing of the IDPL. As the

emphasis of IDPL is more on synthetic drugs, their R&D efforts concentrate more on the field of synthetic drugs.

Even in cases where the drug manufactured is the same like penicillin and streptomycin, the process and technology employed by the two companies are quite different and therefore the problems of research and development would be different and have to be tackled independently. A certain amount of duplication in bio-medical research is not only unavoidable, but also desirable. In view of the different processes and technology employed, there would be, however, no avoidable duplication of efforts."

6.9. As against 5 per cent of the net turn-over for Research and Development now recommended by the Committee on Drugs & Pharmaceuticals Industry, the percentage in HAL works out to 3.6 per cent. On this HAL stated as follows:—

"The Board decided to expand and strengthen R and D and spend about 5 per cent annually on R&D. The entire R&D programme is being reviewed with a view to make it result oriented within the frame work of a time bound programme to serve the present needs as well as future requirements keeping in view the anticipated development of drugs industry in India and in the World. A technical sub-committee of the Board reviews the R&D programmes periodically."

6.10. The Committee were informed by the Managing Director during evidence as follows:—

"Our company is the only company, probably the first to discover antibiotics in India. But, as you know, it requires so much inputs and so much expenditure on R&D even to stabilise this thing. This is where the foreign companies score. For example, even last year, I was going through the R&D efforts and expenditure by some of the big companies. They spend anywhere from 6 to 15 per cent on R&D. This is on their global turnover. They are multi-nationals with a number of branches all over the world and they have a very huge market. Therefore, if they spend 6 to 15 per cent on R&D—this is based on sales you can very well imagine how much money is based on sales—you can very well imagine how much money is invested in R&D. That is why, they are able to standardise

these new drugs. For example, in regard to the drug which we are developing, about which the hon. Committee is aware, even today, we are standardising it. This is because we spend only 3 per cent of our sales on R&D, and with 3 per cent, how much inputs you can put in to standardise a new drug? For example, even the pharmaceutical tests require crores of rupees on one new drug. So, this is where the foreign companies score. They have enormous resources at their disposal to spend on R&D and they have the market for it. They have got branches all over the world to tie up licences. Therefore, they can quickly spread all over the world and they get their money back. Then we invest, we should also have a market. This is what restricts a country like India to put up more and more money and develop its own drugs. Otherwise, there is no reason why our country with all its resources and talent should not be able to develop its own drugs to that extent.

6.11. On an enquiry by the Committee as to what was the total spending on R&D, the Managing Director informed that it was around Rs. 26 lakhs per year which came to around 3 per cent of the turn-over. Asked as to how much he thought should be allocated for R&D, the Managing Director stated:—

“Actually, if you ask my humble opinion, you should spend at last 10 per cent of your turn over. This would come to around rupees one crore.

The Board had decided sometime back to spend about 5 per cent. But even that would be meagre if you really want to develop new drugs. It requires tremendous amount of testing facilities, evaluation facilities, pharmaceuticals facilities. You have to put through these facilities.”

6.12. To this the Secretary of the Ministry added:—

“It is not a question of 10 per cent or 3 per cent. If you take even 5 per cent of what is spent by these foreign firms on R&D, it will mean almost the whole, cent per cent of HAL's turnover. As you know, the turnover is relatively small. It is not a question of 5 per cent or 10 per cent. It depends on what kind of R&D you want to do. One proposal is that, we should set up an Institute of Fermentation Technology and we have suggested to the Department

of Science and Technology that it is not right that they should expect one commercial firm to finance such a thing. We have got the National Chemical Laboratory. This will come up in the Fifth Five Year Plan. The Department of Science and Technology has got it included in the Fifth Plan. We want this to be one additional national laboratory."

6.13. The Secretary of the Ministry further added to it as follows:—

"Foreign companies spend fabulous sums on R&D as a business proposition and we must make this distinction between HAL as a company and these companies. The big firms, the multi-national firms, like Glaxo, Sandoz, Pfizer etc. are vast international empires and they spend a lot of money, as you have said. They make this investment in R&D for the discovery of new drugs. After discovery they immediately use these discoveries for international operations and recoup very quickly the money they spend on R&D. Therefore, their investment, which runs into several millions and billions of dollars, is fully recouped and it is a cent per cent commercial proposition. First of all, we just do not have the amount of money which they put in. I hope a day comes when IDPL and HAL will also be multi-national companies. We are looking forward to that."

6.14. On an enquiry of the Committee that whether or whatever was being spent on R&D, HAL got full benefit out of that, the Managing Director stated:—

"In research, it is very difficult to say whether you have got your money's worth. Sometimes it is a wild goose chase. To find a new drug, you may spend lakhs of rupees for years and get nothing out of it—just like in oil prospecting. In some areas, you can make tangible progress, improving the existing technology. For example, our company has developed a penicillin strain with its own facilities of R&D which gave 10,000 units as against 2,000 with the strain we imported."

6.15. In regard to research programmes, he informed the Committee as follows:—

"We have a sub-committee of the Board which goes into the research aspect. They find out what research is going on

and what is required for the company's future growth and moderate it on those lines. We are intensifying this kind of thinking. For instance, we have the 5th Plan, then the 6th Plan and the country's requirements. Then some drugs may become obsolete. In America some new things have been introduced for leprosy, T.B. etc. We are thinking more and more of time-bound programmes. Within so many years, such and such thing has to come out. If it does not, we shelve it or do something about it. The Board is cognisant of these things. We have well known scientists on the Board. The Director of NCL is there. A senior scientist of the Central Drug Research Institute is there. The Director of Haffkine Institute is our part-time Chairman. We have well known scientists from all walks of life in India to guide and help us. Secondly, we have a consultancy agreement with NCL. There are consultations between our research scientists and their people every month, twice a month when they go over these problems and they assess how far they should be pursued. So this kind of check or audit is going on. We have profited by this. Instead of each man pursuing what he wants, there is a kind of thinking as to what is required for the country, for the company; there should be no overlapping with what is done in other public sector undertakings. So this is being looked into."

6.16. The Science & Technology Plan 1974—79 *inter alia* states as follows:—

"There is heavy domination of foreign companies and foreign owned manufacturing units in the drug industry. The technological task during the next five years would, therefore, require substantial inputs on the R & D side. The HAL is already spending around Rs. 25 to 30 lakhs a year on R&D and has developed laboratory processes for several industrial enzymes as well as new antibiotics. Support to HAL efforts is likely to yield attractive returns in comparatively short time."

6.17. The Committee on Drugs & Pharmaceuticals Industry has made the following observations in connection with the R&D of public sector drug manufacturing units:—

"99. The Committee notes that both the units (IDPL & HAL) have fair sized R&D efforts, there is a lower critical

minimum in men and materials necessary to produce meaningful results. Whereas all the three laboratories at Pimpri, Rishikesh and Hyderabad have some very competent scientists|technologists for their R&D effort, there is need to bring this number up to a level of meaningful productivity. The Committee recommends that each one of these units should take immediate steps to strengthen their R & D effort by reasonably liberal allocations in men, equipment and materials. The Committee recognize that modern R&D, in this sophisticated field, is expensive in terms of investments. The Committee, is however, convinced that a sound R&D base is the best insurance for the growth of the drugs and pharmaceutical industry.

100. Besides recommending the strengthening of R&D laboratories at each plant, the Committee is strongly of the view that as between these three units, avoidable duplication of effort must be discouraged and the results (even the raw research data) of each unit must be available to the related unit in other R&D laboratories. This recommendation is based on the philosophy that as between the two units in the public sector (DPL and HAL) there should be no secrets. Indeed, any improvements, in a strain, a process or a plant developed in the R&D laboratory of one unit, should be freely available for the use to the other unit.
101. The Committee further recommends that both the public sector units must establish the closest liaison with the other R&D laboratories such as the CSIR, ICMR, ICAR, etc., and the State institutions like the Haffkine Institute, the IIT's, Universities, etc. The Committee feels that such coordination is vital for development. The Committee cannot but emphasise the need for such coordination by National drug Authority. The Committee recommends that appropriate facilities should be created in the identified institutions, wherever necessary, to permit time-bound completion of individual projects.
102. The Committee wishes to emphasise that the primary task of the R&D laboratories of the public sector units and their associates should be to constantly upgrade technologies for achieving greater economics in the production of on-stream products and innovate technologies for pro-

ducts proposed to be manufactured in the immediate future.

103. The Committee recommends strongly that the Public Sector should set an example in respect of R&D in this area and must, to begin with, set aside at least 5 per cent of their net turn-over for this purpose. (Chapter III).
36. Sufficient technological skill is available in the public sector and the indigenous private sector to carry out formulations of almost any sophistication. The Committee does not, therefore, consider that there is need to import any formulation technology whatsoever. The Committee, however, recommends that the public sector units should set up a formulation R&D unit as early as possible.
37. The Committee recommends that in order to reduce dependence on import of technology in general, urgent steps should be taken to equip the public sector units of the industry as also the laboratories mentioned above, with such R&D and pilot plant equipment as may be necessary for this work. This would include low-temperature, high pressure and high-temperature equipment including the vapour-phase reaction equipment. The Committee strongly recommends that in consultation with the above laboratories, the specialised equipment may be provided at least at two centres to begin with. (Chapter VII)

6.18. The Committee note that as part of the objectives of setting up of the Company, the Research and Development Organisation of the Company was established in 1955 and its activities fall in two divisions—development research and basic research. According to the management, the research and development activities have to be viewed in relation to (i) contribution to the plant, (ii) efforts at import substitution; and (iii) discovery of new antibiotics.

6.19. Although it has been claimed by the HAL that research laboratory has been continuously rendering technical advice and assistance for improving the quality of products and in suggesting improvements to have higher productivity by selecting improved strains, etc. and also rendering service in the adoption of better fermentation and extraction techniques, as pointed out in the relevant sections of the 'Performance' chapter in this Report, these are not borne out by facts/details. In the opinion of the Committee

not much seems to have been done in regard to upscaling of technology. The improved strain for Penicillin was introduced in 1971 after the old strain had been used for nine years. Even this has to be upscaled and negotiations are there for better technology. Similarly, the new strain for streptomycin was introduced only in 1974-75. The percentage of utilisation in fermentation and extraction were found to be low and the rejections continue to be heavy in the Quality Control Department as well as under the different processes. The Committee feel that R&D wing should direct its efforts to the task of not only absorbing the technology on which the projects of HAL have been set up but upscaling it, suggesting ways and means for improving the utilisation, reducing rejections and cutting down the cost of production.

6.20. In regard to import substitution, the Research and Development wing is reported to have developed processes for conversion of starch to dextrose and the percentage of imported raw materials to total materials consumed has come down from 25 per cent in 1968-69 to 6 per cent in 1974-75. In addition, the Undertaking is reported to have developed new antibiotics like Hamycin, Aureofungin, Dermostatin, Neomycin, Antimoebin and also evolved processes for manufacture of some enzymes. It has been stated that the work on the antifungal antibiotics like Aureofungin and Hamycin are being reviewed due to process difficulties and for standardisation and stabilisation. The Committee have already given their recommendations in regard to these antibiotics in an earlier chapter of this Report.

6.21. The Committee are informed that the Company is spending about Rs. 26 lakhs per year on research and development; i.e. about 3 per cent of the sales turnover while the general level of R&D in big drug companies is stated to be of the order of 6 to 15 per cent. The management is of the opinion that the percentage should be round-about 10 per cent. The Committee agree that it is not the percentage which counts but what really the Undertaking wants to do and achieve. In this connection, the Hathi Committee has recommended that the public sector unit should, to begin with, set aside at least 5 per cent of their turnover for this purpose. The Committee are informed that the Board of Directors had also some time back decided to spend about 5 per cent of the sales turnover on R&D. But according to the Managing Director, even this level of expenditure would be meagre. In this connection, the Committee would like to draw attention to suggestions made by the Hathi

Committee, in paragraph 99 of chapter 3 and paragraph 37 of chapter 7 of their report and recommend that the company should take immediate steps to strengthen its R&D effort to bring it to a level of meaningful productivity and to equip it with such R&D pilot plant equipment as may be necessary for this work as a sound R&D base is the best insurance for growth of drugs in pharmaceutical industry. The Committee also recommend that the personnel selected for R&D should be dedicated and accountable.

6.22. The Committee note that the Standing Technical Committee of the Directors in the meeting held in March, 1970 to examine, inter alia, the various projects being tackled in the research laboratory observed that "most of the schemes placed for consideration. . . . had been under investigation for more than one year but the report did not give sufficient data of the work done in the past year by year as a base for comparison for the progress of work done during the year 1969-70 and there was no statistical analysis of 1969-70 data for comparing with the previous years." The Committee are informed that the Sub-committee of the Board remains in touch with the research programmes of the R&D wing and what is required for company's future growth. The Undertaking is said to be reviewing the entire R&D programme with a view to make it result-oriented within the framework of the time-bound programme to serve the present needs as well as future requirements keeping in view the anticipated development of drug industry in India and the world. The Committee recommend that the projects which have a bearing on the existing working of the plants and maximisation of the existing capacity and future development of the drug industry should be identified for research work by the R&D wing and an analysis of the projects which had been carried forward to the stage of commercial exploitation or are making progress or are stuck up should be made so that it is possible, not only for the R&D wing to take stock of its achievements and failures but also for the Government and the Undertaking to evaluate its performance with reference to investment made in it during the year. The Committee also recommend that a gist of the achievements made by R&D should also be included in the annual report of the Undertaking. The Committee would also like to endorse the suggestion made by the Committee on Drugs and Pharmaceutical Industry (Hathi Committee) in para 101 of Chapter 3 of their Report that the public sector units should establish closest liaison with the other R&D laboratories such as the CSIR, ICMR, ICAR, etc. and state institutions like the Haffkine Institute, the IIT's Universities, etc., as such coordination is vital for development and that

appropriate facilities should be created in the identified institutions, wherever necessary, to permit time-bound completion of individual projects.

6.23. The Committee recommend that there should be a High-powered Committee in the Ministry which should demarcate areas of R&D and allot them to the various institutions and contemporaneously monitor the programmes and review them from time to time with reference to the allocation of money and time schedule.

6.24. The Committee are surprised to note that HAL "has no authentic information in regard to the activities pursued by the R&D wing of the IDPL". When these two public sector units have been manufacturing same drugs (vis. Penicillin and Streptomycin) though based on different processes and technologies, the least that the Committee expect is that there should be a system of coordination between the two public sector units so that one could benefit from the achievements of the other in larger national interest.

6.25. In this connection, the Committee would like to invite attention to the recommendation made by the Hathi Committee in para 100 of Chapter 3 of their Report to the effect that as between these three units (at Pimpri, Rishikesh and Hyderabad), avoidable duplication of efforts must be discouraged and the results available at each unit must be made available to the other related unit. There should be no secrets between the public sector units and any improvements, in a strain, a process or a plant development in the R&D laboratory of one unit, should be freely available for use by the other unit. The Committee hope that HAL would lose no further time in establishing a close liaison and coordination with R&D laboratories of the other public sector drug units on these lines.

INVENTORY CONTROL

The following table brings out the comparative position of inventory and its distribution at the close of the last nine years :—

(Rs. in lakhs)

	31-3-1967	31-3-1968	31-3-1969	31-3-1970	31-3-1971	31-3-1972	31-3-1973	31-3-1974	31-3-1975
	1	2	3	4	5	6	7	8	9
I. Stock at the close of the year									
(i) General Stores and Spares	127.30	122.95	104.32	103.89	99.11	107.35	123.26	104.30	126.57
(ii) Tools	0.25	0.23	0.24	0.24	0.25	0.31	0.18	0.34	0.23
(iii) Stock-in-trade									
(a) Raw materials	132.38	108.67	75.28 (35.36)	75.66 (31.27)	79.89 (26.57)	104.82 (24.45)	101.47	114.37	117.82
(b) Works-in-progress	43.42	51.26	67.10	70.09	61.79	78.44	86.00	65.81	78.52
(c) Finished Goods	58.72	54.00	46.40	38.46	55.56	38.00	63.15	57.30	164.25
(d) Material under re-processing	2.99	4.06	10.61	2.90	4.03	4.84	5.43	3.96	11.16
(e) Goods-in-transit	5.82	14.89							
TOTAL	370.88	356.07	*303.95	291.24	300.63	333.32	379.49	346.08	498.43

*Please see next page.

31-3-1967 31-3-1968 31-3-1969 31-3-1970 31-3-1971 31-3-1972 31-3-1973 31-3-1974 31-3-1975

	1	2	3	4	5	6	7	8	9
II. Total consumption of raw- materials during the year	267.84	259.23	270.22 (68.09)	277.70 (54.68)	269.51 (60.42)	335.84 (38.67)	336.73 (50.94)	358.89 (32.62)	426.30 (26.37)
III. Year-end inventories of raw materials (a+d) as number of months Consumption	6.06	5.22	3.81	3.40	3.74	3.92	3.81	3.96	3.6
IV. Total sales during the year	716.60	646.62	632.55	723.50	619.93	728.01	789.29	785.30	663.36
V. Finished stock as number of months sales	0.98	1.00	0.88	0.64	1.08	0.63	0.96	0.88	2.97

Notes : 1. *As re-grouped by the Company in 1969-70 accounts.

2. The figures within brackets represent the value of imparted raw materials included in the total stock in hand and the total consumption during the year.

