P. A. C. No. 327

PUBLIC ACCOUNTS COMMITTEE
(1971-72)

(FIFTH LOK SABHA)

THIRTY-FOURTH REPORT

[Action taken by Government on the recommendations of the Public Accounts Committee contained in their 125th Report (Fourth Lok Sabha) on Appropriation Accounts (Civil) 1968-69 and Audit Report (Civil), 1970 relating to the Ministry of Health, Family Planning, Works, Housing & Urban Development (Department of Health)]

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Page	Para	Line	For	Read
1.	1.3	Under item (iii)	Insert S.Nos. 5 and 8	
		Under item (iv)	Delete S.Nos. 5 and 8	
3	1.7	6	16th months	16 months
4	1.10	12	i ncharge	incharge
		4th line from bottom	manufactures	manufacturers
15		4	injections or achromy-cin	injections of achromy-cin
		9	These was	There was
		14	In the case	In this case
19		5th line from bottom	ingradient	ingredient
22		19	Depot to in	Depot in
25		8th line from bottom	cheeks	checks
28		18	rostel	hostel
		29	had	have
36		19	defect noticed to	defects noticed in the drugs should be immediately reported to

CONTENTS

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(1971-72)

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Shri T. R. Krishnamachari—*Under Secretary.*

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*Declared elected to the Committee on 3-1-1971 *vice* Shri Niranjan Verma, resigned.

INTRODUCTION

I, the Chairman of the Public Accounts Committee, as authorised by the Committee, do present on their behalf this Thirty-fourth Report on the Action Taken by Government on the recommendations of the Public Accounts Committee contained in their Hundred and Twenty-fifth Report (Fourth Lok Sabha) on Appropriation Accounts (Civil), 1968-69 and Audit Report (Civil), 1970 relating to the Ministry of Health, Family Planning, Works, Housing and Urban Development (Department of Health).

2. On the 8th July 1971, an 'Action Taken' Sub-Committee was appointed to scrutinise the replies received from Government in pursuance of the recommendations made by the Committee in their earlier Reports. The Sub-Committee was constituted with the following Members:

1. Shri B. S. Murthy—*Convener.*
2. Shri Bhagwat Jha Azad
3. Shri Ram Sahai Pandey
4. Shri C. C. Desai
5. Shri Thillai Villalan
6. Shri Shyam Lal Yadav.

—*Members.*

3. The Action Taken Sub-Committee of the Public Accounts Committee (1971-72) considered and adopted this Report at their sitting held on the 24th January, 1972. The Report was finally adopted by the Public Accounts Committee on the 22nd February, 1972.

4. For facility of reference the main conclusions|recommendations of the Committee have been printed in thick type in the body of the Report. A statement showing the summary of the main recommendations|observations of the Committee is appended to the Report (Appendix).

5. The Committee place on record their appreciation of the assistance rendered to them in this matter by the Comptroller and Auditor General of India.

ERA SEZHIYAN,
Chairman,
Public Accounts Committee.

NEW DELHI;
February 22, 1972.
Phalguna 3, 1893 (*S*).

CHAPTER I

REPORT

This Report deals with action taken by Government on the recommendations contained in the Hundred and Twenty-fifth Report of the Public Accounts Committee (Fourth Lok Sabha) on Appropriation Accounts (Civil), 1968-69 and Audit Report (Civil), 1970, relating to the Ministry of Health, Family Planning, Works, Housing and Urban Development (Department of Health), which was presented to the House on the 18th December, 1970.

1.2. Replies to all the 20 recommendations contained in the report have been received from Government.

1.3. The Action Taken Notes/Statements on the recommendations/observations of the Committee contained in the Report have been categorised under the following heads:—

(i) *Recommendations| observations that have been accepted by Government.*

S. Nos. 1, 2, 4, 6, 7, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, and 20.

(ii) *Recommendations|observations which the Committee do not desire to pursue in view of the replies of Government.*

S. No. 3

(iii) *Recommendations|observations replies to which have not been accepted by the Committee and which require reiteration.*

(iv) *Recommendations|observations in respect of which Government* have furnished interim replies.

S. Nos. 5 and 8

Nil

1.4. The Committee will now deal with action taken by Government on some of the recommendations|observations.

Over-indenting of Achromycin injections by Irwin Hospital—Paragraph 1.29 (*S. No.* 2).

1.5. In paragraph 1.29 of their 125th Report (Fourth Lok Sabha), the Committee made the following comments about the over-indenting of Achromycin injections by Irwin Hospital:

"The Committee deprecate the Irwin Hospital's gross over-indenting of Achromycin injections. Against the past annual off-take of 13,600 vials, the hospital ordered 25,000 vials while it could consume only 20,710 vials during the period of one year and four months, between August, 1966 and December, 1967. The Enquiry Officer, appointed after the issue of Audit paragraph, has stated in his report that no basic working sheets were produced by the hospital authorities as to how the demand for 25,000 vials was actually framed. It was deposed to him that the demands for the item were compiled by the Store Keeper on the basis of information he received from doctors incharge of the wards and the trend of expenditure. He has also pointed out that neither the officer-in-charge of stores nor the purchase section, which is under the Director of Medical Services, scrutinised the quantity which was indented for in relation to the average annual off take of the hospital. The Committee find that the instructions about careful assessments of requirements of drugs by the hospitals issued in 1966 pursuant to their observations have also been ignored. The Committee would like to know the steps taken to remedy the situation and action taken against the persons responsible for the gross over-indenting with the attendant consequences in this case."