7.2. The stock of raw materials in terms of number of months consumption showed a declining trend up to 1969-70 but increased thereafter to a maximum of 3.96 months consumption at the end of 1973-74 and again declined to 3.6 months consumption at end of 1974-75. It was, however, within the norms adopted by the Company, viz., three months consumption for indigenous materials and six months consumption for imported items in all the years except in 1969-70 and 1971-72. Thereafter, the position of inventory of raw materials including material under reprocessing at the end of three years ending March, 1973, March, 1974, and March, 1975, the consumption of raw materials during the three years, and the closing stock expressed in terms of number of month's consumption is as follows: While the inventory of the end of 1972-73 to 1974-75 in respect of imported raw materials was within the norms the inventory of the indigenous raw materials was in excess of the norm of three months consumption:

(Rs. in lakhs)

Particulars	1972-73		1973-74		1974-75		Total		
	Indi- genous	Impos- ted	Indi- genous	Impos- ted	Indi- genous	Impos- rted			
1 Inventory	94.81	6.66	101.47	113.03	1.34	114.37	109.60	8.22	117.8
2 Consumption for the the year	258.79	50.94	336.73	326.27	32.62	358.89	399.93	26.37	426.3
3 Years end inventory expressed in number of month's consumption	3.98	1.57	3.61	4.16	0.50	3.82	3.28	3.75	3.32

7.3. The stock of finished goods which gradually declined up to 1969-70 showed substantial increase as on 31st March, 1971. This has been attributed by the Management to delay in the finalisation of orders by the DGS & D. It was also noticed (March, 1975) that Aureofungin Bulk (Rs. 2.89 lakhs), Aureofungin 6 grams packets (Rs. 0.44 lakhs) and Streptocycline packed (Rs. 2.63 lakhs) had heavy accumulations since 1967-68. HAL informed the Committee in a note as follows:—

“As at end of March, 1975, the stock of finished goods was Rs. 164.25 lakhs which is equal to 2.97 months net sale. The large inventory of finished stocks is due to resistance on the part of the viallers to lift bulk which is presumably due to the reduced margin of profit on formulations of Streptomycin and Penicillin. During the year 1974-75, the Company was faced with an acute shortage of vials and rubber stoppers which resulted in lowering of the captive

consumption of the bulk manufactured by the company leading to increase in the bulk stocks.”

7.4. In regard to the accumulation of general stores and spares, the Management have stated that these will be required for replacements when the existing machinery becomes old and worn out. However, stores of the value of Rs. 12.16 lakhs as on 31st March, 1974 had not moved for over three years.

7.5. The value of stores declared surplus and obsolete during the last five years is given in the following table:—

(Rs. in lakhs)

As at the end of	Stores declared surplus and obsolete
1970—71 . . .	2.68
1971—72 . . .	2.92
1972—73 . . .	4.45
1973—74 . . .	3.14
1974—75 . . .	7.27

7.6. In this connection HAL stated in a note as follows:—

“Several of the spares have been imported under actual users’ licence and require clearance from the Government for their disposal which is being obtained. With a view to ensure the best possible utilisation of such items, these have to be first offered to other public undertakings before they are offered for sale in the open market. The equipment and therefore the spares in use in this company are of a highly specialised nature the use of which is limited to the drug industry and in most cases to antibiotics manufacture. As such, there will not be a ready market available in which the surplus items could be disposed off.”

7.7. On an enquiry from the Committee in connection with toning up of Materials Management, HAL submitted the following note: “The Committee appointed by the Board of Directors in 1974 to go into the problems of production have *inter alia* observed that lack of adequate Material Management and absence of scientific inventory control has affected the Company’s working. However, prior to this, the Management had already assessed this situation and taken the following measures in that direction:

(a) From the beginning, the Purchase and Stores Departments were functioning independently, with associated coordination problems. Hence, the stores and the Purchase Departments were integrated into a Materials Management Department under the overall control of Materials Manager, who is charged the responsibility of overall control of Materials Management Department coordination between Stores and Purchase and with other departments.

(b) An inventory control cell has been created under the Materials Manager, to ensure stocking of optimum inventories and to avoid excess procurement.

(c) In order to develop a sound inventory management system and to review, develop and implement an integrated Materials Management System, National Institute for Training in Industrial Engineering (NITIE) Bombay has been appointed as consultant for this assignment. A Task Force consisting of Officers from Materials Management, Engineering, Industrial Engineering on Accounts Department has been constituted to work under the overall guidance of the consultant. The Task Force has so far worked in identification on non-moving stocks, material modification and physical layout of stores.

Recognizing the imperative necessity of such delegating certain powers to the officers of various departments for smooth functioning of the departments, powers have been sub-delegated to various departments including Materials Management Department during the May, 1974, according to which the departments are empowered to take certain decision, not given hitherto. It is felt that this Sub-delegation is adequate and has helped to remove constraints towards smooth functioning of various departments.

Excess inventories of Engineering spares did build up since those were required to be procured along with the original imported equipments. A number of such equipment have subsequently become obsolete and the spares had to be maintained as inventories due to lack of buyers and efforts are being made to dispose them off. Secondly, the Engineering Department being responsible for raising materials purchase requisition for spares, at times there has been excess ordering as they wanted to be in the safe side.

Efforts are being made to dispose of non-moving stocks of spares, and to rationalise procurement policies of spare parts, in order to avoid build up of excess inventories.

7.8. The Committee note that the stock of raw materials in terms of number of months' consumption showed a declining trend till the end of 1969-70 (value Rs. 76 lakhs) but increased thereafter to a maximum of 3.96 months' consumption (Value Rs. 114 lakhs) and again declined to 3.6 months' consumption (value Rs. 118 lakhs) at the end of 1974-75. It was, however, within the norms adopted by the Company viz. 3 months consumption for indigenous materials and 6 months consumption for imported materials except in 1969-70 and 1971-72. While the inventory of imported raw materials in subsequent years was within the norms, in the case of indigenous materials it was in excess of the norms. In spite of this heavy investment in raw materials, the Committee regret to observe that due to shortages/non-availability of essential raw materials like, soya-bean, etc. the undertaking could not keep up the production of streptomycin.

7.9. The Committee also note that the stocks of finished goods which gradually declined upto 1969-70 showed a substantial increase as on 31st March, 1971, which is stated to be due to delay in finalisation of orders by DGS & D. Though it declined thereafter it again increased to almost about 3 months' sales at the end of March, 1975 which is stated to be due to resistance on the part of viallers to lift bulk presumably because of the reduced margin of profit on formulations and due to lower consumption of bulk by the company for formulations on account of acute shortage of vials and rubber stoppers. The Committee are constrained to observe that while on the one hand production of formulations is stated to have suffered due to shortage of vials and rubber stoppers, on the other hand there has been an increase in the inventory of general items and spares from Rs. 99 lakhs at the end of March, 1971 to Rs. 127 lakhs at the end of March, 1975 thus indicating accumulation of non-essential stores.

7.10. The Committee also see no reason for delays in the finalisation of orders by DGS & D. In fact DGS & D should give preference and every facility to public sector undertakings to meet the demands/requirements of Government to the maximum extent. The Committee would also like Government to go in depth into the causes for the delays in finalisation of orders by DGS & D and remove any procedural lacuna which may be responsible for such delays.

7.11. The Committee also note that the finished stock included Aureofungin (Rs. 3.33 lakhs) and streptomycin (Rs. 2.63 lakhs).

accumulated since 1967-68. The Committee have already given their recommendations regarding these products in another chapter of the Report. The Committee are not sure whether these still retain their efficacy and are fit for disposal.

7.12. The Committee also find that the stock of materials under reprocessing has shown a steep increase from nearly Rs. 4 lakhs at the end of 31st March, 1974 to over Rs. 11 lakhs at the end of 1974-75. The Committee have given their recommendations in another chapter of the report regarding the rejections and reprocessing costs. The Committee feel that such expenditure on reprocessing is avoidable. The Committee would like that Government/Undertaking should critically go into the causes for this steep increase and take suitable remedial measures to control the rejections and eliminate reprocessing. The Committee understand that the Committee appointed by Board of Directors in 1974 had observed that lack of adequate Materials Management and absence of scientific inventory control had affected the Company's working. However, prior to this, it has been stated, the management had taken certain measures to tone up the materials management like, integrating the Purchase and Stores Departments into Materials Management Department and placing it under the overall control of the Materials Manager, creating an inventory control cell to avoid excess procurement and ensuring stocks of optimum inventories etc.

7.13. Considering the inventory of general stores and raw material during the last many years and the steep increase in stock of finished goods at the end of 1974-75 the Committee feel that the steps stated to have been taken for toning up materials management have not produced the desired results. They would therefore like that the measures should be reviewed and tightened up to ensure that there is no unnecessary accumulation of inventory resulting in blocking of funds and accentuating the financial difficulties experienced by the undertaking.

7.14. The Committee also note that the value of surplus and obsolete stores has increased from Rs. 2.68 lakhs at the end of 1970-71 to Rs. 4.45 lakhs at the end of 1972-73 and declined to Rs. 3.14 lakhs at the end of 1973-74 and again increased to Rs. 7.27 lakhs at the end of 1974-75. The Committee feel that had suitable maxima minima and ordering levels been laid down and adhered to, the undertaking would not have been faced with such surplus and obsolete inventories. The Committee would like that the Government should go into

2381 LS—14.

the reasons for a steep rise in the inventory and non-moving items at the end of 1974-75. The Committee are informed that efforts are being made to dispose of non-moving and obsolete stock of spares and to rationalise the procurement policies in order to avoid build up of excess inventories. The Committee would like that the undertaking should conduct a review of non-moving and obsolete stores periodically at least once in a year and report the position to the Board of Directors who should carefully go into the causes and take effective remedial measures. The Committee are also informed that a Task Force consisting of officers from various departments has been constituted to work under the over-all guidance of the consultants the National Institute for Training and Industrial Engineering and certain actions have been taken to streamline the materials management. The Task Force has so far worked on identification of non-moving stock, material codification and physical lay out of stores. The Committee recommend that the Task Force should complete its work soon so that inventory control is put on sound footing without delay and the management should report progress made in this regard to the Board.

7.15. The Committee stress the need for timely remedial measures so that inventories are put on most rational and economic basis in the interest of production.

VIII

FINANCIAL MATTERS

A. Capital Structure

The Company was incorporated on 30th March, 1954 with an authorised capital of Rs. 400 lakhs against which the paid up capital amounted to Rs. 99 lakhs as on 31st March, 1955 subscribed wholly by the Government. It obtained an unsecured loan of Rs. 70 lakhs from Government for the first time in 1955-56 at 4-1/2 per cent per annum which was fully repaid by 31st March, 1960. The company in 1974-75 has obtained a non-plan unsecured loan of Rs. 2 crores repayable from 1975-76 in three annual equal instalments carrying an interest of 9-1/2 per annum. By this time the equity capital had gradually been increased from Rs. 99 lakhs to Rs. 247.26 lakhs. As on 31st March, 1975 the authorised share capital and the paid up capital of the company were Rs. 1000 lakhs and Rs. 312.26 lakhs respectively.

8.2. On an enquiry of the Committee as to the reasons for which the normal pattern of financing in the form of equity capital and loans being 1.1 had not been followed, HAL stated in a note as follows:—

“Most of the investment by the Government in Hindustan Antibiotics had been made by 1959, i.e. before the debt equity ratio of 1.1 was prescribed by Government in 1961. Out of the total paid up capital of Rs. 3.12 crores as on 31st March, 1975, Rs. 2.47 crores had been invested by 1959. Since 1959 and up to the year 1974-75, the company had been financing capital expenditure out of its internal resources and no further investment was made by the Government, until 1974-75. During 1974-75, an amount of Rs. 65 lakhs was received from the Government to enable the company finance capital expenditure on Fifth Plan schemes.

The amount of Rs. 2 crores was also received during 1974-75 as short-term loan for working capital requirements. Release of the amount of Rs. 65 lakhs during 1974-75 for capital expenditure in the shape of equity even though the earlier investment of Rs. 2.47 crores had been wholly in the shape of equity, was in consideration of the difficult financial position of the company.

The debt equity ratio on 31st March, 1975 was 2:3.12 taking into account the short-term loan of Rs. 2 crores.”

B. Working Results

8.3 The working results of the Company for the last eight years ending 31st March, 1974 are tabulated below :—

	1966-67	1967-68	1968-69	1969-70	1970-71	1971-72	1972-73	1973-74	1974-75
(a) Sales	716.60	646.62	632.55	723.50	619.93	728.01	789.29	785.30	663.36
(b) Cost of sales	536.21	532.99	522.02	607.48	591.98	699.24	765.67	929.82	992.24
(c) Profit before tax	180.39	113.63	110.53	116.02	27.95	28.77	23.62	(-)144.52	(-)328.88
(d) Provision for taxation	106.77	64.00	68.04	54.83	5.50	14.45
(e) Profit after tax .	73.62	49.63	42.49	61.19	22.45	14.32	23.62	(-)144.52	(-)328.88
(f) Capital Employed	758.90	764.79	790.48	792.00	827.75	754.75	920.48	861.65	817.04
<i>Percentage of :</i>									
(i) Cost of sales to sales	74.83	82.43	82.53	83.96	95.49	96.05	97	118.4	149.6
(ii) Profit loss before tax to sales	25.17	17.57	17.47	16.04	4.51	3.95	3	18.4	(-)49.6
(iii) Profit before tax to capital employed.	23.77	14.86	13.98	14.65	3.38	3.81	2.6	(-)16.8	(-)4.03
(iv) Sales to capital employed	94.43	84.56	80.02	91.35	74.89	96.46	85.7	91.1	81.02

NOTE.— It is not possible to work out the cost of sales separately for bulk products and formulations on account of (i) non-availability of separate figures for work-in-progress, material under reprocessing and finished goods (ii) non-allocation of common sales and distribution expenses and certain other items which are not absorbed in the cost of production.

8.4. During the year 1974-75 the Company incurred a loss of Rs. 328.88 lakhs.

8.5. The fall in profits before tax from Rs. 116.02 lakhs in 1969-70 to Rs. 27.95 lakhs in 1970-71 has been explained by the Management as due to increase in (a) wages and allied expenses (Rs. 9.49 lakhs), (b) Power consumption both quantity and price (Rs. 3.64 lakhs), (c) fuel (quantity increase Rs. 0.50 lakh and price increase Rs. 5.15 lakhs), (d) bonus (Rs. 4.00 lakhs), (e) maintenance (Rs. 5.00 lakhs), (f) discounts (Rs. 1.44 lakhs) and (g) shortfall of sales (Rs. 15.00 lakhs) besides shortfall in the production of Streptomycin. In respect of 1971-72, although there has been an increase in net sales by Rs. 108.08 lakhs, the net profit (after tax) has decreased by Rs. 8.13 lakhs, the main reason being the excess consumption of raw materials to the extent of Rs. 11.25 lakhs as compared with 1970-71 and increase in operating expenses by approximately Rs. 29.74 lakhs.

8.6. The fall in profits during 1972-73 and loss during 1973-74 has been explained by the Management as follows:—

	(Rs. in lakhs)		
	1972-73	1973-74	1974-75
(i) Increase in salaries & wages, bonus and other employment cost.	37.63	48.98	47.75
(ii) Increase in cost of raw materials	..	38.90	67.41
(iii) Increase in Power & fuel charges	11.53	30.85	74.79
(iv) Increase in interest charges on overdraft facilities	4.49	9.55	19.78
(v) Increase in consumption of shares	4.07	9.10	NIL
(vi) Decline in sales	..	3.99	121.94

8.7. On an enquiry of the Committee as to what steps have been taken or are proposed to be taken to check the gradual decline in the profitability of the Company, H.A.L. stated in a note as follows:—

“While seeking an increase in the selling prices of its products, the company is simultaneously taking several steps to improve its profitability as follows:—

- (i) Higher productivity through improved strain and technology:

(a) *Streptomycin*: As a result of introduction of new high-yielding strain for Streptomycin, it has been possible to ensure uninterrupted production of streptomycin and to enhance the average yield per batch to nearly 17,000 to 18,000 u/ml. as compared to about 6,000 m/ul with the earlier strain. In fact, the company has the best technology for streptomycin in the country today, as a result of this, cost of production of Streptomycin has come down significantly and it has been possible to obtain 16 per cent higher production of streptomycin during April—June, 1975 as compared to the same during April—June, 1974 in spite of high incidence of power cut extending to 40 per cent during May and June, 1975. Consequent upon the relaxation of power cut since July 1975, the company expects utilisation of full capacity of Streptomycin plant.

(b) *Penicillin*: Similarly, the company is finalising proposal to acquire an improved strain and technology of Penicillin from M/s. Toya Juzo Co. Ltd., Japan and this is expected to be introduced shortly. M/s. Toya Jozo Co. has guaranteed a minimum increase of 50 per cent in the output of Penicillin G and V in 23 fermentors with 50 HP agitation and accordingly, the prospects of obtaining substantially higher output of Penicillin during the current financial year appear bright.

As Streptomycin and Penicillin in the form of bulk and formulations constitute over 95 per cent of the production and sales of the company, these measures to improve the productivity and bring down cost will improve the working results considerably.

(ii) *Increase in the quantities of formulations*: As formulations are more profitable than bulk manufacture, the company has commissioned recently a new formulations unit to increase the output of formulation of drugs manufactured by the company as well as of drugs imported.

(iii) *Activating the new Projects which had long gestation period*;

(a) *Vitamin C*: Through strenuous efforts, the company has established some stream of production of Vitamin C, and it is expected to produce about 10 tonnes of Vitamin C bulk and about 950 lakhs of Vitamin C 100 mg. tablets during 1975-76.

(b) *Ampicillin*: The Company has started commercial production of Ampicillin from 6 APA for the first time in the country and expects to produce nearly 3 tonnes of Ampicillin during 1975-76. A plant for manufacture of 6 APA from Penicillin first crystals based on a process developed by company's Research and Development Organisation is under commissioning and is expected to be ready by June, 1976. With this, the company expects to meet the country's requirement of Ampicillin during the coming years to the extent of 5 tonnes.

(iv) *Expansion and diversification*:

The Company has submitted plans for expansion and diversification during the Fifth Plan period entailing an expenditure of Rs. 30 crores and two of the nine projects are at an advanced stage of approval by the Government.

(v) *Systems Approach*:

The Company has adopted systems approach for systematic plant maintenance, proper materials management including inventory control system, man-power assessment and disposition with the consultancy support of professional agencies. The system of planned preventive maintenance has already manifested by way of reduced break-downs of production and services units. Necessary measures for improved inventory control and man-power planning systems are under implementation.

(vi) *Toning up discipline*:

The Company has taken several measures to improve security and tone up discipline. A separate cell has been constituted to expedite disciplinary proceedings

to facilitate prompt action in the case of erring personnel. Central Civil Service Rules have been made applicable to the officers of the company in 1974. Powers have also been sub-delegated to the various officers. These measures are showing results.

(vii) *Financial Position:*

In view of phenomenal increase in the cost of inputs during the past few years and only a small increase of about 15/20 per cent sanctioned during 1974 in the selling prices of both Streptomycin and Penicillin bulk prices over prices prevalent during 1967 and 1959 respectively, the Company's ways and means position has been seriously affected. In view of this, the company has approached the Government to fix fair selling prices of the Company's products early which is awaited. The Company will also require cash assistance from the Government to the tune of Rs. 260 lakhs during 1975-76 to finance the operations.

(viii) *Assistance required from the Government:*

In view of commencing commercial production of Vitamin C and Ampicillin, and as the Company utilised its working capital funds for its diversification and expansion projects, the company has approached the Government to permit Hindustan Antibiotics Limited to canalise Vitamin C and Ampicillin for the entire country. Necessary approval of the Government in this respect will improve the working results of the Company.

As a result of all these measures and with the anticipated early fixation of fair selling prices of Penicillin and Streptomycin by the Government, the Company expects to turn the corner during 1975-76 and become profitable thereafter."

8.8. On an enquiry whether the Government had analysed why HAL was going in loss since 1973-74, the Ministry stated in a note as follows:

"The losses suffered by the Company in recent years have been due to an enormous increase in the cost of inputs

while the selling prices are controlled at 1959 and 1967 prices. An idea of the same may be had from the following examples which are, typical but not exhaustive:

Particular	Unit	1970-71 Rate	Current Rate	% increase
Power	Ps./Kwh	8.24	14.67	78
Furnace oil	Rs./kg.	242.23	754.98	188
Groundnut oil	Rs./kg.	5.45	9.09	67
Sugar	Rs./kg.	1.53	2.07	35
Procaine Hydrochloride	Do.	46.94	87.73	87
Dextrose	Do.	2.80	5.47	95
Methanol	Do.	1.42	4.04	184
Acetone	Do.	1.28	4.17	225
Butanol	Do.	3.87	6.64	72
Vials 7.5 cc	Rs./1000 Nos.	43.40	100.55	131
Per capital wages	Rs.	168.58	281.42	67

8.9. The prices of penicillin or streptomycin were not increased in keeping with the increase of the prices of inputs on all accounts, and increase in prices of the drugs were allowed only to the extent of increase in raw materials. The detailed cost examination both penicillin and streptomycin has been completed by BICP. While the report on streptomycin has since been received, the report on Penicillin is awaited. It is expected that when adequate increase in the prices of both these drugs are given, there will be corresponding increase in the profitability of the Company."

8.10. In regard to the steps taken to improve the profitability of the Company, the Ministry stated as follows:—

"The Company have introduced new strains obtained from Glaxo for the manufacture of streptomycin which will not only increase to production of streptomycin but also reduce its cost of production.

In regard to the penicillin the company proposes to adopt improved strains and know-how from Toyo Jozo. The activity of the penicillin from Toyo Jozo is expected to

have an yield of 30,000 u/ml. The collaboration terms have since been approved by the Government except for the tax-payment portion.

The Company also have various measures in hand to improve the production of Vitamin 'C', Hamycin and other drugs, even though it may not be substantial, to some extent the profitability might improve."

8.11. The Company has been paying dividend on equity capital from 1961-62 onwards. During 1961-62 and 1962-63, the dividend was paid at the rate of 6-1/4 per cent, while in the succeeding years @ 10 per cent free of tax upto 1969-70 and 5 per cent during 1970-71 and 1971-72 (in addition to a special dividend of 5 per cent and 4 per cent during 1966-67 and 1967-68 respectively). From inception to 31st March, 1972, the Company earned a profit of Rs. 1627.37 lakhs before tax. Thereafter the Company incurred a loss of Rs. 148.21 lakhs during 1973-74 and Rs. 331 lakhs during 1974-75. No dividend has been declared from the year 1972-73. The total amount paid as dividend upto the end of 1971-72 works out to 101.5 per cent of the paid up capital of Rs.2,47,26,000.

8.12. No records are available to indicate the total sales and the cost of sales of each product. The Ministry have stated (September, 1973) that it is proposed to open separate heads of accounts to collect direct selling expenses and to apportion them to products in the ratio of product-wise sales. It is also proposed to allocate the selling and office and other expenses on a similar basis. This system shall be implemented in the accounts for 1973-74 in acceptance of the Audit suggestion.

8.13. *Average earnings and average sales per employee:* The table below shows the average earnings (including salaries and wages, bonus, contribution to Contributory Provident Fund, gratuity and also share of Staff welfare expenditure, and the average sales per employee for the last seven years:

	1967-68	1968-69	1969-70	1970-71	1971-72	1972-73	1973-74
1. Employees on roll (Nos.)	2,026	2,100	2,124	2,257	2,341	2,517	2,568
2. Average earnings per employee per annum (Rs.)	6,135	6,145	6,560	7,095	7,539	8,546	10,167
3. Average sales per employee (Rs.)	31,916	30,121	34,063	27,467	31,098	31,358	30,580

8.14. The Committee regret to note that though the number of employees had gradually increased from 2,026 in 1967-68 to 2,568 in 1973-74 and the average earnings per employee have also correspondingly increased from Rs. 6,135 to Rs. 10,167 the average sales per employee has come down from Rs. 31,916 to Rs. 30,580. The Committee cannot but conclude from this that the productivity of employees has been going down from year to year and the undertaking does not appear to have taken any tangible action to arrest the decline. The Committee have also given their recommendations in the earlier chapters of this report about the shortfall in production of bulk and formulations due to absenteeism, loss of shifts etc. which have affected the productivity. The Committee recommend that the Corporation should make a critical study of the reasons for the decline in productivity and take concerted measures to bring it up to the optimum level.

8.15. The Committee note that the profit before tax of the undertaking has been decreasing from Rs. 180 lakhs in 1966-67 to Rs. 110 lakhs in 1968-69 and though it increased to Rs. 116 lakhs in 1969-70, it showed a sharp decline to Rs. 27.95 lakhs in 1970-71 which reduced further to Rs. 23.26 lakhs in 1972-73 and turned into a loss of Rs. 144 lakhs in 1973-74. The loss further increased to Rs. 328 lakhs in 1974-75. Apart from the general reasons like increase in wages and allied expenses, power consumption, fuel, maintenance, etc., items like shortfall in sales besides shortfall in production of streptomycin, excess consumption of raw materials and increase in operating expenses, contributed to the major share of decline in profits or increase in loss. The Committee are led to conclude that the undertaking had been complacent about the general overall profitability in spite of the reduction in profits year after year from 1966-67 and had not taken any effective action to improve the position. The Committee have already pointed out that there had been a lag in the technical development of the strain for Penicillin and streptomycin and their consequent effect on production and production costs. Though the company could develop a strain for Penicillin only in 1971, consistency in yield could not be maintained and even the yield from the new strain did not compare favourably with the yields from foreign countries like Japan. In regard to streptomycin, the undertaking did not keep itself posted with the improvements with the collaborators for 4 years and it was only in 1974-75 that it obtained an improved strain. Although sale of formulations was more profitable than sale in bulk, major share of the different products was sold by the undertaking in bulk form to private formulators in spite of the fact that the undertaking was not fully utilising

its vialling, capsulation and tableting capacities and it was even cancelling orders received for formulations without making any determined effort to fully utilise at least the existing formulation capacity nor was any effort made by company to build up suitable marketing organisation and sale of antibiotics to the public in general was left in the hands of private viallers who had been taking advantage of their purchase in bulk from the undertaking and in the case of companies with foreign equity participation repatriating their profits. No study has also been made to determine the optimum product-mix and no records are available to indicate the total sales or cost of sale of each product. The productivity has also been found to be decreasing. In spite of increase in wages and salaries the average sales per employee have come down. The Committee are constrained to observe the lack of foresight and the serious managerial lapses in properly organising the undertaking to maintain and improve the productivity and profitability. The Committee need hardly stress that it is the primary responsibility of the Management to keep a meaningful watch on the working of the undertaking and take appropriate remedial measures in time to set right any deficiencies. The Committee recommend that the entire matter should be thoroughly investigated with a view to fixing responsibility for these grave and avoidable lapses which have turned a profit-making undertaking into a losing enterprise and a report furnished to the Committee within six months.

8.16. The Committee are informed that besides seeking an increase in the selling price of its products, the undertaking has taken certain measures to check the decline in profitability as a result of introduction of new high yield strain for streptomycin which has been able to increase its production by 16 per cent during the first quarter of 1975-76 and reduce the cost of production and improve utilisation of capacity. In the case of Penicillin it is stated to be finalising proposals for acquiring improved strain and technology. It has been stated that a new formulation unit has been constructed to increase the output of drugs. A systems approach is being adopted for systematic plant maintenance, proper material management, manpower assessment, etc. As a result of these measures the company expects to turn the corner in 1975-76 and become profitable. The Committee hope that with the steps now taken and with the implementation of the recommendations of the Committee in this report it should be possible for the undertaking to improve the productivity and thereby profitability.

C. Costing system

8.17. The Company is following the process costing system. The yearly budgeted quantities of production and costs are treated as wordsticks for control of costs and comparison with actual costs. Prior to 1966-67 only the consumption of raw materials was booked against work orders opened for each section and other common expenses were allocated to different processes on an *ad hoc* basis. From 1966-67, the Company started booking of expenditure cost-centre-wise to facilitate computation of process-wise costs of production. The cost centres are grouped into five categories (i) Administrative and Welfare, (ii) Utilities, (iii) Services, (iv) Production and (v) Selling and Distribution. The expenses under the first three categories are finally allocated to various processes under item (iv).

8.18. The main cost centres for Penicillin products and subdivided products are (1) fermentation, (2) extraction, (3) sterile area. Direct costs (*viz.* raw material, direct wages, direct expenses) and indirect expenses in respect of each cost centre are booked separately.

8.19. Standard costing has not been introduced so far. The Company is of the view that introduction of full fledged standard costing would be cumbersome considering the nature of production which involves multiple processes with multiple products. The comparison of actual cost is, however, made with budgeted costs which are stated to be based on standard quantities and quality of raw materials, standard efficiencies and other norms formally or informally adopted by the Company with particular reference to the conditions anticipated in each budget year.

8.20. The cost of raw materials in respect of each process is directly booked under the respective process. Direct wages are booked on the basis of labour engaged at each process centre, and other expenses like indirect materials, repairs and maintenance, etc. are taken as direct expenses. Administration and welfare costs are allocated in the proportion of the number of employees engaged at each cost centre.

8.21. The operating cost of utilities (workshop, transport, sewage disposal plant etc.) is allocated on the basis of technical De-age estimates given by the Production and Engineering Departments based on the utilisation of services at the receiving cost centres. Stores overhead expenditure is allocated directly to the production in proportion to the cost of raw material consumed.

8.22. The cost of services (steam, water, power, refrigeration and compressed air) are allocated on the basis of technical estimates indicated each year by the Engineering Department with reference to the planned activities of the cost centres as no measuring instruments and metres have so far been installed to record accurately the consumption of services.

8.23. The Company stated in February, 1972 as follows:—

“The cost of allocating services to the various processes/products by meter readings would not be commensurate with the results to be obtained, as substantial capital and recurring expenditure would be involved in installing and maintaining the measuring instruments/meters and on maintenance of consumption readings. Hence allocation on technical estimates are considered to be reasonable. These estimates are reviewed each year and revised only if necessary.

Meters for controlling production and consumption at important points are in process of installation. Yet allocations to processes/products will still have to be maintained on technical estimates.”

8.24. Meters have been fixed at some major consumption points. Consumption for Streptomycin plant and Pencillin plant are now available separately. Further action to fix additional meters is in progress.

8.25. The cost of production was being compiled quarterly upto April, 1970. Thereafter, monthly cost sheets are prepared. While the quarterly cost data was available by the end of the quarter following the quarter to which it pertained, the monthly costs (after April, 1970) became available in the following month. The cost accounts are not reconciled with the financial accounts.

8.26. Asked as to what measures have been taken or are proposed to be taken to control cost of production of different products, H.A.L. stated in a note as follows:—

“With the new technology the productivity of fermentation operation has increased from 7000 units per ml to 16,000 units per ml. resulting in reduction of about 15 per cent in the cost of product. The company has plans to acquire improved strain and technology for the manufacture of

Pen. bulk. The proposal is in an advanced stage. It is estimated that with the new strain and technology, the activity in fermentor would increase by 50 per cent, and there would be a reduction in the cost of final product by about 8 per cent. The company is also considering the possibility of obtaining an improved technology for the manufacture of Vit. C bulk. It has already got technology for the manufacture of Ampicillin bulk from a collaborator. The company's R & D unit is also engaged in constantly improving the existing technologies.

In addition to acquiring improved technology the company has also taken steps to scale up capacities of production by providing additional extraction equipment both in the case of Penicillin and Streptomycin in respect of which the fermentation capacity has or would increase following introduction of improved technology. Some of these are included in the 5th Plan Projects. With scale up of capacity, the cost of production would further come down. Measures have also been taken to control the loss due to spillage and overage and there has been an appreciable reduction in this during the last three years."

8.27. The Committee note that the Company has been following the process costing system only and no standard costing has been introduced. It has been stated that introduction of a full fledged standard costing would be cumbersome considering the nature of production involved but costs are compared with budgetted costs based on standard quantities, quality, efficiencies, norms formally and informally adopted with reference to conditions in each year. Since the Committee have already, in the relevant sections in the chapter on Performance Analysis, given their recommendations in regard to the standard norms, efficiency fixed informally on an ad hoc basis so far, etc. the Committee would like that these standards/norms efficiencies should be reviewed and revised with reference to adoption of new strain and standard costs of each process worked out and adopted for purposes of an effective comparison of actual costs with reference to such standards and for analysing variances with a view to taking timely remedial action.

8.28. The Committee find that the cost of services are allocated on the basis of technical estimates each year with reference to

planned activities of cost centres and no measuring instruments and meters have been installed to record accurately the consumption of services. The Committee are surprised to find that while on one side it is stated that the cost of allocating services to various processes/products by meter readings would not be commensurate with the results to be obtained, on the other hand it is stated that meters for controlling production and consumption at important points are in the process of installation and yet allocations to processes/products will still have to be on technical estimates. The Committee do not understand the apparent contradiction in this regard nor the rationale/reason as to why, even after installation of meters, allocation should be on technical estimates only and not on meter readings which will be more accurate.

8.29. The Committee note that while cost of production was being compiled quarterly till April, 1970 and thereafter monthly cost sheets are prepared and monthly cost data are available in the following month, the cost accounts are not being reconciled with financial accounts. The Committee are not sure as to how in the absence of reconciliation of cost figures with financial figures, the accuracy of cost figures is proved.

8.30. The Committee recommend that the cost sheets duly reconciled with financial accounts and the analysis of the variances should be reviewed and a report of the review and the action taken thereon should receive the special attention of the management and the Board of Directors in the interest of taking timely remedial measures towards reduction of cost. The Committee recommend that the system of cost accountancy should be put on a scientific basis and cost reports should form part of the quarterly financial reviews to be submitted to the Board of Directors for their consideration along with the financial accounts.

8.31. The Committee have observed that the cost of production of various bulk drugs and formulations has more than doubled since 1966-67 and in most cases the cost of production has been higher than the selling price fixed by Government. The increase in cost of production is stated to be due to increase in the price of furnace oil, power tariff and raw materials and increase in wages due to revision of D.A.

8.32. The Committee are informed that HAL has taken a number of measures to control cost of production. It has been stated that with the introduction of new technology the productivity of

Fermentation operation has improved from 7000 to 16000 units resulting in 15 per cent reduction in cost. It has also proposals for obtaining improved strain and technology for Penicillin which would increase fermentation-activity by 50 per cent and reduce cost by 8 per cent. There are also possibilities of obtaining improved technology for Vitamin C. The Committee have given their recommendations in the sections relating to different processes regarding underutilisation of capacities, non-observation of norms or efficiency in operations, consumption of materials, excessive rejections, pricing etc. The Committee would like that the undertaking to critically go into each one of these operations and the factors which are contributing to the costs and take suitable action to improve efficiency and reduce consumption of materials bring down the percentage of rejections and wastages and achieve reduction in cost at the different stages and ultimately of the finished products.

8.33. The Committee would also like that R&D should also be closely associated so that they may suggest ways and means of improving the techniques and reducing costs without sacrificing quality of the products.

D. Credit Control

8.34. The Company has not laid down any credit policy except in respect of supplies to distributors which constitute about 5 per cent of the total sales. Credit, however, is being extended as per trade practice to different customers as under:—

- | | |
|--|--|
| 1. Bulk sales | Payment for supply of Penicillin within 30 days from the date of supply and against delivery in the case of Streptomycin. |
| 2. Government and Semi-Government parties. | Within 30 days from the date of supply. |
| 3. Agents | 30 days, extended to 45 days from October, 1967, from the date of supply and also supported by bank guarantee as fixed by the Company. |
| 4. Private parties | Supply made against advance payments. |

8.35. Credit facility on bulk sales was withdrawn from March, 1971 and the practice of appointing distributors was discontinued from October, 1970 except in the States of Maharashtra and Bihar.

8.36. On an enquiry of the Committee that in view of the fact that debts in terms of number of days had increased, whether a

2381 LS—15.

review of policy was not called for, HAL informed the Committee as follows:—

Bulk Sales

“Except in a few cases, no credit is being allowed on bulk sales which are made against cash received or on the bill discounting scheme under which immediate credit is afforded by our bankers by debit to the purchaser's bank. Recently, during the year 1975-76, sale of bulk has been made in some cases against 45 days sight draft. In the face of reluctance on the part of viallers to lift bulk, it has been found necessary to offer this inducement to give a fillip to bulk sale.

Sale to Agents

The volume of sale through agents is small and needs to be developed. Imposition of credit curbs would adversely affect the growth of the business and is not, therefore, proposed. The credit offered is covered by a Bank guarantee required to be furnished by the agents.

Sale to Government/Semi Government parties

Only 30 days' credit is allowed which takes into account the transit time. It however, takes 2-3 months on the average to receive payment from Government/Semi-Government Institutions. As there is now keen competition from private viallers in the Government market, it is not possible to insist on more favourable terms of payment.”