1.6. The Department of Health in their reply dated 12-8-1971 have stated as follows:—

"The records of utilisation of injections have been thoroughly scrutinised and it has been found that for the year 1965-66, 18,750 vials and not 13,600 as intimated to the Enquiry Officer, were consumed. The demand for 1966-67 was formulated on the basis of above consumption (viz. 18,750 vials) plus the forecast requirements received from the Wards. Thus, there was no over-indenting of the item particularly when 25 per cent excess is purchased for all the life-saving drugs etc. Moreover, the indent for the period in question was checked by the Deputy Medical Superintendent, who is the Incharge of the Purchase Department of the Hospital and by the Medical Officer Incharge Stores.

"Working sheets, as pointed out by the PAC were not maintained properly. Instructions have been issued to remedy this defect."

1.7. The Committee note that although the annual average consumption of Achromycin injections according to the information given to the Enquiry officer was 18,000 vials, the actual consumption during 1965-66 was 18,750. However, the fact remained that as against the quantity of 25,000 vials of the injections indented for one year (1966-67) only 20,710 vials were consumed in 16th months between August, 1966 and December, 1967. The Committee would, therefore, like Government to examine whether the present system of provisioning of medicines on the basis of 25 per cent over the previous year's consumption needs revision in the light of this experience.

Storage conditions in Irwin Hospital and failure to detect visible deterioration of the drug—
Paragraph 1.32 (*S. No.* 5).

1.8. Dealing with the storage conditions in Irwin Hospital and failure to detect the visible deterioration of the drug (Achromycin injections), the Committee observed as follows in paragraph 1.32 of the Report:

> "The Committee find that the DGHS had in a communication addressed to all the Medical Superintendents of major Hospitals in Delhi including the Irwin Hospital as far back as in May, 1966 stated *inter alia* that the stores attached to the hospitals must be placed under the charge of a competent pharmacist who should be responsible for the maintenance of proper storage conditions. He added that the pharmacist-in-charge of the stores should carry out fortnightly inspections of the stocks and that in case he noticed visual signs of deterioration in any drugs, the stocks should be frozen, sending the samples for testing through the local Drugs Inspector. In view of what has happened in this case the Committee have to take the view that these instructions have not been fully followed by the Irwin Hospital. The Committee would like to know whether the responsibility of the person in charge of stores in regard to improper storage conditions and failure to detect the visible deterioration of the drug in this case was examined."

1.9. The Department of Health have furnished the following remarks in their note dated 12-8-1971:—

> **"The hospital authorities are fully aware of the instructions issued by the Directorate General of Health Services. The**

Senior-most Pharmacist of the Institutions Group is Incharge of the Irwin Hospital Pharmacy. He is a qualified Pharmacist. Besides, the Senior Medical Officer is Incharge of the Medicine Stores and it is his duty to see that the instructions are followed.

"At a meeting of State Drug Controllers held in February, 1971, a specific recommendation was made that an adequately qualified pharmacist, preferably a graduate in Pharmacy, should be appointed to supervise the working of the Hospital Store and Pharmacy in all hospitals with 200 or more beds. Instructions have been issued to the State authorities to tighten the quality control measures over the activities of the Hospital Stores and Hospital Pharmacies."

"These instructions, among other things, call for proper supervision and inspection by a qualified and competent person (Page 46)."

"The question of fixing responsibility for unsatisfactory storage does not arise in view of the satisfactory reports both the Drug Controller of India and the Drug Inspector, Delhi Administration."

1.10. The Committee desired to know whether the responsibility of the person in charge of stores in regard to improper storage conditions and failure to detect the visible deterioration of the drug in this case was examined. The Ministry in their reply have merely stated that the question of fixing responsibility for unsatisfactory storage does not arise in view of the satisfactory reports of both the Drug Controller of India and the Drug Inspector, Delhi Administration. As some vials of Achromycin injections were stated to have become discoloured and turned dark brown, by the Drug Inspector who examined the stock and submitted a report on the 19th December, 1967, the Committee fail to understand how the person i ncharge of the stores did not notice the discolouration earlier if he had carried out the fortnightly inspections of stocks regularly as required. The Committee would, therefore,, like to reiterate that the failure in this regard should be investigated and responsibility fixed.

Jurisdiction of Delhi Administration for launching prosecutions against drugs manufactures for supply of defective medicines— Paragraph 1.35 *(S. No.* 8).

1.11. On the question of jurisdiction of Delhi Administration for launching prosecutions against drugs manufacturers for supply of

defective medicines to hospitals in Delhi through the Medical Stores Depots outside Delhi, the Committee made the following recommendation in paragraph 1.35 of the Report:

> "The Committee note that the Delhi Administration had at one stage seriously considered the question of prosecuting the firm but they were advised by the Judicial Department of the Delhi Administration against it on the ground that the Drug Controller, Delhi could not prosecute the firm for want of jurisdiction as the drug in question was supplied by the firm to the Medical Stores Depot, Karnal. The Committee would suggest that the Delhi Administration might take the opinion of the Ministry of Law in the matter for future guidance. They, however, feel that the Central Government could have prosecuted the firm if there was a prima facie case."

1.12. In a reply dated 12th August, 1971, the Department of Health have stated as below:

> "There was no *prima facie* case to show that the manufacturing firm was responsible for the defect in Achromycin injection. The fact that supplies from the same batches used by other hospitals and institutions did not produce any adverse reaction or had not been reported to have changed colour and the fact that the investigations carried out by the Director, Drug Control Administration, Gujarat on the record samples from the same batch maintained by the manufacturing firm did not reveal any deficiencies, gave sufficient indication that the cause for the defects noticed by the Irwin Hospital authorities had to be established by checking on the conditions of storage of the drug from the point it left the manufacturer's premises."

1.13. The Committee suggest that the question of jurisdiction of Delhi Administration for launching prosecution against manufacturers of drugs for supply of defective medicines through Medical Stores Depots located outside Delhi should be examined in consultation with the Ministry of Law for future guidance. The Committee wish that this had been done earlier as they had specifically raised this point in their 125th Report (Fourth Lok Sabha).

Continued use of 'spotted' tablets after noticing the defect— Paragraphs 1.59, 1.60 and 1.61 *(S. Nos.* 12, 13 *and* 14).

1.14. In paragraphs 1.59, 1.60 and 1.61 of the Report, the Committee made the following observations regarding the continued use of

'spotted' Ferrous Sulphate Sugar-coated tablets even after noticing the defect:

> "1.59. The Committee regret to note that although the Irwin Hospital complained that the tablets in a majority of the tins were 'spotted' and the Drug Inspector also found spotted tablets in all the tins opened by him (pertaining to seven manufacturing batches) a sample from only one batch was sent for analysis with the result, further use of the tablets pertaining to that one batch alone was stopped."

> "1.60. It is regrettable that some quantities of tablets (0.51 lakh) were issued by the Irwin Hospital even after the defect in them had been reported to the Controller of Drugs by them."

> "1.61. The Committee would like Government to fix responsibility as to why samples were not sent to Central Government testing laboratory from all the manufacturing batches which appeared to be defective and why effective action was not taken by the Hospital forthwith to suspend issue of the medicine to the patients."

1.15. In their note dated 12th August, 1971, the Department of Health have stated that on scrutiny by the Medical Superintendent, Irwin Hospital, it was found that on 20th November, 1967 the Bin Cards showed a balance of 3.23 lacs tablets of Ferrous Sulphate. The Drugs Inspector had, however, found only 2.72 lacs tablets on that date. According to the Department of Health, it is therefore reasonable to surmise that the so called subsequent issues of 0.51 lacs tablets were made on a date prior to 20th November, 1967 but the entries on sub-store bin cards were irregularly made on subsequent dates. Instructions have been issued to ensure that Bin Cards and other relevant records are maintained upto-date. Necessary instructions have also been issued by the Delhi Administration to the Drugs Inspector that in case of suspicion, sample should be taken of all the suspected batches for test, (vide their order No. 1(23)/71-DHS dated the 9th March, 1971—Pages 40-41).

The Department of Health have further stated that although the Drugs Inspector had drawn samples only from one batch and sent for test to the Central Drugs Laboratory, Calcutta, further issue of this drug was suspended from the Central Stores of the hospital.

1.16. The Committee are surprised that the earlier issues of the Ferrous Sulphate Tablets pertaining to the period prior to 20th November, 1967 were irregularly entered in the bin cards after the inspection by the Drug Inspector. The Committee suggest that responsibility for not maintaining the bin cards properly should be fixed.

Possibility of life-expired tablets being administered due to non-indication of the date of expiry of life—

Paragraph 1.63 (*S. No.* 16).

1.17. Observing that the date of expiry of life of the tablets was not indicated on the batches, the Committee made the following observation:

> "The Committee have also noticed that though the batches showed the date of manufacture of the tablets they did not indicate the date of expiry of their life. In the absence of such a vital fact the possibility of the medicine being administered beyond its useful life cannot be ruled out. The Committee would like to know what action Government propose to take to guard against such a contingency."

1.18. In their reply dated 12th August, 1971, the Department of Health have stated:

> "It may be mentioned that only drugs such as Sera, vaccines, anti-biotics, hormones and other thermolabile drugs, which deteriorate or are likely to acquire undue toxicity on storage, are required to bear on their label the date of expiry. The Drugs Technical Advisory Board which is a statutory body to advise the Central and State Governments on technical matters arising out of the administration of the Drugs and Cosmetics Act, had considered the question of laying down the date of expiry of drugs. A list of all drugs which require the display of a date of expiry and the maximum period upto which the date of expiry should be calculated for each category of drugs, was drawn up by the Drugs Technical Advisory Board (on the basis of the recommendation made by a Sub-Committee of the Board which went into the question in all its aspects). The board did not include Ferrous Sulphate Tablets in the new Scheduled—P. to the Drugs and Cosmetics Rules which gives such date of expiry. None

of the Pharmacopoeias suggest a date of expiry for this drug.

"Ferrous Sulphate Tablets are made with 'Ferrous Sulphate' which is likely to be oxidised if the active substance in the tablet comes in contact with air. Ferrous Sulphate Tablet is, therefore, required to be sugar coated. In a tropical country like India, the sugar-coating may peel off on keeping and result in the development of the dark 'patches' or 'spots'. Recently the Drugs Consultative Committee, which consists of the Central and State Drugs Control authorities, had recommended that Ferrous Sulphate Tablets could be prepared by shellac coating. If this method of coating is adopted by manufacturers, the scope for the peeling of the coating, as it often happens with sugar coated tablets, will be reduced considerably. In view of this, it may not be necessary to lay down the date of expiry for Ferrous Sulphate Tablets in the Drugs and Cosmetics Rules. It may be added that therapeutic agents which are made from stable chemicals generally do not bear a date of expiry of potency.

"However, manufacturers of Ferrous Sulphate tablets have been advised to adopt film or shellac coating for the tablets instead of sugar coating and that in the event of the tablets being sugar-coated show a cautionary note that the tablets should not be used if they are discoloured or spotted."

1.19. The Committee note that manufacturers of Ferrous Sulphate Tablets have been advised to adopt film or shellac coating for the tablets instead of sugar-coating; or, in the event of the tablets being sugar-coated, show a cautionary note that the tablets should not be used if they are discoloured or spotted. The Committee would, however, suggest that it should be examined whether instead of sugar-coating, film or shellac coating of the tablets should not be made obligatory to avoid health hazards due to peeling off of sugar-coating.