E. BOOK DEBITS

8-37 Book debts outstanding at the end of each year against each category of customers from 1966-67 to 1973-74 were as follows :—

(Rupees in lakhs)

Year	Govt- ment/ Semi- Govt. parties	Private Vallars	Agents	Others	Total	Net sales	Debits in terms of number of days' sales
1966-67	91.51 (16.81)	20.44 (0.04)	2.76	..	114.71 (16.85)	716.60	58
1967-68	118.87 (18.14)	25.91 (0.03)	3.62 (1.48)	0.16 (0.15)	148.58 (19.80)	646.62	84
1968-69	98.53 (17.56)	51.79 (0.94)	0.91 (0.26)	0.25 (0.18)	151.48 (18.94)	632.55	87
1969-70	91.19 (12.74)	56.78 (15.01)	0.87 (0.10)	0.20 (0.09)	149.03 (27.94)	723.50	75
1970-71	117.76 (14.65)	23.25 (1.20)	1.21 (0.08)	0.35 (0.24)	142.57 (16.17)	619.93	84
1971-72	125.48 (22.47)	49.00 (1.17)	0.37 (0.10)	0.92 (0.21)	175.77 (23.95)	728.01	88
1972-73	156.04 (20.23)	43.00 (1.06)	0.34	1.62 (0.44)	201.01 (21.73)	789.29	93
1973-74	151.75 (27.66)	42.86	0.30	1.29 (0.69)	196.21 (28.38)	785.30	91

Notes : 1. Figures in brackets represent outstandings for more than six months,

2. Figures of book debts are in respect of sale of antibiotics only.

8.38. The Committee note that the book debts outstanding in terms of number of days' sales had been increasing from 84 days in 1970-71 to 88 days in 1971-72, 93 in 1973-74 and 91 in 1974-75. The bulk of the outstandings represent dues from Government/Semi-Government parties to whom a credit facility of only 30 days from the date of supply had been given. In spite of this the Committee find that amounts have been outstanding for more than 6 months and at the end of 1974-75 more than Rs. 27 lakhs was outstanding for over 6 months out of total dues of Rs. 151.75 lakhs. The Committee also do not see any justification for huge outstanding from private viallers to the extent of Rs. 43 lakhs, when the credit system permits only supplies to them against advance payments. The Committee find that instead of realising the dues of about Rs. 2 crores from the Government departments and private viallers in time the undertaking has obtained Rs. 2 crores as short-term loan for working capital requirement on which it has to pay interest charges. The Committee stress that the Government/HAL should undertake a review of the credit arrangements obtaining so far with a view to ensuring that such arrangements are in the best interests of the undertaking. The Committee would also like that the billing and recovery system should be streamlined so as to ensure realisation of outstandings within the credit periods allowed to the parties. The Committee also recommend that in respect of outstandings in the Government departments, the matter should be taken up with the appropriate Governments/Ministries and amounts realised without further delay.

F. Saving in Foreign Exchange

8.39. The value of production of major products viz. Penicillin and Streptomycin, of the Company during the years 1968-69 to 1973-74 on import parity basis (average C.I.F. value of imported bulk) amounted to Rs. 1,414.27 lakhs. After deducting the expenditure incurred in foreign exchange, the net saving in foreign exchange effected by the Company works out to Rs. 1,015.71 lakhs (approx) as detailed below:

(Rupees in lakhs)

Expenditure in foreign exchange	Earnings		
	1	2	3
(i) Cost of imported raw materials .	151.65	Average CIF value of the products 1,414.27	
(ii) Cost of imported spare parts and components consumed .	96.93		

1	2	3
(iii) Depreciation on value of imported plant and machinery	129.00	
(iv) Expenditure on payment of royalty	20.98	
Balance representing saving in foreign exchange	1,015.71	
Total	1,414.27	1,414.27

NOTE: Average C.I.F. value for 1972-73 and 1973-74 based on imports of 1971-72.

8.40. The Committee are glad to note that the Company has been able to effect a net saving in foreign exchange to the extent of over Rs. 10 crores from 1968-69 to 1973-74 by producing drugs which were previously being imported. The Committee expect that the HAL should strive to contribute to more import substitution, develop new technologies towards indigenisation and upscale technology already absorbed with a view to save more in foreign exchange.

G. Organisational structure

8.41. The overall control of the affairs of the Company rests with the Board of Directors which as on 31-3-1975 comprised a part time Chairman, a Managing Director and seven part-time Directors.

8.42. The day-to-day business of the Company is conducted by the Managing Director who has been delegated administrative and financial powers by the Board of Directors. The Managing Director is assisted by the Works Manager, the Financial Adviser and Chief Accounts Officer, the Superintendents, Research and Quality Control, the Material Manager and other heads of departments who are responsible to him.

8.43. All matters having financial implications, excepting those falling within certain specified monetary limits, and requiring sanction of the Managing Director are routed through the Financial Adviser and Chief Accounts Officer. The scope of the financial scrutiny to be exercised by the Financial Adviser in these matters has been specified in the delegation of powers made by the Board of Directors to the Managing Director.

H. Accounting system and Internal Audit

8.44. The Company started production in 1961-62 but has not prepared so far (December, 1972), the accounting manual laying down the detailed procedure for compilation of accounts. The Management stated in August, 1972 that preparation of the Accounts Manual was being taken up and that it was not taken up earlier as they were waiting for the stabilisation of application of data processing in certain new areas of accounting.

8.45. Accounts Manual has been prepared by the Company and got approved by the Board at their meeting held on 19-6-1974. The same is being implemented for the working of Accounts Department since the year 1974-75.

8.46. The Internal Audit Section is headed by an Internal Auditor who works under the control of the Financial Adviser and Chief Accounts Officer. Internal audit (including stock verification, where necessary) of different departments is taken up according to an annual programme drawn up in advance with the approval of the Financial Adviser and Chief Accounts Officer. Internal Audit Reports are put up to Financial Adviser and Chief Accounts Officer who, at his discretion, puts up matters of importance to the Managing Director.

8.47. There is no regular system of reporting the important points raised by the Internal Audit Section to the Board of Directors. The Ministry stated in September, 1973 that "As suggested by the Audit, important points raised by the Internal Audit Section along with action taken will be reported to the Board of Directors." The system of reporting to the Board, through Managing Director, has since been introduced in 1974-75.

8.48. No manual outlining the procedure and functions of internal audit has been prepared by the Company so far. In this connection HAL informed the Committee as follows:—

"In this Company, the Internal Audit, forms a part of Accounts Department and is under control of FA&CAO. Therefore, the Internal Audit's manual is prepared and compiled as part of Accountants Manual. The Manual has been implemented since 1974-75."

8.49. The Committee on Public Undertakings in their Fifteenth Report (Fourth Lok Sabha—April, 1968) on Financial Management in Public Undertakings recommended that the functions of the internal audit should include a critical review of the systems, procedures and operations as a whole. The Ministry of Finance (Bureau

of Public Enterprises) while accepting the above recommendation directed the Public Enterprises in September, 1968 to introduce such a system. No such appraisal has been made so far by the Internal Audit Section of the Company.

8.50. HAL informed the Committee in this connection as follows:—

“Partial appraisal at the Company’s working was made in the year 1974-75. However all instructions in the BPE’s circular could not be followed. In future attempts will be made to follow the BPE’s circular fully.”

8.51. The Committee regret to note that though the undertaking started production as far back as 1961-62, there was neither an accounting manual laying down the detailed procedure for compilation of accounts nor was there a system of reporting the points raised by internal audit and action taken thereon to the Board of Directors. It is stated that these have been introduced and implemented from 1974-75. The Committee need hardly stress that observations and comments made by Internal Audit should receive prompt attention of management at all levels and necessary follow-up action taken expeditiously. The system of cost accounting should be on scientific lines and appraisal thereof should be included in the programme of internal audit.

8.52. The Committee also regret to note that only partial appraisal of the Company’s working was made in the year 1974-75 in terms of the recommendations of the Committee on Public Undertakings contained in their Fifteenth Report (4th Lok Sabha) on Financial Management in Public Undertakings which required that the functions of internal audit should include a critical review of systems, procedures and operations as a whole. The Committee emphasise that such a critical appraisal is all the more necessary in a public undertaking which has started losing after making profits for years. The Committee recommend that HAL should implement this recommendation which has been accepted by Government in letter and spirit. The critical review should also receive the special attention of the management/Board/Government who should take appropriate follow up action.

NEW DELHI;
March 11, 1976

Phalguna 21, 1897 (S)

NAWAL KISHORE SHARMA
Chairman,
Committee on Public Undertakings.

APPENDIX I

(vide paragraph 2.163)

INTERIM REPORT OF THE TASK FORCE ON VITAMIN C— HINDUSTAN ANTIBIOTICS LIMITED

The Task Force set up by the Government of India, Ministry of Petroleum and Chemicals, vide Office Memorandum No. A&I—4(5)/75 dated 26th April, 1975, to examine the production capacity of Vitamin C Plant at Hindustan Antibiotics Limited (HAL) met at Pimpri on 2nd and 3rd July, 1975. The following were present:—

- (1) Brig. B. J. Shahaney, Secretary Technical Development *Chairman*
- (2) Dr. B. B. Gaitonde, Director Haffkine Institute, Bombay *Member*
- (3) Sh. K. V. S. Murthy, Director Planning Commission *Member*
- (4) Dr. C. V. S. Ramnam, Managing Director, National Research Development Corporation of India *Member*
- (5) Dr. P. R. Gupta, Adviser (Drugs) Ministry of Petroleum and Chemicals *Member Secretary*

Earlier to this, both the HAL and NCL had prepared and given comprehensive background papers relating to the project and the Chairman had visited the plant on 16th June, 1975, as a result of which techno-economic evaluation data was compiled.

The Task Force took the opportunity of discussing the subject at a great length with Sh. C. N. Chari, Managing Director, HAL along with the other experts associated with this project and also Dr. B. D. Tilak, Director, National Chemical Laboratory (NCL), Poona and other NCL Scientists involved in the development of the technology for the manufacture of Vitamin C. The members also went round the plant and had detailed discussions with the plant personnel.

The production figures of Sorbitol and Vitamin C as have been achieved at this plant are given below:—

Period	Vitamin C (kgs.)	Sorbitol (Tonnes)
1973-74	85.5	66.78
1974-75	618.0	125.11
April to June, 1975	257.25 (+225 kgs. under test)	..

The plant was designed to achieve the capacity at the rate of 125 tonnes per annum. Obviously, this expectation has not materialised so far and is not likely to be so in the future, in view of the various problems as summarised below:—

The process for the manufacture of Vitamin C was developed by NCL as far back as 1960. The NCL scientists had carried out successful trials of production of Vitamin C in their laboratory as well as in their Pilot Plant and satisfied the management of the Company. Based on this, a joint report of HAL and NCL was accepted by the Board of Directors of HAL in 1961. Due to management changes and other events, the question of a Pilot Plant study to be made once again at HAL was accepted and in 1965, further Pilot Plant trials were carried out at HAL jointly by HAL and NCL. On going through the joint report and the results achieved in the Pilot Plant, the Task Force noted that while at certain points of operations, the yields as claimed by the collaborators were attained at the plant level, some statements and assumptions were made in the Joint Report which perhaps at that point of time may have been justifiable considering the scale of production and facilities available, on the basis of which the desired efficiencies were expected to be achieved in the scaling up of the operations. It will be relevant to reproduce the concluding para of the joint report which is as under:—

“On the whole, it could be stated that the efficiencies indicated in the original report have, by and large, been achieved, and there is every justification to expect that in properly designed and installed production plant, this could be bettered”.

The Task Force also noted that after 1965, while HAL was going ahead with the designing and erection of the plant, the NCL, was not actively associated. It was, however, noted that with the limited expertise available with HAL at that time, the designing and scaling up of operations were done by HAL, but these were got checked and approved by the NCL experts.

It was decided in 1963, that the Government of India would appoint a Committee to examine the techno-economic evaluation of the entire project based on the data obtained in the Pilot Plant at HAL. However, this was not done perhaps in the light of the expectation reposed in the Joint Pilot Plant Report. The Task Force noted that since the development of the technology by the NCL in 1960, a lot of advances in the Vitamin C production technology have

occurred. Since NCL scientists were not pursuing this problem, the benefit of any improvement could not accrue to HAL. It may also be noted that a steep escalation in the prices of raw materials and wages has taken place during this interim period. Since the raw materials constitute a major cost centre in the cost of production of Vitamin C, any such escalation is bound to result in a significant impact on the economic viability of the project. It was also noted by the Task Force that whereas the management did consider techno-economic analysis at various times, this, however, tended to be of limited nature as subsequent events have proved.

On the basis of data provided by HAL, the Task Force noted that the loss on Vitamin C operations, based on current efficiencies, will be around Rs. 75 lakhs per annum. Assuming that the efficiencies claimed by the collaborators are achieved by HAL, the project would still continue to incur a loss of Rs. 34 lakhs per annum on the basis of the current approved price for the bulk drug and the data provided by HAL (Annexure I). The management also stated that they could obtain Vitamin C conforming to I.P. only after making some modifications in the technology in the final stage. The management also informed the Task Force that the yields at two stages, viz., Sorbose Recovery and final crystallisation of Vitamin C are considerably lower than those claimed in the Project Report and this has resulted in significantly lower overall efficiencies. The Company has also encountered several difficulties in maintaining uninterrupted production, apart from other aspects, due to constraints such as malfunctioning of the refrigeration units and non-availability of essential solvents such as Acetone. While approving this project, the Board had noted that the Company would attain a break-even point and even make a small return to the extent of 3 to 10 per cent on the production of bulk and formulations, taken together. In addition to this, one of the important factors in accepting this project was an invisible benefit that the country would gain by way of saving foreign exchange to the tune of Rs. 40 lakhs through indigenous production of Vitamin C.

As will be seen from the data indicated earlier, the plant has not been able to achieve the rated capacity nor it is expected to do so in the near future unless remedial measures both in respect of technology as well as equipment are taken. After going through the statement submitted by the management of HAL, the Task Force was informed that out of the 7 stages in the technology of the manufacture of Vitamin C, the claimed efficiencies have been achieved in the first two stages viz., hydrogenation and fermentation. But, in the case of sorbose recovery (the third stage), the efficiency ob-

tained is considerably lower than that claimed (average 52 per cent as against 80.7 per cent claimed). In the case of the subsequent stages, i.e. Oxidation and enolisation efficiencies are about 10 per cent to 12 per cent less than these claimed. In the case of final stage, i.e. oxystallisation of Vitamin C, the efficiency is considerably lower (average 33 per cent as against 90 per cent claimed). This brings the overall efficiency to an average figure of 6.35 per cent as against 38.25 per cent claimed in the project report. On the other hand, Director, NCL stated that the above lower yields of the plant have to be examined in the context of whether the recommended procedures for carrying out reaction sequences were followed.

In view of the above and since the plant has not been able to maintain continuous operations, particularly because of the constraints on refrigeration facilities, it has not been possible for the Task Force to quantify the present production capacity of Vitamin C. The Task Force also feels that the two problem areas, viz (i) recovery of sorbose from the fermented broth and (ii) crystallisation of Vitamin C after enolization, require immediate attention for improving the overall efficiencies. The Task Force, therefore, recommends that the management should immediately explore the possibility of maximum utilization of the plant already installed by constituting a joint working group comprising of the scientists of HAL and NCL and also of the National Research Development Corporation of India, who is a party to the agreement, which should go into the details of the technology and the design of the plant in order to assess the techno-economic viability of the entire project afresh. The Management should simultaneously explore the possibility of obtaining an improved technology which would make the present project economically viable with the minimum inputs. This work has to be undertaken with a time bound programme. With this in view, the Task Force recommends that a working group should be immediately constituted comprising of the following:—

Representatives of HAL

- (1) Dr. S. Ramachandran, Superintendent Research
- (2) Sh. K. V. Rao, Deputy Supdt. Chemical Engineering in-charge of Projects
- (3) Sh. D. V. Karve, Deputy Supdt. Production in charge of Vitamin C Plant

Representatives of NCL

- (1) Dr. L. K. Doraiswamy, Deputy Director
- (2) Dr. V. Jagannathan, Assistant Director
- (3) Sh. M. V. Kunte, Assistant Director

Representatives of NRDC

- (1) Sh. P. Soundararajan, Chemical Engineer

Dr. L. K. Doraiswamy will be the leader of this working group.

The terms of reference of this working group will be as under:—

- (i) to explore the possibility, with or without modifications of the working of the Vitamin C Plant at the rated capacity;
- (ii) to identify the changes necessary in the process, equipment, design etc., with cost estimates, equipment availability, indigenous or imported; and
- (iii) to present an economic viability analysis on a long term basis and make recommendations for its implementation involving improvements to the present technology, the time frame etc. which will ensure early commercialisation and stabilization of production to the rated capacity.

It was further decided that in its working, if any when necessary, the working group may consult any suitable Design Engineering Firm. The report of the group will be submitted to the Task Force within a period of 3 months. The Task Force also desires that the group should commence its functioning from 3rd July, 1975.

The travelling and daily allowances incurred by the members of this group or the fees payable to the Design Engineering firm will be borne by HAL.

In the event of any major differences of opinion on a matter, technical or otherwise, the working group will refer the same to a committee comprising the following:—

- (1) Dr. B. B. Gaitonde, Chairman, HAL.
- (2) Dr. B. D. Tilak, Director, NCL, Poona.
- (3) Sh. C. N. Chari, Managing Director, HAL.

As a concurrent approach, on a tentative basis the Task Force recommends that the management of HAL should also immediately explore the possibility of obtaining better technology either local or imported, which will ensure better returns on the investment already made with minimal additional inputs.

The Task Force feels that the final report on the recommendations, as per terms of reference of the Task Force, can only be made after examining the report of the Working Group constituted as above and the results of the efforts of HAL management to obtain better technology from elsewhere. It is, therefore, necessary to extend the tenure of this Task Force by another four months, i.e. upto the end of November, 1975. A letter to this effect should be addressed to the Government.