Lapse in the implementation of Planning Commission's decision regarding Central assistance for training nurses—

Paragraph 1.76 (*S. No.* 18).

1.20. Dealing with a lapse in the implementation of the decision of the Planning Commission regarding Central assistance admissible

to institutions/hospitals for training nurses under the scheme of integration of public health with basic course in nursing, the Committee, in paragraph 1.76 of the Report, made the following comments:

> "The Committee regret to observe that there was a serious lapse in implementing the decision of the Planning Commission regarding central assistance admissible to the various institutions/hospitals for training nurses under the scheme of integration of public health with basic course in nursing. Although the assistance approved for the Second Plan period was substantially curtailed by the Planning Commission for the Third Plan period, the Ministry of Health continued to give assistance as per the formula approved for the Second Plan period till the overpayment was brought to notice by the Finance Secretary in October, 1967. According to the Ministry of Health the instructions of the Planning Commission reducing the scales of assistance for the Third Plan period were not received by them. An enquiry held into the matter revealed that the Planning Commission's orders could not be proved to have reached the concerned section in the Ministry of Health. Although at the time of making the budget provision the files were referred to the Ministry of Finance they failed to detect that the Ministry of Health had not made the provision in accordance with the revised formula approved by the Planning Commission as according to the representative of Finance at that stage no detailed check of individual proposals was contemplated. The Committee would like to know what checks are available now to prevent a mistake of the kind that occurred in this case, either on account of non-receipt of the communication from the Planning Commission or through an oversight. The Committee desire that there should be a second look at the pattern adopted by the various Ministries for the Plan assistance by the Ministry of Finance."

In their reply dated 29th July, 1971, the Department of Health have stated as follows:

1.21 "There are two types of schemes included in the Fourth Plan namely Purely Central Schemes and Centrally Sponsored Schemes. Purely Central Schemes are those for which budget provision is normally made in the grants controlled by the ministries administering the schemes. For Central-

ly Sponsored Schemes the budget provision is made in the grants controlled by the Ministry of Finance and assistance is initially given through ways and means advances and regularised at the end of the year by issuing provisional sanction for grants-in-aid followed by final sanction later after the State Governments furnish certified expenditure figures.

With reference to the Committee's query as to what checks are now available to prevent a mistake of the kind that occurred in this case either on account of non-receipt of communication from the Planning Commission or through an oversight it may be mentioned that the following checks are available—

1. During the Fourth Plan period all Centrally Sponsored Schemes are financed by 100 per cent Central grant/loans and as such there is no scope for making overpayments.

2. While formulating budget proposals for the Plan Schemes, the administrative Ministry invariably indicates the allocation agreed to by the Planning Commission for the particular scheme.

3. All sanction letters laying down the pattern invariably indicate that it has the concurrence of the Ministry of Finance.

4. Where, in exceptional cases, provisions are made in the budget pending finalisation of the pattern, the administrative Ministry ensures that no expenditure is incurred until the pattern has been laid down in consultation with the Planning Commission/Ministry of Finance.

5. At the time of issue of final sanction releasing the Central assistance in respect of Centrally sponsored schemes, the Ministry ensures that the quantum of grants released is based on the approved pattern and the amounts agreed to by the Finance Ministry.

6. According to the procedure laid down for the release of Central assistance for Centrally Sponsored Schemes copies of the sanction letters and the explanatory notes if any, are invariably sent to Plan Finance Division"

As regards the second point made out by the Committee that there should be a second look at the pattern adopted by

the various Ministries of the plan assistance by the Ministry of Finance this is primarily for the Ministry of Finance to look into. It may however be mentioned that this Ministry in the Department of Health has already made a detailed scrutiny of the various schemes in operation during the 4th Plan and it has been found that assistance has invariably been released after the pattern/proposal has been accepted by the Planning Commission/Ministry of Finance. There are however a few schemes where the pattern of assistance has yet to be laid down. The Planning Commission/Ministry of Finance will as usual be consulted before final decision on these matters are taken by this Ministry."

1.22. The Committee wish to reiterate that their earlier recommendation that there should be a second look by the Ministry of Finance at the pattern adopted by the various Ministries for Plan assistance should be examined by the Ministry of Finance.

CHAPTER II

RECOMMENDATIONS/OBSERVATIONS THAT HAVE BEEN ACCEPTED BY GOVERNMENT

Recommendation

The Committee take serious note of the series of lapses in this case in regard to indenting, inspection, storage and issue of the life saving drug Achromycin in the Irwin Hospital, New Delhi. These lapses resulted in not only deterioration of the drug but also produced adverse reactions of the patients. There was also inordinate delay in giving warning about the deficiency and adverse effects of the injections to the supplying agency and the hospitals and others to whom these had been supplied out of the affected batches.

[S. No. 1 of Appendix II (Para 1.28) of 125th Report (4th Lok Sabha)].

Action taken

The indenting system followed in the Irwin Hospital is based on the previous years consumption and subsequent demand from the user ward. Usually 25 per cent excess demand is made in the subsequent year. This procedure has been advantageous in the past and has proved the test of time and no accumulation has taken place in past years.

The senior-most pharmacist is incharge of the drug store and he is constantly available in the store. He inspects every drug that is issued to the wards. The storage facility available has been inspected by both the Drug Controller of Delhi and Drug Controller, Government of India and the arrangement has been found adequate. The adverse effect of the injection was reported to the Drugs Controller, Delhi after a week. This delay was due to the time taken to check whether the defect was inherent in the drug or there were deficiencies in the method of administration of the drug to the patients.

[Ministry of Health & Family Planning (Department of Health) letter No. F. 12-39/70-H (Pt. II), dated 12-8-1971].

Recommendation

The Committee deprecate the Irwin Hospital's gross over-indenting of Achromycin injections. Against the past annual off take of

13,600 vials, the hospital ordered 25,000 vials while it could consume only 20,710 vials during the period of one year and four months, between August, 1966 and December, 1967. The Enquiry Officer, appointed after the issue of Audit paragraph, has stated in his report that no basic working sheets were produced by the hospital authorities as to how the demand for 25,000 vials was actually framed. It was deposed to him that the demands for the item were compiled by the Store Keeper on the basis of information he received from doctors incharge of the wards and the trend of expenditure. He has also pointed out that neither the officer-in-charge of stores nor the purchase section, which is under the Director of Medical Services, scrutinised the quantity which was indented for in relation to the average annual offtake of the hospital. The Committee find that the instructions about careful assessments of requirements of drugs by the hospitals issued in 1966 pursuant to their observations have also been ignored. The Committee would like to know the steps taken to remedy the situation and action taken against the persons responsible for the gross over indenting with the attendant consequences in this case.

[S. No. 2 of Appendix II (Para 1.29) of 125th Report (4th Lok Sabha)].

Action taken

The records of utilisation of injections have been thoroughly scrutinised and it has been found that for the year 1965-66, 18,750 vials and not 13,600 as intimated to the Enquiry Officer, were consumed. The demand for 1966-67 was formulated on the basis of above consumption (*viz.* 18,750 vials) plus the forecast requirements received from the Wards. Thus, there was no over-indenting of the item, ptrticularly when 25 per cent excess is purchased for all the life-saving drugs etc. Moreover, the indent for the period in question was checked by the Deputy Medical Superintendent, who is the Incharge of the Purchase Department of the hospital and by the Medical Officer Incharge Stores.

Working sheets, as pointed out by the PAC were not maintained properly. Instructions have been issued to remedy this defect.

[Ministry of Health & Family Planning (Department of Health) letter No. 12-39/70-H, (Pt. II) dated 12th August, 1971]

Recommendation

The Committee feel that this controversy could have been avoided had a representative of the Delhi Administration been associated with the enquiry from the beginning.

[S. No. 4 of Appendix II (Para. 1.31) of 125th Report (4th Lok Sabha)]

Action taken

The Delhi Administration were consulted regarding the composition of the Enquiry Committee and they had intimated that they had no objection to an officer of the Directorate General of Health Services looking into the conditions of storage and supply of the medicines in Irwin Hospital. The Delhi Administration at that time did not suggest the Association of their representative with the Enquiry Committee.

[Ministry of Health & Family Planning (Department of Health) letter No. F. 12-39/70-H (Pt. II) dated 12th August, 1971]

Recommendation

According to the Ministry the doctors/nurses in the ward administering the achromycin injections could have noticed the discolouration depending on the degree of deterioration. The Committee are at a loss to know how the deterioration escaped notice although according to the drug inspector the contents of some vials stored in the hospital had become discoloured and turned dark brown when he examined them on the 16th December, 1967. It is unfortunate that enquiry was instituted after a lapse of 2-1/2 years from this date by which time all the House physicians who were working in the wards were stated to have left the institution. The Committee, however, find from the statement given before the Enquiry Officer by a Sister that she continued to observe the adverse effects of the injections for a week whereafter the matter was reported by her to the medical officer and the store keeper. But no written complaint was made to the Registrar and the Medical Superintendent. The Committee feel unhappy over the continued use of the drug for a week even after noticing the adverse effects. The Committee cannot too strongly stress that written record duly verified by doctors on duty should have been maintained so that it could be used to bring home to the supplier the defective nature of supplies.

[S. No. 6 of Appendix II (Para 1.33) of 125th Report (4th Lok Sabha)]

Action taken

Although it is a fact that some of the drug samples taken by the Drug Inspector were found to be discoloured, the discolouration

of the contents of the Vials actually used in the Hospital was not noticed by the Doctor or the Nurses. The first thing noted by the House Surgeons and Nurses in the ward was that abscess formation took place after injections or achromycin and the fault could have been either with the drug or with improper sterilisation of the syringes and needless. The weeks delay in reporting to the Drug Inspector was because of the investigations that were made to exclude possibility of contamination by use of unsterile syringes.

The absence of a written complaint was an omission. These was no doubt, delay in instituting an enquiry.

[Ministry of Health & Family Planning (Department of Health) letter No. F. 12-39/70-H (Pt. II) dated 12th August, 1971].

Recommendation

The Committee find that in the case there was a delay of one month in reporting the deterioration of the drug to the Drug Control Administration, Gujarat and of three months in reporting to the Medical Stores Depot, Karnal. The testing of the sample by the Government Analyst, Calcutta, took more than three months. The Committee deprecate such delays. They in particular would like to emphasise that with a view to immediately preventing further use of any sub-standard drug by all the institutions in the country any deterioration noticed in drugs should be promptly reported on telephone or telegraphically to the supplying medical stores depots who should in turn advise suitably without delay all the depots and indent holders concerned to suspend immediately administration of such a drug pending detailed analysis so as to obviate any risk to the lives of patients by the continued use of the sub-standard drug.

[S. No. 7 of Appendix II (Para 1.34) of 125th Report (4th Lok Sabha)]

Action taken

The delay pointed out by the Public Accounts Committee did take place but instructions are being issued to obviate this in future.

Comprehensive instructions have been issued to all the depots *vide* para 15 and 16 of Instructions issued with the Directorate General of Health Services Memorandum No. 17-52/70-S.II, dated the 8th September, 1970 and No. 17-52/70-S.II, dated the 23rd April, 1971 (Annexure I and II, pages 29—35).