Sd/-

(B. J. Shahaney)

Sd/-

(B. B. Gaitonde)

Sd/-

(C. V. S. Ratnam)

Sd/-

(K. V. S. Murthy)

(P. R. Gupta)

PIMPRI

 4-7-75

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APPENDIX II

(Vide paragraph 3-47)

Statement showing standard consumption, standard spillages and the actual consumption of Penicillin and Streptomycin

I	2	1966-67		1967-68		1968-69		1969-70		1970-71		1971-72		1972-73		1973-74		1974-75	
		Penicillin (Lac Units)	Streptomycin (Kgs.)																
1. No. of vials filled (in lacs)		@513.01		@558.60		@449.24		@544.94		@522.72		@549.73		529.02		533.67		434.54	
2. Standard consumption		1,59,06,465	23,573.712	1,06,04,132	38,004.213	80,10,742	30,798.189	1,27,24,612	33,224.972	1,06,09,682	36,005.515	1,48,95,500	32,227.406	16,730,336	30,951.320	14,804,019	32,209.437	7,662,055	34,972.921
3. Standard overages (%)		7,95,322	1,178.686	5,30,216	1,900.210	4,00,536	1,539.909	6,36,230	1,661.249	5,33,504	1,800.276	7,44,774	1,613.670	836,965	1,547.566	740,200	1,610.471	383,103	1,748.646
4. Standard spillages (%)		7,95,322	1,178.686	5,30,216	1,900.210	4,00,536	1,539.909	6,36,230	1,661.249	5,33,504	1,800.276	7,44,774	1,613.670	836,965	1,547.566	740,200	1,610.471	383,103	1,748.646
5. Actual consumption		1,91,55,716	31,139,909	1,26,58,221	44,044,369	95,92,080	36,645,298	1,50,41,566	38,292,696	1,27,05,491	41,325.711	1,74,01,018	36,483.711	18,849,692	34,782.827	16,556,017	36,213.686	8,640,551	29,478.788
6. Actual overages and spillages		32,49,251	7,566.197	20,52,889	6,040.156	15,81,338	4,847.409	23,16,954	5,067.724	20,35,809	5,320.226	25,05,518	4,200.630	2,110,356	3,831.597	1,751,698	4,009.249	97,8,476	4,505,867
7. Actual spillages (as collected on the stop floor)		14,22,083	2,345.162	7,42,932	2,658.891	6,29,379	2,121.595	9,20,680	2,043.451	8,41,620	2,108.718	9,50,178	1,762.811	1,181,195	2,018.620	1,690,574	2,217.080	606,467	2,588.822
8. Actual overages		18,27,168	5,221.035	13,10,957	3,381.265	9,51,959	2,725.904	13,96,874	3,024.273	11,94,189	2,211.508	15,55,340	2,437.819	9,29,161	1,612.887	663,424	3,792.169	372,009	1,917.045
9. Excess of actual spillage over standard spillage (%)		62,6761	1,166.476	2,12,716	758.681	2,28,843	581.596	2,83,850	382.202	3,08,116	308.442	2,05,404	149.141	3,44,230	477,054	350,374	606,609	223,364	840,176
10. Excess of actual overages over standard overages (%)		10,31,846	4,022.349	7,80,741	1,481.055	5,51,423	1,185.995	7,60,644	1,363.024	6,60,685	1,411.232	8,10,566	824.149	93,196	265.321	78,776	1,181.693	13,994	1,68,399
11. Loss due to excess spillage (Rs.)		63,352	96,668	28,495	63,828	29,098	53,792	40,534	37,587	45,495	30,421	32,834	13,375	89,873	(+99,032)	(-1,624,569)	(+65,771)	(-89,723)	(-), 109,397
12. Loss due to excess consumption of overage (Rs.)		2,43,251	8,42,647	2,50,285	3,83,687	1,91,029	3,24,145	3,65,171	3,74,592	2,02,251	2,77,075	3,44,540	2,49,218	(+), 35,284	(+), 78,747	(-), 38,517	(-), 18,477	(-), 388,304	(-), 388,304
13. Total loss (Rs.)		3,06,603	9,39,315	2,78,690	4,47,515	2,20,127	3,77,937	3,45,795	4,12,179	3,37,716	3,07,496	3,77,374	2,66,593	1,25,127	1,378,379	64,022	47,204	82,676	497,901
		12,45,918	7,26,205	5,98,004				6,45,242				6,39,907							
14. Percentage of actual overage to standard consumption		11.49	22.15	12.36	8.90	11.88	8.35	10.98	9.10	11.19	8.92	10.44	13.02	5.5	5.86	4.47	5.56	4.86	5.48
15. Percentage of actual spillage to standard consumption		8.94	9.95	7.01	7.00	7.86	6.89	7.23	6.15	7.89	5.86	6.38	5.46	7.06	6.52	7.37	6.88	7.93	7.10
16. Percentage of excess overage and spillage to standard consumption		10.43	22.10	9.37	5.90	9.74	5.74	8.21	5.25	9.08	4.78	6.52	3.02	2.61	2.38	3.83	2.45	2.77	2.88

@ Separate figures of Penicillin and streptomycin vials cannot be worked out as one of the products 'strepto-penicillin' consumes both Penicillin and Streptomycin.
NOTE.— Loss against items 11 and 12 has been worked out on the basis of cost of the production of the respective year.

APPENDIX III

(Vide paragraph No. 4-13)

Cost of production of Formulations since 1966-67 expressed as indices (taking 1966-67 as the base year)

Products	Unit	Cost of production									
		1966-67	1967-68	1968-69	1969-70	1970-71	1971-72	1972-73	1973-74	1974-75	
1	2	3	4	5	6	7	8	9	10	11	
(f) Vials											
1. Benzyl Penicillin Sodium .	5 lacs	100	140	143	137	163	157	133	156	231	
2. —do— Potassium	5 lacs	100	128	134	
3. —do— Procaine C-Sod.	4 lacs	100	..	128	124	145	138	137	159	247	
4. Benzyl Penicillin C-Pot.	4 lacs	100	107	121	
5. Benzyl Penicillin Proc. C-Sod.	20 lacs	100	114	109	95	110	161	
6. Benzyl Penicillin C-Pot.	20 lacs	100	118	
7. Sterile Pen. Streptomycin suspension	1 gm.	100	112	125	122	133	130	136	150	234	
8. Streptomycin sub-phate	1 gm.	100	109	128	109	118	126	129	135	233	
9. Benzyl Penicillin Sodium .	10 lacs	100	..	119	119	173	183	108	128	196	
10. Benzyl Penicillin Potassium.	10 lacs	100	151	165	

1	2	3	4	5	6	7	8	9	10	11
11. Benzyl Penicillin Procaine Rorts Inj.	15 lacs	100	111	115	128	140	132	136	151	249
12. Sterile Pen. Streptomycin suspension	1/2 mg.	100	114	128	121	135	140	136	155	241
<i>(ii) Tablets and Capsules</i>										
1. Tetracycline Hydrochloride	250 mg. 4 capsules	100	103	111		
2. Penicillin 'V' Tablets	65 mg. 12 tab.	100	91	98	109	112	153	149	169	255
3. Hamycin Tablets	10 tablets		100	79	64	37	49	51	40	..
4. Pen. 'V' Tablets	65 mg. 120 tablets		100	106	118	135	167	162	182	268
5. Pen. 'V' tablets	125 mg. 12 tab.	..		100	116	135	150	150	206	243
6. Pen. 'V' Tablets	120 tab.	100	116	135	149	150	206	243
7. Tetracycline Hydrochloride	250 mg. 100 cap.	100	104	112	120	125	135	164	157	173
8. Tetracycline Hydrochloride	Folder of 10 capsules				100	105	113	164	157	173
9. Hamycin Glycerin suspension	10 mg. bottle	100	248	172	298	173	266	513	123	676

NOTE : Bulk content in the vial is valued at bulk selling price or cost of production whichever is lower.

APPENDIX IV

Summary of Conclusions/Recommendations of the Committee on Public Undertakings contained in the Report

Sl. No.	Reference to paragraph No. in the Report.	Summary of Conclusions/Recommendations.
(1)	(2)	(3)
<i>Penicillin</i>		
1	2.14	The Committee regret to note that the installed capacity or the norms of production of Penicillin at different stages have not been indicated in the Project Report. It has been stated that the targets for production of fermentation batches were fixed at lower levels for want of extraction capacities because of an accident in 1967 to the extractor which was replaced only in March, 1970. The Committee regret to note that it took the Company three years to replace the extractor, and the production was allowed to suffer during all these years. The Committee would like the reasons for delay in this regard to be enquired into and responsibility fixed for such excessive delay which resulted in heavy loss in production.
2	2.15	The Committee, however, find that higher output per batch was achieved from 1967-68 onwards and this made up for lesser volume of batches. If it be so, the Committee see no reason why such higher output could not be sustained. As in the absence of any norms with regard to the number of batches harvested to the batches seeded, the efficiency of harvesting operations is not susceptible of evaluation, the Committee recommend that the Management should not lose

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any further time in fixing the norms after a study of such standards obtaining both in India and abroad so that they can evaluate the efficiency of harvesting operations from time to time and take suitable remedial measures to prevent the efficiency going below the norms.

3 2.16 The Committee do not see any reason why it should not be possible to fix suitable norms for draining on the basis of experience during all these years and taking into consideration the state of equipment, operating conditions etc. The Committee would like the undertaking to take steps without further delay to fix appropriate norms for draining of batches so that deviations therefrom could be watched and timely remedial action taken so as to reduce the loss on account of drainage to the minimum.

4 2.25 The Committee regret to observe that in spite
and of the knowledge about the potency of the strain
2.26 going down no serious attempts appear to
 have been made from 1962 to 1971 to improve
 the potency of strain for obtaining better
 titre yield. They learn that the Company is
 now negotiating with a Japanese party for a
 strain which has a yield of 30,000 units/ml. In
 view of the fact that the country has all through
 this period been importing Penicillin (total
 foreign exchange outgo on this score being
 Rs. 1.92 crore from 1966-67 to 1971-72 as men-
 tioned in of this report, in the opinion of the
 Committee, it would have been better and in the
 national interest if a new strain which is now
 sought to be imported had been imported much
 earlier and titre yield and consequently produc-
 tion of penicillin improved and import of peni-
 cillin reduced to that extent. The Committee
 stress that the Government Undertaking should

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		finalise without further delay the negotiate for import of the best suited and most efficient new Penicillin strain and take suitable measures to maximise the titre yield and the production of Penicillin.
5	2.27	The Committee would also like the Research and Development Wing of HAL to keep itself abreast of the developments elsewhere so as to take advantage of any improvements in the technology from time to time.
6	2.28	The Committee also recommend that a case study of the manufacture should be undertaken, so as to determine the national loss due to not keeping pace with the technical developments in improving the strains. The Undertaking should draw appropriate lessons from this experience in order to obviate recurrence of such a situation in pharmaceutical and other industries, where technological changes are rapidly taking place.
		The Committee suggest that a study should be made and a report prepared once a year comparing the output and technology used in the Undertaking with units in the country and if possible with efficient units outside the country, and considered in depth by the Board of Directors who should give their recommendations for improving efficiency and production.
7	2.32	The Committee note that the undertaking fixed a standard efficiency of 70 per cent for extraction of first crystals from the fermented broth. The Committee are not sure about the basis on which the percentage of efficiency has been fixed at 70 per cent. The Committee feel that with the introduction of new strain in 1971

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the Undertaking should review the performance and fix suitable standards with a view to assessing the performance with reference to such standards. The Committee also note that the Company had been progressively revising the standards of yield of first crystal per harvested batch from 1961-72, the last revision having been made in 1972-73. The actual average yield was however less than these standards in the case of penicillin G during 1966-67, 1969-70, 1970-71, 1971-72, 1973-74 and 1974-75 and in case of penicillin V during 1966-67, 1969-70, 1970-71, 1971-72, 1973-74 and 1974-75. The Committee feel that normally the yield should not be lower than standard yield and recommend that the Undertaking should identify the factors depressing the yield so as to take suitable concerted measures for improving the performance. The Committee also recommend that for a realistic assessment of the yield of first crystals, the undertaking should review the percentage of the standard for extraction efficiency and the yield and fix realistic standards for assessing the performance.

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2.48

The Committee note that utilisation of installed capacity for production of first crystals gradually increased from 1966-67 to 1972-73 though there was a set-back in 1967-68 and 1970-71 but it again showed an increasing trend upto 1972-73 and thereafter declined. The Committee were informed that the target is fixed as high as possible to motivate the production personnel and the yield of first crystals depended on the activity of strain in fermenter. The Committee are not convinced of this argument and feel that it should have been possible for the undertaking to take timely remedial measures to attain at least the targetted capacity.

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9	2.49	<p>The Committee regret to note that the efficiencies actually achieved in the conversion of first crystals into bulk Penicillin (with the addition of Potassium, Sodium and Procain salts) were generally less than the standard efficiencies of 90 per cent, 70 per cent, 80 per cent and 75 per cent fixed by the Management during the period 1966-67 to 1973-74 except in the case of Penicillin V where the percentage of efficiency was more than the standard in 1968-69, 1969-70 and 1972-73. 1973-74 and 1974-75 and Sodium during 1974-75 Potassium during 1972-73 and 1973-74. The Committee are informed that loss of production in this regard was due to lack of enforcement of protocol laid down for optimum efficiency of production e.g. non-observance of operating parameters like maintenance of optimum temperatures and air pressures in the fermenters caused by lack of facilities like temperature controls, monitoring agents, leakage of steam, non-availability of crucial raw materials, obsolescence of equipment and negligence on the part of employees. The Committee see no reason why the protocols laid down for optimum efficiency of production could not be enforced. The Committee feel that had there been a proper and effective system of control over the different stages of production, it should not have been difficult for the management to have identified the causes of low efficiency and taken concerted measures to realise the protocol standards.</p>
10	2.50	<p>The Committee are informed that the matter was gone into in depth and action had been taken to remove the Head of the engineering division and the Head of production and also for replacement of equipments. The Committee recommend that the management should draw lessons at least new and introduce without any further</p>

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delay an effective system of management control over the different stages of production so that deficiencies at each stage are identified promptly and suitable remedial measures taken without loss of time and production.

- 11 2.51 In regard to the replacement of equipment, the Committee are informed that an expenditure of Rs. 20 lakhs has already been incurred and it is proposed to have further replacements for the next three years by spending Rs. 27 lakhs. The Committee are also informed that piecemeal replacement of equipment of improved design would not provide a substitute for a completely new plant of modern design which would cost Rs. 3 crores and it is not proposed to discard the existing plant and replace it by a new plant of up-to-date design. The Committee would like the comparative economics of replacement of equipments in piecemeal *vis-a-vis* wholesale substitution to be most carefully gone into with particular reference to the new strain proposed to be imported. The Committee would like to be informed of the result of such a study.
- 12 2.60 In the opinion of the Committee targets fixed for production of Penicillin G by the Undertaking represent what can actually be achieved. If so, the Committee see no reason why it should not have been possible to achieve such targets by concerted efforts instead of revising them downwards because of constraints or inefficiency in production.
- 13 2.61 The Committee are informed that shortage of essential raw materials like butyle acetate, phosphoric acid, sulphuric acid and phenyle acetic acid was one of the reasons for short-fall in production of Penicillin during 1973-74 and 1974-75.
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It has been stated that as a result of the shortage of cash, the suppliers' bills remained outstanding for long due to which requirements of the undertaking received lower priority. The Committee are shocked at this state of affairs in the working of a Public Undertaking where credit worthiness of the undertaking has become so low as to have affected even the purchase of essential raw materials and production of an essential drug like Penicillin was allowed to suffer on this account. The Committee recommend that this matter should be enquired into and responsibility fixed. The Committee feel that these are matters which should have been gone into by Board of Directors particularly the Managing Director and the Government representative on the Board.

14	2.62	<p>The Committee also recommend that a case study should be made to draw suitable lessons in order to obviate recurrence of such a situation in this or any other public sector undertaking. The Committee would like that this matter should be gone into in depth so as to take corrective action and to streamline procedure in order to ensure that such a situation does not recur.</p>
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15	2.63 and 2.64	<p>The Committee are surprised to note that it was only in May, 1971, i.e. 16 years after the commissioning of the plant, that the Management took serious note of shortfall due to break-down of machinery and introduced a scheme of preventive maintenance of the plant and machinery. The Committee cannot but view it as an instance of gross negligence on the part of Management that they operated the plant for 16 years without any regular system of preventive maintenance. The Committee also find that frequent break-down of production equipments were reported to be due to considerable short-</p>
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comings in the working of engineering department which do not appear to have been investigated. The Committee recommend that the entire matter regarding lack of preventive maintenance for such a long time should be investigated immediately with a view to fix responsibility for the lapse.

The Committee also regret to note that even after introduction of the system of preventive maintenance in 1971 the preventive maintenance schedule has not been implemented fully during the period 1971 to 1975. The Committee are not convinced by the reasons advanced for non-implementation of the maintenance schedules which, as the undertaking has confessed, affected production. The Committee cannot but deprecate the negligence shown by the Management first in not introducing any regular preventive maintenance schedules for 16 years and thereafter not implementing the schedules regularly. They recommend that the reasons for non-implementation of the maintenance schedules since 1971 should also be investigated with a view to fix responsibility and adequate measures taken to ensure that at least in future the schedules for maintenance of the plant and equipment are adhered to. The Committee also recommend that Government/Board of Directors would ensure that preventive maintenance protocols are in-built into the system right from the inception and such protocols are actually adhered to.

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2.103
and
2.104

The percentage of drained batches to seeded batches has widely varied from 6.3 per cent in 1970-71 to 1.3 per cent in 1974-75. The Committee regret to note that no norms have so far been laid down by the Management with regard to the harvesting of seeded batches with the result that

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the efficiency of harvesting operations could not be properly evaluated. The Committee recommend that the undertaking should, after keeping in view the equipment, the technology, operating conditions etc. and after a study of the norms obtaining with the collaborator for such operations, fix appropriate norms for harvesting so as to evaluate the efficiency of harvesting operations from time to time and take suitable remedial measures to keep the drainage within limits.