In regard to the time taken for testing by the Government Analyst, Calcutta it may be stated that the Central Drugs Laboratory, Calcutta is engaged in the testing of samples sent to it by (a)

the Port Officers from imported consignments, (b) disputed samples sent by courts, and (c) samples sent by the State Drugs Inspectors. The Central Drugs Laboratory is at present acting as a Government Analyst for 16 States and Union Territories. The work-load on the Central Drugs Laboratory is much more than it can shoulder. This is the main reason for the time taken in the issue of the test reports. In order to ensure speedy issue of test reports, it is necessary that the testing facilities of the Central Drugs Laboratory at Calcutta are augmented. Under the Fourth Five Year Plan, it is proposed to expand the Central Drugs Laboratory so that its testing capacity is increased three-fold which *inter alia* will also ensure that such delays in issuing test reports do not occur.

The need for expediting reports on certain urgent samples was considered by the Drugs Consultative Committee, which is a Statutory body, constituted under the Drugs and Cosmetics Act and which consists of the Central and State Drugs Control Authorities. It was agreed that whenever samples of drugs are required to be tested on a priority basis the State Drug Control Authorities should write to the Director, Central Drugs Laboratory, Calcutta demi-officially indicating the background of the case against which the sample has been sent so that priority could be accorded, for testing. The Director, Central Drugs Laboratory, will, in such cases, ensure that the test report is issued expeditiously. This will minimise the chances of delay in issuing reports on urgent samples.

As regards the question of speedily communicating the contents of the test reports to the Medical Store Depots, in case the supply has been made from a Depot, necessary instructions in this connection have been issued to the State Drugs Control authorities. A copy of the letter is attached (Annexure III, page 35-37).

[Ministry of Health & Family Planning (Department of Health) letter No. F. 12-39/70-H (Pt. II) dated 12th August, 1971].

Recommendation

Another disquieting feature that has come to light is that though the Medical Store Depot, Karnal, has two cold storage rooms, these get completely filled at times and the medicines required to be stored at a particular temperature are not kept there. According to the Enquiry Officer, this was one such occasion and the storage instructions for this drug were not complied with by the Medical Store Depot.

[S. No. 9 of Appendix II (Para 1.36) of 125th Report (4th Lok Sabha)]

Action taken

Detailed instructions have been issued to the Depots from time to time *vide* the Directorate General of Health Services Memo No. 17-52/70-11, dated the 8th September, 1970 (Annexure I, pages 29—33), 14th May, 1970 (Annexure IV, pages 37—39) and No. 17-27/70-S. II, dated the 31st October, 1970 (Annexure V, pages 39-40).

[Ministry of Health & Family Planning (Department of Health) letter No. F. 12-39/70-H (Pt. II) dated 12th August, 1971].

Recommendation

The Committee hope that learning from this case the Government would institute necessary remedial action to remove all the defects and deficiencies in the system. The Committee would in particular like the following to be attended to:—

(i) The indenting procedure followed in the Irwin Hospital and other hospitals should be rationalised to avoid over-provisioning of medicines. The supplies of medicines should be properly phased during the year according to requirements so that due to lack of proper storage accommodation these are not kept under adverse storage conditions.

(ii) There should be periodical and thorough inspection of medicines in the stores by competent and fully qualified persons.

(iii) It should be ensured that analytical facilities provided in the Central laboratories are adequate so that the samples sent to these laboratories are tested immediately and the results are made available within a short time.

(iv) Cold storage facilities in various hospitals/stores should be reviewed and where these facilities are lacking or are inadequate, special steps may be taken to provide them on a top priority basis so that in all the hospitals/stores there is adequate capacity to keep injections and other medicines which are liable to deterioration.

(v) Remedial measures suggested by the Hospital Review Committee which carried out a detailed examination of the hospitals in Delhi as also those suggested by the Inquiry Officer for adoption by the hospitals and Medical Stores Depots should be speedily implemented.

[S. No. 10 of Appendix II (Para 1.37) of 125th Report (4th Lok Sabha)]

Action taken

The Delhi Administration have taken steps to comply with all the suggestions made by the Committee.

Purchase Committee has been constituted in Irwin Hospital to scrutinise the demand of all items. This Committee ensures that excessive demand is checked and phasing of supply is ensured. The Central Drugs Inspectors are visiting the stores of the hospitals in Delhi frequently and any defects noticed are being pointed out to the authorities.

The storage facility at Irwin Hospital as already stated above was considered adequate by the Drug Control Authority. An additional room, however, has been added where items requiring storage at lower temperature are kept.

Stores are being inspected and checked more frequently by the Drug Control Authority besides the check exercised by Medical Officer Incharge of Stores.

Remedial measures as suggested by both the Hospital Review Committee as also by the Enquiry Officer have already been taken as per instructions attached to the Directorate General of Health Services Memo. No. 17-52/70-S.II, dated the 8th September, 1970 (Annexure I, page 29). Periodical checks of stores held in stock are also carried regularly.

In regard to the time taken for testing by the Government Analyst, Calcutta, it may be stated that the Central Drugs Laboratory, Calcutta is engaged in the testing of samples sent to it by (a) Port Officers from imported consignments, (b) disputed samples sent by courts, and (c) samples sent by the States Drugs Inspectors. The Central Drugs Laboratory is at present acting as the "Government Analyst" for 16 States and Union Territories. The work load on the Central Drug Laboratory is much in excess of what it can shoulder. This is the main reason for the delay in the issue of test reports. In order to ensure that samples sent to the Central Drugs Laboratory are speedily reported on, it is necessary that the testing facilities of the Central Drugs Laboratory in Calcutta are augmented. Under the Fourth Five Year Plan, it is proposed to expand the Central Drugs Laboratory so that its testing capacity is increased three-fold which, *inter-alia*, will also ensure that such delays in test report do not occur.

[Ministry of Health & Family Planning (Department of Health) letter No. 12—39/70—H (Pt. II) dated 12-8-1971)].

Recommendation

The Committee note that the Government Analyst who tested the sample observed that the medicine was not of acceptable quality. The firm was granted permission to manufacture ferrous sulphate tablets in 1958 and in view of the inability of the firm to manufacture the product of acceptable quality, due to improper techniques adopted, as revealed in this case, the permission was withdrawn and the firm was asked on 18th January, 1969 to stop manufacture of these tablets. The Committee are shocked to note that a firm without employing proper manufacturing techniques continued to manufacture a medicine for 10 years without being detected. The Committee desire that there should be periodical follow-up action after the grant of licences to check up whether the firms in fact possessed the capacity including necessary techniques to manufacture drugs of the expected quality and whether they were employing the same for manufacturing their products.

S. No. 11 of Appendix II (Para 1.58) of 125th Report (4th Lok Sabha)]

Action taken

The firm M/s....who are the manufacturers of Ferrous Sulphate Tablets, were granted licence for manufacture of drugs in the year 1951 but at that time they were not permitted to manufacture tablets. Permission to manufacture tablets was given to the firm on the 24th December, 1958. Permission for manufacture of sugar coated tablets, like Ferrous Sulphate tablets was given for the first time on the 4th March, 1964. The firm possessed adequate premises, necessary machinery and equipment as required under the provision of Drugs and Cosmetic Act and Rules for manufacture of drugs, including sugar-coated tablets. The premises of the firm have been regularly inspected. During the last five years, 13 such inspections were carried out. The sample of Ferrous Sulphate Tablets under reference was declared *not* of acceptable quality by the Government Analyst for the sole reason that there were dark patches on tablets. According to the Government Analyst's report, the sample had passed the tests for:—

(i) identification of ingradient:

(ii) disintegration of tablets:

(iii) uniformity of weight of tablets: and

(iv) Assay *viz.* percentage of main active therapeutic ingredient *i.e.* Ferrous Sulphate.

It may, however, be stated that the defect in the Ferrous Sulphate Tablets under reference was such that even if a manufacturer possessed adequate premises, necessary machinery and equipment and the technical competence to produce the drug, the sugar coating on the tablets may peel off because of the extremely hot and humid climate prevailing in many parts of the country. One of the ways to avoid such deficiency would be to provide an alternative coating for Ferrous Sulphate Tablets. This aspect was examined by the Drugs Consultative Committee which has recommended that Ferrous Sulphate Tablets may be permitted to be manufactured by shallac coating. If this method of coating is adopted by manufacturers the scope for peeling-off of the coating as it often happens with sugar-coated tablets, will be reduced, considerably.

It is, however, being ensured that after permission to manufacture a preparation is granted, samples are drawn from the first few batches, manufactured by the firm in order to ascertain that the firm is in a position to manufacture the product of proper quality. A running check is also proposed to be kept on the quality of the product, if necessary by drawing samples till the licensing authority is satisfied that the firm has the necessary competence to manufacture quality product. The State Drugs Control Authorities are being requested to take similar action keeping in mind the observations of the Public Accounts Committee.

[Ministry of Health & Family Planning (Department of Health) letter No. F. 12-39|70-H (Pt. II) dated 12th August, 1971]

Recommendation

The Committee regret to note that although the Irwin Hospital complained that the tablets in a majority of the tins were 'Spotted' and the Drug Inspector also found spotted tablets in all the tins opened by him (pertaining to seven manufacturing batches) a sample from only one batch was sent for analysis with the result, further use of the tablets pertaining to that one batch alone was stopped.

[S. No. 12 of Appendix II (Para 1.59) of 125 in Report (4th Lok Sabha)].

Action taken

Further enquiries and verifications were made by the Medical Superintendent, Irwin Hospital. It appears that on 20th November, 1967 the Bin Cards show a balance of 3.23 lakh tablets of Ferrous Sulphate. The Drugs Inspector, however, found only 2.72 lacs tablets, on that date. It is therefore, reasonable to surmise that the so called subsequent issues of 0.51 lakh tablets were in actuality

issued on a date prior to 20th November, 1967 but the entries in sub-store bin cards were made on subsequent dates.

Steps are being taken to avoid such mistakes in the maintenance of bin cards.

[Ministry of Health & Family Planning (Department of Health) letter No. F. 12-39/70-H (Pt. II) dated 12th August, 1971].

Recommendation

It is regrettable that some quantities of tablets (0.51 lakh) were issued by the Irwin Hospital even after the defect in them had been reported to the Controller of Drugs by them.

[S. No. 13 of Appendix II(Para 1.60) of 125th Report (4th Lok Sabha)].

Action taken

On scrutiny by the Medical Superintendent, Irwin Hospital, it has been found that on 20th November, 1967 the Bin Cards show a balance of 3.23 lacs tablets of Ferrous Sulphate. The Drugs Inspector, however found only 2.72 lacs tablets on that date. It is therefore, reasonable to surmise that the so called subsequent issues of 0.51 lacs tablets were made on a date prior to 20th November, 1967 but the entries on sub-store bin cards were irregularly made on subsequent dates. Instructions have been issued to ensure that Bin Cards and other relevant records are maintained upto date.

[Ministry of Health & Family Planning (Department of Health) letter No. 12—39/70—H (Pt. II) dated 12-8-1971)]

Recommendation

The Committee would like Government to fix responsibility as to why samples were not sent to Central Government testing laboratory from all the manufacturing batches which appeared to be defective and why effective action was not taken by the Hospital forthwith to suspend issue of the medicine to the patients.