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2.105

The Committee would like the Ministry to examine critically in consultation with the authorities concerned as to how far the action of Mercks in not informing HAL about the improved strain was correct with reference to terms of collaboration agreement, so that suitable action may be initiated by HAL. The Committee also see no justification for the delay of 4 years on the part of HAL in deputing its officers to Merck & Co. when it was known that Mercks was getting higher titre yield even from 1967 and when the agreement gave the right to the officers of Company to visit the plant once a year. As admitted by HAL even the question of delay and negligence in this regard has not been investigated so far.

18

2.106

In the opinion of the Committee it should be the specific responsibility of Management, more specially of the heads of Research and Development and Production to keep themselves fully posted with the performance of similar units in India and abroad particularly of the collaborators. The R&D should also keep a close watch on the trends of requirements of the undertaking with a view to taking timely action to regulate modify/diversify the pattern of production. The Committee deprecate the complacency and the negligence on the part of HAL in not keeping itself concurrently informed of the

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developments and improvements in the strain of streptomycin by Mercks. The Committee recommend that Government should investigate the matter and fix responsibility for the lapse.

- 19 2.107 The Committee note that the undertaking had
 and obtained the new strain from Glaxo through
 2.108 Government free of cost on the condition that
 it would not be sold or passed on to others, and
 HAL has been able to attain, on an average, a
 titre yield of 18,000 units/ml. and occasionally
 24-25,000 units/ml. from the new strain. The
 Committee see no reason why the Ministry/HAL
 could not have selected the technology and strain
 from Glaxo even in the initial stages instead of
 the Merck & Co.

The Committee would like HAL to take all the necessary measures not only to get the maximum yield from the new strain but also to improve the output and effect reduction in the cost of production. The undertaking should also review the performance with reference to the new strain and take action to revise the standards of titre yield with a view to evaluating the performance with reference to such standards.

- 20 2.109 The Committee are informed that because of
 stoppage of import of soyabean meal used for
 production of streptomycin, there was shortage in
 supply till the quality of soyabean meal fit for
 use in antibiotics industry was established in the
 country. The Committee feel that the undertaking
 should have taken timely action to identify
 suitable indigenous quality and built up sufficient
 stock when it was known that import of soyabean
 was to be stopped, although the problem is how-
 ever now reported to have been solved. Similar-
 ly, the problem of dextrose, which also affect-
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ed production is stated to have been solved with the replacement of dextrose by starch which is easily available. The Committee recommend that now, when HAL has located sources of good quality raw materials within the country, it should make long term arrangements for their timely supply and storage of raw materials may not affect the production of this vital drug hereafter. The Committee would also like HAL to review the production performance of streptomycin with reference to new strain and revised the standard efficiency and capacity so that evaluation of production could be done in a meaningful way.

21	2.110	<p>The Committee are also informed that prior to 1971, there had been no system of planned preventive maintenance for the plant and equipment with the result that there were frequent breakdowns which affected the availability of services. The planned preventive maintenance is reported to have been introduced since 1971. The Committee deprecate the neglect of so vital a plant for over 9 years and strongly reiterate, as already recommended in this Chapter, that a thorough investigation into this matter may be held expeditiously and responsibility fixed for not introducing a schedule of preventive maintenance right from the beginning. They would further recommend that the Corporation should take all possible measures to ensure that at least now the preventive maintenance schedule is strictly followed for all plant and machinery so that they can be kept in good running condition.</p>
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Hamycin

22	2.132 to 2.134	<p>The Committee do not see the rationale behind the decision to increase the capacity of Hamycin Plant from 15 kgs. to 50 kgs. even before the pilot plant was set up and results of</p>
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pilot plant study were known. While the Committee commend the development of this drug by the R & D Wing of the undertaking, they feel that HAL should have set up the 15 Kg. plant as originally envisaged on a pilot basis, and after testing the product, stabilising it in consultation with the ICMR/IMA and Federal Drug Administration of USA, established the demand for the product after a proper demand survey and only thereafter gone in for production on a large scale. The Committee regret to note that the undertaking went on increasing the capacity to 250 kgs. and even set up the plant with 250 kgs. capacity at a cost of Rs. 65 lakhs in November, 1968 merely on the basis of a demand from USA which was only "anticipated but was not even got verified. The Committee fail to understand as to why the demand of the product could not have been assessed and firmed up even in the earlier stages before going in for increase of capacity and why the approval of the Federal Drug Administration of USA which is now consider necessary for the systematic use of Hamycin could not have been obtained.

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2.135
and
2.136

The Committee find that on account of the various problems the production of Hamycin was discontinued from December, 1974, with the result that entire expenditure of Rs. 65 lakhs incurred in setting up the plant and the recurring maintenance charges incurred thereafter have proved to be infructuous. The Committee regret to observe that in spite of the long period of nearly eight years, the undertaking has not been able to get the problem solved. Since the chemical/drug technology is fast developing, the Committee feel that unless the problems are solved with expedition, the possibility of the technology on which the plant was based becoming obsolete and overtaken by latest advancements is not ruled

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out. The Committee would like the whole matter to be thoroughly investigated with a view to fix responsibility for the lapses.

The Committee also recommend that the undertaking should find the best alternative use to which the plant and machinery could be put. The Committee suggest that Ministry/Under-taking should derive a lesson from this experiment and ensure that whenever investments are made for manufacture of experimental drugs in future, the plant and machinery are such as could be used for more than one product.

Vitamin C

24

2-164

The Committee note that on the basis of a process developed by NCL for production of Vitamin C in 1960 a preliminary project report for a capacity of 50 tonnes per annum was prepared in June, 1960 for establishing the capacity in HAL after the management of HAL was satisfied about the successful trials of production in the NCL laboratory as well as in NCL pilot plant. Since Vitamin C was already under production in the country, the Committee feel that Government should have made a thorough evaluation of the technology and cost of production before the go-ahead order was given. The Committee find that in February, 1963 in an interministerial meeting it was decided that since HAL had no experience in the manufacture of Vitamin C, HAL should first establish pilot plant. This was again confirm in an interministerial meeting in July, 1963 where it was decided that the pilot plant should be established in about 4 months and a joint report with NCL about pilot plant runs should be submitted to Government by January, 1964. It was also decided that a decision regarding large scale production should be taken after a technical committee appointed by

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		<p>Government had examined the joint report by HAL and NCL. The Committee fail to understand as to why the techno-economic evaluation of the project based on the joint report of HAL and NCL was not undertaken as envisaged earlier and a decision was taken by Government without making sure of upscaling the technology or examining the cost. The Committee would like that this aspect should be investigated and responsibility fixed for the lapse.</p>
25	2.165	<p>The technology for Vitamin C which was developed in 1960 is stated to be obsolete in today's context. While the Committee are all for affording every encouragement to indigenous know-how, the Committee now hardly stress that every prudent care should have been taken to have selected the appropriate technology and no efforts should have been spared to critically evaluate the same before taking the investment decision.</p>
26	2.166	<p>The Task Force has also recommended that the two problems require immediate attention for improving over-all efficiency and suggested that the management of HAL should immediately explore the possibility of obtaining better technology either locally or imported which will ensure better return on the investment already made with the minimal additional inputs and HAL should immediately explore the possibility of maximum utilisation of the plant already installed by constituting a joint working group comprising the scientists of HAL, NCL and also National Research Development Corporation to go into the details of the technology and the design of the plant in order to assess the techno-economic viability of the entire project afresh. The Committee feel that HAL should have evaluated in depth the NCL technology at the pilot plant stage in consultation with Indian Council</p>

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of medical Research, NRDC and other experts in the field especially when even at the pilot plant stage according to the Secretary doubts were expressed. The Committee feel that the pilot plant studies were not carefully done before setting up a plant for large scale production. The Committee recommend that HAL should without any further delay, take concerted measures to overcome the immediate problems affecting the production.

27	2.167	<p>The Committee do not understand as to why, when IDPL another Public Sector Undertaking under the same Ministry is also producing Vitamin C, the assistance of that Public Undertaking could not be taken for revamping the plant. The Committee recommend that a careful evaluation of the available technologies should be made and the appropriate technology selected so that the plant is capable of operation on an economic basis. The Committee need hardly stress that it should be endeavour of the Public Sector Undertakings dealing with drugs to ensure that essential drugs of assured quality including those for prevention of diseases are made available at most competitive prices and in adequate quantities.</p>
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Aureofungin

28	2.179 and 2.180	<p>The Committee feel that both the Ministry of Petroleum and Chemicals and HAL should have taken the assistance of the Ministry of Agriculture and the ICAR for testing the product Aureofungin—a product developed by its own R & D efforts—in the field establishing its efficiency and popularising and standardising it as a pesticide before taking up production on a large scale. If it is established as a pesticide, or even as an antibiotic for agricultural products, the Committee feel that the undertaking should have passed on the know-how to another public undertaking</p>
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		<p>dealing with the pesticide or to the Ministry concerned for further processing and development. The Committee regret to note that, instead, the Company went on manufacturing the product though on a moderate scale without obtaining any firm commitment of indents from the State Governments and produced 1250 kgs. till the end of March, 1975 at a cost of Rs. 39 lakhs. The Committee see no justification for the company to have gone on with the production during 1972-73, 1973-74 and 1974-75 when there was already an accumulation of stock in 1971-72 and the shelf life of product was only two years especially when there were no firm indents/commitments from the State Governments.</p>

The Committee find that the off-take of the product has not even been 50 per cent of the production to the end of 1974-75 and even the stocks lying with the company are not usable with the result that the company has been put to a loss of over Rs. 20 lakhs calculated on the basis of total cost of production. The Committee would like that the entire matter should be thoroughly investigated with a view to fixing responsibility for the loss.

Other Items

29	2-193	<p>The Committee regret to note that even though there is no legal ban on the production of Tetracycline, now, it would not be possible for the undertaking to produce Tetracycline at competitive prices as others are already in the field with the result that the plant could not be used for the purpose for which it was set up while Tetracycline itself is being imported in bulk form to produce capsules. The Committee find that this pilot plant was used for production of Chlorotetracycline again on the basis of</p>
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know-how developed by research division and even this had to be abandoned on account of lack of demand. The Committee are informed that the plant was dismantled in 1970-71 and the machinery transferred to other plants for use and the entire Chlorotetracycline produced had been sold by 31st March, 1972. The Committee regret to observe that this is yet another instance of taking up experimental production without assessing the demand and developing the market for the product.

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2.194
and
2.195

The Committee also note that the Board approved in December, 1969, setting up of a plant for the manufacture of 5,000 kgs. of semi-synthetic penicillin per annum at an estimated cost of Rs. 50 lakhs during the Fourth Five Year Plan. According to management, the plant would be commissioned by June, 1976. The Committee also note that in the mean time manufacture of semi-synthetic penicillin capsules was started, in November, 1971, and out of 17.52 lakhs capsules manufactured, 14.67 lakhs were sold up to 31st March, 1975, 0.80 lakhs were scrapped (produced in May, 1972) leaving of a balance of 1.05 lakhs in stock. The low volume of sale was stated to be due to inherent difficulties in introducing a new formulation in the market.

The Committee feel that the undertaking should have made intensive efforts for marketing this new drug. Now that the plant would be commissioned by June, 1976, the Committee recommend that the undertaking should intensify its efforts to develop the market for the product and also take steps to get the problems regarding efficacy and shelf life of the product resolved. The Committee would also like to

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		reiterate that in the sphere of drugs, particularly the new drugs, it is always advisable to take up production on a pilot basis before going in for production on a commercial scale.

31	2.196	<p>The Committee are informed that the preliminary feasibility reports show that the projects for Industrial Enzymes and Amunoglycosidic antibiotics will be financially feasible while that of Erythromycin would not be financially feasible on the basis of the technology available with the undertaking at present and therefore efforts are being made to obtain improved technology before the project is processed further. The Committee would like that a thorough study of the technologies, if any, available, in India for the manufacture of these products should first be made before considering import of any foreign technology and the feasibility and economic viability of the projects should be critically examined before taking up the projects. In case selection of foreign technology is inevitable, the Committee would like that the undertaking should select the best technology capable of producing the drugs at most economic prices. The Committee also caution that the earlier mistakes of taking up manufacture of Hamycin, Aureofungin etc. should not be repeated while taking up manufacture of the new drugs and every care should be taken to ensure that the drugs produced will be efficacious, stable and have a viable market for them.</p>
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Rejections

32	2.209	<p>The Committee find that the percentage of rejects to total production in the case of penicillin</p>
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		<p>bulk has come down from 12.4 per cent in 1967-68 to 8.3 per cent in 1969-70. Though it increased to 10.3 per cent in 1971-72, it again came down to 1.09 per cent in 1973-74. In the case of streptomycin, though the percentage of rejects to the total production was the maximum of 26.5 per cent in 1968-69, the percentage came down to 0.54 per cent in 1972-73. It, however, increased to 3.4 per cent in 1973-74. The Committee see no reason why the undertaking should not sustain the low percentage of rejections so far achieved. The Committee recommend that it should be the endeavour of the undertaking to ensure that the rejects are further brought down.</p>
33	2.210	<p>The Committee regret to note that while there is a record of the tablets and vials rejected out of the total production, no separate figures of rejections in respect of the capsules are available with the undertaking. The Committee feel that in the interest of assessing the quality of the finished capsules, it is desirable that a record of rejects in respect of capsules is also maintained separately.</p>
34	2.211 and 2.212	<p>The Committee would like that a record of rejects of vials from the market should be maintained and analysed in depth and deficiencies identified with a view to taking corrective measures. The Committee need hardly stress that such rejections on account of quality not only affects the image of the company but also involves risks to patients.</p>
35	2.213 to 2.215	<p>In the opinion of the Committee it should not be difficult for the undertaking to have a sample test check of batches if any lying unsold for more than six months to ensure that the efficacy of such batches remains intact before</p>

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they are actually sent to the market. The Committee feel that 'withdrawals from market' do not leave a good image of a public undertaking on the public mind. The Committee find that a maximum number of batches of potassium penicillin 'G' were withdrawn and they pertained to the period—October 1965 to March, 1966, April, 1967 to September, 1967 and October, 1967 to March, 1968, and the withdrawals were mainly on account of non-conformity to specifications. The Committee fail to understand how such batches which did not conform to specifications passed the quality control tests.

The Committee were also informed that during 1972-73 and 1973-74, batches have been withdrawn following complaints from the market in regard to reactions particularly fatal reactions and also due to failure of the stability which could be noticed as a result of test carried out by the Quality Control Department of the Company. The Committee view with concern how such batches were passed by quality control department before they found their way into the market. The Committee would like that the deficiencies in the products which resulted in the fatal reaction should be thoroughly investigated without loss of time and deterrent action taken against all those responsible for the delinquency. The Committee also recommend that Board/Government should ensure a conclusive action and also take suitable measures to avoid recurrence of such cases.

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The Committee feel that these problems are not insurmountable and could have been controlled by the management by contemporaneous monitoring. The Committee would like that the undertaking should critically go into the reasons for the very high percentage of rejections

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and see how far they were avoidable. The Committee recommend that on the basis of the experience of working and with reference to norms obtaining in undertakings manufacturing similar drugs, the undertaking should fix appropriate norms for rejections and also tighten its quality control measures to see that the percentage of rejections does not exceed the norms.

Consumption of raw materials

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and

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The Committee view with concern that in spite of steep increases in the value of excess consumption of materials which contribute to the increase in cost of production, no action seems to have been taken to investigate into the reasons for such excesses. The Committee feel that in the absence of information records to indicate the corrective action taken on variance reports, it is neither possible to verify whether action has actually been taken or to fix responsibility for any lapse in this regard. In the opinion of the Committee this only indicates casualness of approach and laxity on the part of the management. The Committee therefore recommend that the undertaking should not rest content with merely preparing a statement of variances between standards and actual consumption but also indicate and endure corrective action.

A statement of variances along with action taken should be included in the monthly/quarterly financial review and placed before the Board of Directors who would no doubt examine in depth about the adequacy of remedial and other measures taken.

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It has been stated that the criterion followed for revision of any standard in any particular raw material was that the standard was

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fixed or revised keeping in view the optimum consumption best suited to efficient production. Since improved strains have been introduced in the case of penicillin from 1971 and in the case of streptomycin during 1974-75, the undertaking should watch the performance of the new strains and take action to revise the standards after the production gets stabilised so that a realistic assessment of the consumption of raw materials with reference to such standards can be worked out.

The Committee recommend that any upward/downward revision of norms should be done only after a detailed objective analysis of the consumption of materials for a period, consistent with efficiency and quality of the product and with the specific approval of an officer not lower in rank than Managing Director and after consultation with Finance. Such revision of standards should also receive the special attention of Board of Directors.

Utilisation of Services

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and
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The Committee regret to note that no yardsticks have been prescribed for exercising control over actual consumption of power steam and compressed air nor is there any arrangement for recording actual consumption at different plants and/or for different processes. The Committee are informed that the most important point of consumption of services being at the fermentation stage, the Management roughly compared consumption of important services per fermentation batch in the absence of necessary instruments. The Committee cannot comprehend how a rough comparison of consumption of services, only at the fermentation stage could enable the management to exercise control over the consumption of services at the

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different stages|processes of production which is essential to control costs and cut out wastages at each stage|process. The Committee are informed that meters are gradually being installed and till then the control would be with reference to estimates. The Committee feel that installation of meters or other measuring instruments should have been done along with the equipment themselves and recommend that the undertaking should lose no further time in fixing the meters and exercising proper control over consumption of services, which has a bearing on over-all cost of production.

The Committee recommend that Government/BPE should issue standing directions that measuring control instruments should invariably be provided along with the machines|equipment and should in fact form an integral part of the machines.

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The Committee also find that percentage of the consumption of steam has been the maximum—53.37 per cent in 1973-74 while consumption of compressed air has been the maximum 99 percent in 1970-71 of the installed capacity. The Committee would like that the reasons for abnormal increases should be critically examined with a view to taking suitable remedial action.

The Committee are also informed that although there had been stand-by capacity for other services, which had to be progressively utilised in the case of refrigeration the under-utilisation of installed capacity was due to frequent breakdowns.

The Committee are informed that with the introduction of planned preventive maintenance introduced after 1971, the percentage of break-

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down has come down from 22 per cent in 1972-73 to 3 per cent in 1974-75. The Committee feel that it is not so much the absence of standby but lack of preventive maintenance which had been responsible for such frequent breakdowns. The Committee have given their comments elsewhere in this report about non-observance of preventive maintenance schedules.

Machine/Labour Utilisation

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to
2.252

The Committee regret to note that the undertaking has not maintained any record to indicate the idle labour hours and only a record of idle machine hours is maintained and that too only in fermentation and filling section. The Committee see no reason why record of machine utilisations should not be maintained in the other sections and fail to understand how in the absence of such a record, allocation of costs is done and idle hours controlled. The Committee recommend that the undertaking should take steps to maintain suitable records to indicate the utilisation of machinery in the different sections and processes.

The Committee feel that in the interest of assessing the efficiency and productivity of labour it is necessary that records of utilisation of labour and idle labour hours and the reasons therefor are maintained.

The Committee recommend that information regarding idle machine hours and man hours should be reflected in the monthly/quarterly reports to the Management and Board of Directors. The Committee also suggest that the internal audit should critically examine the records of idle machine/man hours and report

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to the Management Board of Directors to enable them to take conclusive follow-up action. The Committee need hardly stress that high percentage of idle hours of men or machinery will only add to the cost of production, with the result the prices would cease to become competitive.

The Committee note that the bulk of the idle machine hours has been due to contamination turnover time and breakdown of machinery. The Committee feel that there are areas which could be controlled by efficient management and the idle hours could be brought down. The Committee would like that the undertaking should take concerted measures to control idle hours on account of these factors in the best interest of production.

The Committee find that besides turnover time and shortage of raw materials and contamination has also contributed to idle hour. The Committee see no reason why the undertaking should not have kept sufficient buffer stock of raw materials and obviated the necessity of keeping machines idle for want of raw materials. The Committee would like that the undertaking should take suitable steps to control idle hours due to contamination in the best interest of production.

The Committee would also recommend that the reasons for the very high percentage of idle machine hours during 1974-75 should be investigated to see whether any of the reasons are avoidable.

Vials

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The Committee note that as against the installed capacity of 48,000 vials per shift based on

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continuous working for 8 hours about stoppage, the Ministry considered a capacity of only 36,000 vials per shift as practicable. As against this, the management assumed the working capacity to be 25,000 vials per shift. The Committee find that number of shifts actually worked was less than the available shifts, on account of absenteeism among workers, lack of trained operators, shortage of rubber stoppers, breakdown of machines, etc. The Committee regret to note that HAL has not analysed the loss of shifts on account of each one of these reasons. The Committee agree with the Ministry that the undertaking should not have reduce the capacity because of the alleged loss of 2 hours in a shift but should find out ways and means of ensuring that the machines are actually worked for the full 8 hours so that vialling could go up. The Committee would like HAL should improve the utilisation of capacity and bring it to the level of 48.000 vials without further loss of time and money. The Committee would like to be informed of the concerted measures taken and the results achieved.

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The Committee regret to note that the actual production fell short of not only capacity based on 36000 vials per shift but even the reduced vialling capacity of 25000 assumed by the Management, the lowest production being 20,781 in 1974-75. The Committee recommend that the vialling capacity of each machine and the question of optimum number of working shifts should be gone into in depth with a view to identifying the constraints which affect the working of the plant at 48,000 vials and suitable measures taken to attain the full capacity under a time bound programme and the Committee informed. The Committee are also informed that the Undertaking

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has also now taken some measures to see that the humidity is maintained at proper level to control rejections. This being a management function, the Committee fail to understand as to why this could not have been taken care of at the appropriate time and rejections controlled. The Committee recommend that the measures now taken should be kept under continuous watch so that humidity is maintained at the proper level.

4 3.26 In regard to rubber stoppers, though the problem is reported to have been solved by shifting to synthetic rubber, the Committee see no reason why this could not have been taken care of by proper planning. The Committee find that the need for strengthening the inventory control procedure, building up of adequate reserves and keeping close liaison with the suppliers was emphasised by the Board as early as 1970. The Committee expect that the Management would keep their instructions in view and observe them so as to avoid recurrence of shortages of rubber stoppers and other vital accessories.

45 3.27 The Committee note that one of the reasons for the shortfall in vialling operations has been reported to be shortage of vials. The Committee find that HAL has been getting the vials of BP 58 specification produced by only one private sector firm situated as an ancillary unit on the land belonging to HAL. The Committee feel that agreement should have contained suitable provision for meeting the demand of the main undertaking in full and also the price to be paid for supplies should have been indicated in some detail keeping in view the cost of production and international price etc. The Committee are of

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the opinion that the private firm which was nurtured as an ancillary unit with all the attendant facilities, should have given priority of supplies to the main undertaking HAL according to the terms of the agreement and even if there had been any dispute about rates those could have been resolved by arbitration etc. at a later stage. The Committee fail to understand as to why no legal action was taken against the private firm by the undertaking to enforce the terms of the contract. The Committee are constrained to observe that HAL allowed a situation to develop in which the private sector company was able to hold it to ransom by interrupting supplies of glass vials and forcing it to agree to price increase just to avoid stoppage of production. The Committee are led to conclude that the agreement with the Company either did not adequately safeguard the public interest or the provisions thereof were not effectively and promptly invoked. The Committee would like that the agreement and the role of HAL in drawing and implementing it should be thoroughly investigated with a view to fixing responsibility for the lapses. The Committee would like to be informed of the precise action taken in pursuance of this recommendation.

The Committee recommend that Government/BPE should on the basis of experience of the working of the agreement define the role and obligation of the ancillary industries *vis-a-vis* the main industry. They should draw up a model agreement for such ancillary industries making it obligatory for them to meet the requirements of Public Undertakings in full and supplies made by them to the Public Undertaking should be most competitive with reference to the price charged by other units/International price/cost of production.

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| 46 | 3.30 | The Committee recommend that, since the public sector drug companies HAL and IDPL are reported to be facing considerable difficulties in obtaining the requisite quality and quantity of vials, Government should consider the feasibility of setting up captive vial making capacity with the public sector units after carefully examining the technical and financial implications thereof. |
| 47 | 3.43 | The Committee regret to observe that in spite of the heavy percentage of rejections no norms were fixed prior to 1973 and there was no system of controlling the rejections. The Committee strongly recommend that all the long term and short term measures recommended by the technical Committee of the Corporation should be implemented scrupulously without avoidable delay so as to ensure that the rejections are minimised and in any case kept within the norms. The Committee would also like that a report about the rejections compared to the norms together with the remedial measures taken should be included as a standing item in the agenda for the Board meeting so that the Board of Directors may have an opportunity of reviewing them. |
| 48 | 3.44 | The Committee are further informed that during 1973-74 one of the likely causes of the higher rejections was that the supplies of glass vials were not strictly according to specifications and the rubber stoppers did not adhere properly to the vials. They are surprised to learn that instead of compelling the supplier to adhere rigidly to the specifications, the glass vials deviating from the prescribed specifications were accepted |
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and the specifications of the rubber stoppers changed to match those of the glass vials received. They are unhappy to find that HAL agreed to compromise on standard laid down for glass vials and accepted below-specification vials to avert cessation of production in view of the monopoly of the supplier in this field. The Committee fail to understand as to why HAL could not have enforced the technical specifications laid down in the contract. The Committee deprecate the lack of foresight on the part of HAL in allowing such a situation to develop in which it found itself completely at the mercy of a private sector company for glass vials and recommend that the matter should be investigated with a view to fixing responsibility.

49	3.45	<p>The Committee are informed that a large number of vials making plants have been licenced in the last two years and if 60 to 70 per cent of that licenced capacity comes to fruition, the shortage of vials will no longer be there. The Committee recommend that Government should ensure that the plants which have been licenced are really set up and commissioned on schedule and that scarcity conditions in the matter of availability of vials are not allowed to develop.</p>
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Spillage and Overage

50	3.51	<p>The Committee are concerned to note that the spillages and overages have always been in excess of standard and the cumulative loss on this account during the last 8 years was of the order of Rs. 50.33 lakhs. The Committee stress that the reasons for such spillages and overages should have been critically analysed and timely action taken to arrest such excess spillages and overages. The Committee also recommend that</p>
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the standards which were fixed in the initial stages should be reviewed by the R & D wing of the company in the context of the present stage of equipments and processes and stricter standards evolved for the purpose of assessment of the efficiency of the vialling operations.

51	3.52	<p>The Committee are informed that by adopting more rigorous controls and changes in processes, the losses on account of spillages and overages have been brought down from an average of Rs. 8 lakhs during 1966-67 to 1971-72 to Rs. 3 lakhs on an average during 1971-72 to 1974-75. The Committee feel that the improvements made during the last three years should not create a sense of complacency in the Management and the Management should continue to keep the percentage of spillage and overage under review so that suitable remedial steps may be taken in time to keep them within the norms fixed for the purpose.</p>
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Tableting and capsulation

52	3.65	<p>The Committee were informed that the operable installed capacities of tableting and capsulation machines these were fixed on the basis of actual trials and were lower than mechanical capacity of machines on account of lack of ancillary equipment. The Committee see no reason as to why such ancillary facilities could not have been provided along with the machines so as to utilise the full capacity and why only 58 per cent of the capacity was put to effective use. The Committee are informed that these facilities have since been provided in tableting section and new machines have been added and the installed capacity has been increased to 1800 lakh tablets and machines have been added and the installed capacity is now rated as 1248 lakhs and 137 lakhs per</p>
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annum respectively. The Committee do not see the rationale behind fixing the operable capacity at a reduced figure even after addition of new machines and facilities and stress that concerted measures should be taken to ensure full utilisation of the installed capacity for tableting and capsulation.

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The Committee regret to note that even after the installed capacity of tableting has been increased, the percentage of utilisation of operable capacity has been of the order of 9.6 per cent in 1972-73, 15.7 per cent in 1973-74 and 12 per cent in 1974-75. In the case of capsules, the percentage of utilisation varied from 42 per cent to 55 per cent although earlier it varied from 47 per cent in 1968-69 to 71 per cent in 1970-71. The Committee are informed that production programme is sale-oriented and market for tablets and capsules is being developed gradually and is at present much below installed capacity. The full capacity of tableting could be achieved after air-conditioning facilities could be commissioned in November, 1975. The Committee see no reason why these facilities could not have been provided along with the installation of ancillary equipments and additional punching machines and capacity utilisation augmented and why the undertaking could not have developed the market for tablets and capsules. The Committee would like that the undertaking|Government should critically examine the constraints, if any, in the marketing of tablets and capsules and the reasons for the underutilisation of capacities when there is larger margin of profit in sale of tablets and capsules which would be of direct service to the common man.

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54	3.69 to 3.71	<p>The Committee regret to note that in spite of the fact that vialling, tableting and capsuling capacities had been underutilised, the quantities issued for vialling and tableting have been less than the quantities produced. The Committee regret to note that while on the one hand the undertaking was not utilising its vialling and capsulation/tableting capacity in full, on the other hand it had been cancelling orders in various years due to inability of the Company to meet the demand for formulations. The Committee regret to observe that in spite of formulations being a profitable proposition, the undertaking did not make any attempt to increase the capacity for formulations. The Committee are doubtful whether this underutilisation of capacity was deliberate and they would like that this matter should be critically gone into. In this connection the Hathi Committee on Drugs and Pharmaceutical Industry have recommended in April, 1975 that at least 60 per cent of bulk drugs produced by the Public sector industry should be formulated by itself and in the disposal of the remaining 40 per cent first preference should be given to meet the needs of the Indian sector particularly the small scale/units.</p>

The Committee are informed that the Government have accepted these recommendations of Hathi Committee. At the present moment, the Company has the capacity to formulate 45 per cent but it is operating this capacity either for Penicillin or for Streptomycin, depending on which is more advantageous to formulate. They would like HAL to investigate the constraints on the optimum utilisation of the existing formulation capacity, take conclusive measures to remove these constraints and ensure that not less than 60 per cent of production is utilised for formulations.

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Bulk vis-a-vis Formulations

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The Committee note that major portion of the total production of different products of HAL is sold in bulk form to private viallers, although sale in vialled formulations was more profitable than sale in bulk. They are unable to appreciate why the Company has not been fully utilising its vialling capacity and why it cancelled orders for formulations and why the Government thought that they "had also an obligation to supply the bulk drug to private viallers" even though the bulk sales has been a substantial factor contributing toward losses which the Company has been sustaining currently.

The Committee are constrained to conclude that by showing excessive concern for the requirements of private viallers and by keeping HAL's formulation capacity under-utilised all through this period, the administrative Ministry as well as HAL have not acted as the guardian and promoter of the interests of the public sector but has rather helped the private firms, particularly the foreign firms to earn huge profits at the expense of the public sector and national interest. They recommend that Government should thoroughly investigate into the reasons for the under-utilisation of formulation capacity, indifference to the need to augment the formulation capacity and develop markets for HAL's products, the so-called "obligation" to supply bulk drugs to private viallers and cancellation of orders for formulations in spite of having unutilised capacity, with a view to fixing responsibility and inform the Committee of the precise action taken in the matter.

The Committee recommend that the company should identify such of the formulations which

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are a losing proposition and critically go into all the factors which have been affecting the profitability on formulations so as to take suitable remedial action without further delay. Since the cost of formulation also depends on the cost of bulk drugs, the Committee recommend that the undertaking should take concerted measures to bring down the cost of bulk production, the cost of vialling and elimination of all wastages and heavy rejections by stricter management controls. They would like this matter to be included as a regular item of the agenda at the meetings of the Board of Directors so that it receives contemporaneous attention and effective measures are taken to bring down the cost of production of bulk and formulations.

The Committee note that the cost of production of bulk in most cases exceeds the selling price which is fixed for them with the result that the private viallers find it an attractive proposition to purchase bulk from HAL and to make formulations therefrom and this gives them a better margin of profits.

In this connection the Hathi Committee have recommended that if the multinationals are to continue in the field of drug production, they should continue under certain disciplines and should be required to go into bulk production and to give at least 50 per cent of their bulk production to associated formulators. These recommendations are stated to be under the consideration of the Government. The Committee would like the Government to take an early decision in the matter so as to ensure that the public sector does not have to continue to supply bulk products to formulators, more particularly foreign drug Companies, at a loss to itself and the Committee informed of the deci-

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sion taken in the matter within three months of the presentation of this Report.

Pricing Policy

56	4.27 to 4.35	<p>The Committee note that the cost of production of various bulk drugs and formulations by HAL has more than doubled since 1966-67 in most cases and the cost of production of many items has been higher than the selling prices fixed by the Government. The Committee recommend that the Undertaking should take concerted measures to reduce its cost of production by better utilisation of the capacity, improving its efficiency and controlling rejections and eliminating all wastages.</p>
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The Committee recommend that the Government may expeditiously examine the various aspects of the pricing of bulk drugs and formulations in the light of the Reports of the Bureau of the Industrial Costs and Prices and the assurance given by the Minister in the House about Hathi Committee's recommendations and evolve a pricing policy by which the public sector should play a dominant role in drug industry by making essential drugs available both to the hospitals and the common man at most competitive prices. The public sector should also have appropriate blend of bulk and formulations so as not to make losses, but generate adequate margins on capital invested to make it self-reliant and growth oriented.

The Committee note that the assurance given by the Minister on the floor of the House in regard to the price of essential drugs and stress that in so far as essential drugs are concerned, their prices should not go up. In order to keep the prices of essential drugs lower and within the reach of the common man, the Committee

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would also like Government to consider the feasibility of introducing a dual taxation structure so that essential bulk drugs may be given concessions in the rates of customs and excise duties and the resultant loss in tax receipt offset by increasing the duties on non-essential drugs.

Market participation

- 57 5.7 The Committee regret to note that the share of HAL in the trade on the basis of licensed capacity and actual production, instead of going up with the passage of time has decreased from 52.45 per cent in 1967 to 25.3 per cent in 1974, in the case of Penicillin, while in the case of streptomycin from 51.27 per cent in 1967 to 30 per cent in 1974. The Committee are surprised to note that private sector units have been allowed to have installed capacity more than their licensed capacities. The Committee would recommend HAL should take concerted measures to improve its performance so as to have a significant if not a dominant role in the market.

Marketing

- 58 5.18. The Committee also note that even the total sales has only increased marginally from Rs. 712.97 lakhs in 1967-68 to 748.90 lakhs in 1974-75. But the sale expenses have nearly doubled from Rs. 19 lakhs in 1967-68 to Rs. 33 lakhs in 1974-75. The Committee cannot appreciate the phenomenon of rising sales expenses *vis-a-vis* declining sales and why strict watch was not kept on this aspect. They would like HAL/Government to analyse the various factors comprising the sales expenses and the reasons for the increase under any or all the items so that suitable action may be taken to effect economies in sales expenses.
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59	5.19 and 5.20	<p>The Committee had in paragraph 5.79 of their 40th Report on 'Role and Achievements of Public Undertakings' presented to Parliament in September, 1973, recommended that Government should evolve, if possible, a centralised sales and marketing set-up for each type of industries and, if that is not possible, at least for specified products which are manufactured by more than one Public Undertakings. The Ministry has stated that the aspects concerning creation of one more marketing organisation in a big way will have to be gone into in greater depths. The Committee feel that the Government have already taken over 2½ years to take a final decision about the shape and size of the centralised marketing set up for HAL and IDPL even though the need to strengthen the marketing organisation has been accepted in principle. They would like the Government not to lose any more time to decide about the set up of a central marketing organisation which would not only be economical but would also lead to greater co-ordination, evolution of effective sales strategies and development of expertise in the field of sales and management. The Committee also stress that there should also be a regular feed back of market intelligence so that the Undertaking may plan/regulate its production/sales operations accordingly.</p>

Discount on Sales

60	5.25 to 5.27	<p>The Committee would like that the system of giving discounts should be placed on a sound and rational basis to avoid any complaints in this regard and would like that Government Departments/Hospitals etc. place their orders directly on the Public Undertakings on regular basis and the price of the drugs should be settled well in advance by DGS&D on behalf of the customers.</p>
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The Committee are informed that the Company is now not offering higher discount against tenders and even when higher discounts were offered in certain cases, parties who used to place direct orders were in a more advantageous position as they were entitled to a uniform discount on all products. The Committee would like that the new arrangements are kept under continuous and constant review and modified if necessary in the best interest of Undertaking and Government institutions.

Appointment of Distributors

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The Committee find that the company has in addition to the distributors appointed thirteen sales representatives.

Considering the performance of sales representatives, the Committee feel that they have hardly been able to justify their existence, although it is understood that Sales Representatives are one of the media for promotion of sales. The Committee would like that the Undertaking should go into the reasons for the poor performance of sales representative with a view to draw lessons therefrom.

The Committee also feel that such stray attempts at sales promotion as have been made by the Company so far are not likely to make any worthwhile dent in the highly competitive market which is at present dominated by multinational and big private companies. Unless the products of the company are detailed to the medical profession, unless the medical profession is convinced of the high quality, easy availability and competitive prices of the Company's products, and unless the net work of distributors, stockists and also of the sales representatives are made result-oriented, no sales promotion campaign can

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hope to achieve the desired success. The Committee would like HAL to undertake a study in depth as to how leading pharmaceutical firms in the country have built up their sales organisation for efficient sale service and distribution of drugs to consumers, so that the Company can take advantage of such studies in planning its sales and distribution mechanism.

The Committee also recommend that pending the setting up of the Central Marketing Organisation the industry should review the working of the existing marketing agencies and functionaries, spell out their roles and targets, introduce schemes of incentives and take positive measures to ensure that all of them put in all possible efforts to promote the sales of the Company's products. The Committee regret to find that even though none of the six distributors appointed all over the country, lifted even half of the stipulated minimum during 1968-69 and 1969-70 the Company did not enforce the refund clause in the agreement.

The Committee are not satisfied with the justification for not enforcing the recovery clause for non lifting of minimum quantity especially when according to Management the minimum quantity was decided on ideal share that HAL should have in market.

The Committee are not convinced as to why in spite of the earlier poor performance of distributors in Maharashtra and Bihar the distribution arrangement in these two States were continued. The Committee find that even during the years 1970-71 to 1973-74, sales effected by the distributors in Maharashtra and Bihar have been much below the stipulated minimum. In the opinion of the Committee penal clauses which are incorpora-

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ted in agreements but are not enforced encourage the trade not to take the company seriously and instead of providing incentive to effecting greater sales of the company's products embolden them to ignore HAL's interests and pay greater heed to the products of other companies which seriously enforce such clauses. The Committee would like Government to take immediate steps to enforce the penal provision and effect the recovery of due. The Committee would also like Government to go into the causes of the poor off-take of distributors. The Committee recommend that HAL should impress upon the distributors the need to take serious interest in promoting the sales of its products and to make it known to them that if they do not discharge their obligations under the agreements, not only the penal clauses will be enforced but the award of distributorships to them may also have to be reviewed. This is all the more necessary now when HAL is poised for entry in the open market at a much bigger scale. The Committee are not sure whether proper distributors were selected by the Undertaking to promote the sales of its products. They would like the undertaking to select established distributors who have standing and experience in the field for marketing its products.

Exports

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and
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The Committee note that the Company entered the export market from 1965-66 under a commitment made to Government in 1962 in consideration of release of free foreign exchange amounting to Rs. 34 lakhs for streptomycin expansion project. Though it was obliged to export products worth Rs. 34 lakhs, the Committee regret to observe that the Undertaking had not been able to fulfil the commitment and till 1974-75 it had exported products worth only Rs. 11.14 lakhs and that too resulted in a loss of

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Rs. 3.66 lakhs. The Committee need hardly stress that profit or loss should be reckoned on the total price and not separately on fixed or variable costs. The Committee also do not appreciate the justification sought to be given viz. that domestic market was also not favourable and the Company was to lose either in exports or in domestic sales. If so, the Committee fail to understand as to why the offer of the Ministry to get a waiver of the legal obligation to export was not availed of. The Committee are surprised to note that while, on the one hand, Penicillin 'G' and Streptomycin are being imported in bulk for being converted into vials to meet the internal demand, on the other hand, HAL has been exporting its vialled products at a loss.

The Committee recommend that Government should review its orders of 1962 and consider revising them suitably so as not to put the undertaking into losses in the fulfilment of its export obligations. The Committee also stress that so long as the country is dependent on imports for the essential drugs, the company would do well to concentrate all its marketing efforts on sales in the domestic market and after establishing a name in domestic market for formulations consider extending its sales activities in foreign markets.

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The Committee are not aware as to how M/s. Unichem were selected for exporting the products of the company and whether any offers of other companies in this regard and their terms and conditions were examined. The Committee would like that this matter should be investigated by Government to see how far the terms and conditions and arrangements with M/s Unichem have subserved the interest of the undertaking

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and whether HAL products are not being sold under the Unichem's brand names.

Research and Development

64	6.18 and 6.19	<p>Although it has been claimed by the HAL that research laboratory has been continuously rendering technical advice and assistance for improving the quality of products and in suggesting improvements to have higher productivity by selecting improved strains, etc. and also rendering service in the adoption of better fermentation and extraction techniques, as pointed out in the relevant sections of the 'Performance' chapter in this Report, these are not borne out by facts/details. In the opinion of the Committee not much seems to have been done in regard to upscaling of technology.</p>
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The Committee feel that R&D wing should direct its efforts to the task of not only absorbing the technology on which the projects of HAL have been set up but upscaling it, suggesting ways and means for improving the utilisation, reducing rejections and cutting down the cost of production.

65	6.20 and 6.21.	<p>The Committee are informed that the Company is spending about Rs. 26 lakhs per year on research and development; i.e. about 3 per cent of the sales turnover while the general level of R & D in big drug companies is stated to be of the order of 6 to 15 per cent. The management is of the opinion that the percentage should be round about 10 per cent. The Committee agree that it is not the percentage which counts but what really the Undertaking wants to do and achieve. In this connection, the Hathi Committee has recommended that the public sector unit should, to begin with, set aside at least 5 per cent of their turnover for this purpose. The</p>
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Committee are informed that the Board of Directors had also some time back decided to spend about 5 per cent of the sales turnover on R & D. But according to the Managing Director, even this level of expenditure would be meagre. In this connection, the Committee would like to draw attention to suggestions made by the Hathi Committee, in paragraph 99 of chapter 3 and paragraph 37 of chapter 7 of their report and recommend that the company should take immediate steps to strengthen its R & D effort to bring it to a level of meaningful productivity and to equip it with such R & D pilot plant equipment as may be necessary for this work as a sound R & D base is the best insurance for growth of drugs in pharmaceutical industry. The Committee also recommend that the personnel selected for R & D should be dedicated and accountable.

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The Committee recommend that the projects which have a bearing on the existing working of the plants and maximisation of the existing capacity and future development of the drug industry should be identified for research work by the R & D wing and an analysis of the projects which had been carried forward to the stage of commercial exploitation or are making progress or are stuck up should be made so that it is possible, not only for the R & D wing to take stock of its achievements and failures but also for the Government and the Undertaking to evaluate its performance with reference to investment made in it during the year. The Committee also recommend that a gist of the achievements made by R & D should also be included in the annual report of the Undertaking. The Committee would also like to endorse the suggestion made by the Committee on Drugs and Pharmaceutical Industry (Hathi Committee) in

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para 101 of their Report that the public sector units should establish closest liaison with the other R & D laboratories such as the CSIR, ICMR, ICAR, etc. and state institutions like the Haffkine Institute, the IIT's, Universities, etc., as such coordination is vital for development and that appropriate facilities should be created in the identified institutions, wherever necessary, to permit time-bound completion of individual projects.

The Committee recommend that there should be a High-powered committee in the Ministry which should demarcate areas of R&D and allot them to the various institutions and contemporaneously monitor the programmes and review them from time to time with reference to the allocation of money and time schedule.

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The Committee are surprised to note that HAL "has no authentic information in regard to the activities pursued by the R&D wing of the IDPL". When these two public sector units have been manufacturing same drugs (*viz.* Penicillin and Streptomycin) though based on different processes and technologies, the least that the Committee expect is that there should be a system of coordination between the two public sector units so that one could benefit from the achievements of the other in larger national interest.

In this connection, the Committee would like to invite attention to the recommendation made by the Hathi Committee in para 100 of Chapter III of their Report to the effect that as between these three units (at Pimpri, Rishikesh and Hyderabad), avoidable duplication of efforts must be discouraged and the results available at each unit must be made available to the other related unit. There should be no secrets between

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the public sector units and any improvements, in a strain, a process or a plant developed in the R&D laboratory of one unit, should be freely available for use by the other unit. The Committee hope that HAL would lose no further time in establishing a close liaison and coordination with R&D laboratories of the other public sector drug units on these lines.

Inventory Control

68	7.8	While the inventory of imported raw materials in subsequent years was within the norms, in the case of indigenous materials it was in excess of the norms. In spite of this heavy investment in raw materials, the Committee regret to observe that due to shortages/non-availability of essential raw materials like soyabean, etc. the undertaking could not keep up the production of streptomycin.
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69	7.9 and 7.10	The Committee are constrained to observe that while on the one hand production of formulations is stated to have suffered due to shortage of vials and rubber stoppers, on the other hand there has been an increase in the inventory of general items and spares from Rs. 99 lakhs at the end of March, 1971 to Rs. 127 lakhs at the end of March, 1975 thus indicating accumulation of non-essential stores.
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The Committee see no reason for delays in the finalisation of orders by DGS&D. In fact DGS&D should give preference and every facility to public sector undertakings to meet the demands/requirements of Government to the maximum extent. The Committee would also like Government to go in depth into the causes for the delays in finalisation of orders by DGS&D and remove any procedural lacuna which may be responsible for such delays.

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70	7.11	The Committee also note that the finished stock included Aureofungin (Rs. 3.33 lakhs) and streptomycin (Rs. 2.63 lakhs) accumulated since 1967-68. The Committee have already given their recommendations regarding these products in another chapter of the Report. The Committee are not sure whether these still retain their efficiency and are fit for disposal.
71	7.12 and 7.13	<p>The Committee also find that the stock of materials under reprocessing has shown a steep increase from nearly Rs. 4 lakhs at the end of 31st March, 1974 to over Rs. 11 lakhs at the end of 1974-75. The Committee feel that such expenditure on reprocessing is avoidable. The Committee would like that Government/Undertaking should critically go into the causes for this steep increase and take suitable remedial measures to control the rejections and eliminate reprocessing.</p> <p>Considering the inventory of general stores and raw material during the last many years and the steep increase in stock of finished goods at the end of 1974-75 the Committee feel that the steps stated to have been taken for toning up materials management have not produced the desired results. They would therefore like that the measures should be reviewed and tightened up to ensure that there is no unnecessary accumulation of inventory resulting in blocking of funds and accentuating the financial difficulties experienced by the undertaking.</p>
72	7.14 and 7.15	The Committee also note that the value of surplus and obsolete stores has increased from Rs. 2.68 lakhs at the end of 1970-71 to Rs. 4.45 lakhs at the end of 1972-73 and declined to Rs. 3.14 lakhs at the end of 1973-74 and again increased to Rs. 7.27 lakhs at the end of 1974-75. The Committee feel that had suitable maxima minima

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and ordering levels been laid down and adhered to, the undertaking would not have been faced with such surplus and obsolete inventories. The Committee would like that the Government should go into the reasons for a steep rise in the inventory and non-moving items at the end of 1974-75.

The Committee would like that the undertaking should conduct a review of non-moving and obsolete stores periodically at least once in a year and report the position to the Board of Directors who should carefully go into the causes and take effective remedial measures. The Committee are also informed that a Task Force consisting of officers from various departments has been constituted to work under the over-all guidance of the consultants. The National Institute for Training and Industrial Engineering and certain actions have been taken to streamline the materials management. The Task Force has so far worked on identification of non-moving stock, material codification and physical lay out of stores. The Committee recommend that the Task Force should complete its work soon so that inventory control is put on sound footing without delay and the management should report progress made in this regard to the Board.

The Committee stress the need for timely remedial measures so that inventories are put on most rational and economic basis in the interest of production.

Working Results

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The Committee regret to note that though the number of employees had gradually increased from 2,026 in 1967-68 to 2,568 in 1973-74 and the average earnings per employee have also correspondingly increased from Rs. 6,135 to Rs. 10,167 the average sales per employee has come

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down from 31,916 to Rs. 30,580. The Committee cannot but conclude from this that the productivity of employees has been going down from year to year and the undertaking does not appear to have taken any tangible action to arrest the decline. The Committee recommend that the Corporation should make a critical study of the reasons for the decline in productivity and take concerted measures to bring it up to the optimum level.

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The Committee are led to conclude that the undertaking had been complacent about the general overall profitability in spite of the reduction in profits year after year from 1966-67 and had not taken any effective action to improve the position. The Committee have already pointed out that there had been a lag in the technical development of the strain for penicillin and streptomycin and their consequent effect on production and production costs.

The Committee are constrained to observe the lack of foresight and the serious managerial lapses in properly organising the undertaking to maintain and improve the productivity and profitability. The Committee need hardly stress that it is the primary responsibility of the Management to keep a meaningful watch on the working of the undertaking and take appropriate remedial measures in time to set right any deficiencies. The Committee recommend that the entire matter should be thoroughly investigated with a view to fixing responsibility for these grave and avoidable lapses which have turned a profit-making undertaking into a losing enterprise and a report furnished to the Committee within six months.

The Committee are informed that besides seeking an increase in the selling price of its products, the undertaking has taken certain measures to check the decline in profitability as a result of introduction of new high yield strain

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for streptomycin which has been able to increase its production by 16 per cent during first quarter of 1975-76 and reduce the cost of production and improve utilisation of capacity.

In the case of Penicillin it is stated to be finalising proposals for acquiring improved strain and technology. It has been stated that a new formulation unit has been constructed to increase the output of drugs. A systems approach is being adopted for systematic plant maintenance, proper material management, man-power assessment, etc. As a result of these measures the company expects to turn the corner in 1975-76 and become profitable. The Committee hope that with the steps now taken and with the implementation of the recommendations of the Committee in this report it should be possible for the undertaking to improve the productivity and thereby profitability.

Costing System

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The Committee note that the Company has been following a process costing system only and no standard costing has been introduced. Since the Committee have already, in the relevant sections in the chapter on Production Analysis, given their recommendations in regard to the standard norms, efficiency fixed informally on an ad hoc basis so far, etc. the Committee would like that these standards/norms efficiencies should be reviewed and revised with reference to adoption of new strain and standard costs of each process worked out and adopted for purposes of an effective comparison of actual costs with reference to such standards and analysing variances with a view to taking timely remedial action.

While on one side it is stated that the cost of allocating services to various processes/products

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by meter readings would not be commensurate with the results to be obtained, on the other hand it is stated that meters for controlling production and consumption at important points are in the process of installation and yet allocations to processes/products will still have to be on technical estimates. The Committee do not understand the apparent contradiction in this regard nor the rationale/ reason as to why, even after installation of meters, allocation should be on technical estimates only and not on meter readings which will be more accurate. The Committee are not sure as to how in the absence of reconciliation of cost figures with financial figures, the accuracy of cost figures is proved.

The Committee recommend that the cost sheets duly reconciled with financial accounts and the analysis of the variances should be reviewed and a report of the review and the action taken thereon should receive the special attention of the management and the Board of Directors in the interest of taking timely remedial measures towards reduction of cost. The Committee recommend that the system of cost accounting should be put on a scientific basis and cost reports should form part of quarterly financial reviews to be submitted to the Board of Director be their consideration along with the financial accounts.

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The Committee would like that the undertaking should critically go into each one of the operations and the factors which are contributing to the costs and take suitable action to improve efficiency and reduce consumption of materials bring down the percentage of rejections and wastages and achieve reduction in cost at the different stages and ultimately of the finished products.

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The Committee would also like that R&D should also be closely associated so that they may suggest ways and means of improving the techniques and reducing costs without sacrificing quality of the products.

Credit Control

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The Committee do not see any justification for huge outstanding from private viallers to the extent of Rs. 43 lakhs, when the credit system permits only supplies to them against advance payments. The Committee find that instead of realising the dues of about Rs. 2 crores from the Government departments and private viallers in time the undertaking has obtained Rs. 2 crore as short-term loan for working capital requirement on which it has to pay interest charges. The Committee stress that the Government/HAL should undertake a review of the credit arrangements obtaining so far with a view to ensuring that such arrangements are in the best interests of the undertaking. The Committee would also like that the billing and recovery system should be streamlined so as to ensure realisation of outstandings within the credit periods allowed to the parties. The Committee also recommend that in respect of outstandings in the Government departments, the matter should be taken up with the appropriate Governments/Ministries and amounts realised without further delay.

Savings in Foreign Exchange

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The Committee are glad to note that the Company has been able to effect a net saving in foreign exchange to the extent of over Rs. 10 crores from 1968-69 to 1973-74 by producing drugs which were previously being imported. The Committee expect that the HAL should st-

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rive to contribute more import substitution, develop new technologies towards indigenisation and upscale technology already absorbed with a view to save more in foreign exchange.

Accounting System and Internal Audit

79	8.51 and 8.52	<p>The Committee regret to note that though the undertaking started production as far back as 1961-62, there was neither an accounting manual laying down the detailed procedure for compilation of accounts nor was there a system of reporting the points raised by internal audit and action taken thereon to the Board of Directors. It is stated that these have been introduced and implemented from 1974-75. The Committee need hardly stress that observations and comments made by Audit should receive prompt attention of management at all levels and necessary follow-up action taken expeditiously. The system of cost accounting should be on scientific lines and appraisal thereof should be included in the programme of internal audit.</p>
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The Committee also regret to note that only partial appraisal of the Company's working was made in the year 1974-75 in terms of the recommendations of the Committee on Public Undertakings contained in their Fifteenth Report (4th Lok Sabha) on Financial Management in Public Undertakings which required that the functions of internal audit should include a critical review of systems, procedures and operations as a whole. The Committee emphasise that such a critical appraisal is all the more necessary in a public undertaking which has started losing after making profits for years. The Committee recommend that HAL should implement this recommendation which has been accepted by Gov-

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ernment in letter and spirit. The critical review should also receive the special attention of the management/Board/Government who should take appropriate follow up action.

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