[S. No. 14 of Appendix II(Para 1.61) of 125th Report (4th Lok Sabha)].

Action taken

Necessary instructions have been issued by the Delhi Administration to the Drugs Inspector *vide* their order No. F. I(23)/71—DHS dated the 9th March, 1971 (Annexure VI, Pages 40-41).

Although the Drugs Inspector had drawn the samples only from one batch and sent for test to the Central Drugs Laboratory, Cal-

cutta, further issue of this drug was suspended from the Central Stores of the hospital.

Further enquiries and verifications were made by the Medical Superintendent, Irwin Hospital. It appears that on 20th November, 1967 the Bin Cards show a balance of 3.23 lakh tablets of Ferrous Sulphate but the Drugs Inspector, however, found only 2.72 lacs tablets, on that date. It is therefore, reasonable to surmise that the so called subsequent issue of 0.51 lakh tablets was in actuality issued on a date prior to 20th November, 1967 but the entries in sub-store bin cards were made on subsequent dates.

[Ministry of Health & Family Planning (Department of Health) letter No. 12-39|70—H (Pt. II) dated 12-8-1971].

Recommendation

The Committee are distressed to learn that the defect noticed in the tablets in November, 1968 was not intimated to the Medical Stores Depot, Karnal by the Irwin Hospital/Drug Controller, Delhi until November, 1969 although the Government Analyst's report had been received in April, 1969. Strangely enough it was the firm which first reported the matter to the Depot to in August, 1969 and it took 2 months for the Depot to instruct all the institutions to whom they had distributed the tablets to discontinue their further use. The Committee strongly deprecate the gross delay of about a year in issuing instructions to indentor hospitals regarding the defective nature of supplies. As suggested earlier in the report any defects noticed in the drugs should be immediately reported to the supplying medical stores depot who should arrange to inform all the depots and hospitals with a view to promptly suspending further use.

[S. No. 15 of Appendix II(Para 1.62) of 125th Report (4th Lok Sabha)]

Action taken

Although the use of the drug was suspended in the Irwin Hospital, the Drugs Controller, Delhi was informed about the defects on 20th November, 1968. The Hospital authorities did not inform Medical Stores Depot, Karnal which they should have done.

The Depot has been directed *vide* Directorate General of Health Services letter No. 17—52/70-S.II, dated th. 23rd April, 1971 (Annexure II, pages 34-35) to report to D.G.A.F.M.S. and other Depots: on the very date a sub-standard drug comes to their notice for the indentors of the Depot proper it may take another 24 hours.

As regards the suggestion that Medical Store Depots should be quickly apprised of the results of the test reports, wherever the drugs are not found to be of standard quality instructions have already been issued to the State Drugs Control authorities, *vide* comments against para 1.34.

[Ministry of Health & Family Planning (Department of Health) letter No. 12—39|70—H (Pt. II) dated 12-8-1971].

Recommendation

The Committee have also noticed that though the batches showed the date of manufacture of the tablets they did not indicate the date of expiry of their life. In the absence of such a vital fact the possibility of the medicine being administered beyond its useful life cannot be ruled out. The Committee would like to know what action Government propose to take to guard against such a contingency.

[S. No. 16 of Appendix II(Para 1.63) of 125th Report (4th Lok Sabha)].

Action taken

It may be mentioned that only drugs such as Sera, vaccines, anti-biotics, hormones and other thermolabile drugs, which deteriorate or are likely to acquire undue toxicity on storage, are required to bear on their label the date of expiry. The Drugs Technical Advisory Board which is a statutory body to advise the Central and State Governments on technical matters arising out of the administration of the Drugs and Cosmetics Act, had considered the question of laying down the date of expiry of drugs A list of all drugs which require the display of a date of expiry and the maximum period upto which the date of expiry should be calculated for each category of drugs, was drawn up by the Drugs Technical Advisory Board (on the basis of the recommendation made by a Subcommittee of the Board which went into the question in all its aspects). The board did not include Ferrous Sulphate Tablets in the new Scheduled-P to the Drugs and Cosmetics Rules which gives such date of expiry, None of the Pharbacopoeias suggest a date of expiry for this drug.

Ferrous Sulphate Tablets are made with 'Ferrous Sulphate' which is likely to be oxidised if the active substance in the tablet comes in contact with air. Ferrous Sulphate Tablet is, therefore, required to be sugar coated. In a tropical country like India, the

sugar-coating may peel off on keeping and result in the development of the dark 'patches' or 'spots'. Recently the Drugs Consultative Committee, which consists of the Central and State Drugs Control authorities, had recommended that Ferrous Sulphate Tablets could be prepared by shallac coating. If this method of coating is adopted by manufacturers, the scope for the peeling of the coating, as it often happens with sugar-coated tablets, will be reduced considerably. In view of this, it may not be necessary to lay down the date of expiry for Ferrous Sulphate Tablets in the Drugs and Cosmetics Rules. It may be added that therapeutic agents which are made from stable chemicals generally do not bear a date of expiry of potency.

However, manufacturers of Ferrous Sulphate tablets have been advised to adopt film or shellac coating for the tablets instead of sugar coating and that in the event of the tablets being sugar-coated show a cautionary note that the tablets should not be used if they are discoloured or spotted.

[Ministry of Health & Family Planning (Department of Health) letter No. F. 12—39|70—H (Pt. II) dated 12-8-1971].

Recommendation

The Committee were given to understand that the rate contracts for the purchase of ferrous sulphate tablets were introduced only on the Ist April, 1968. A suggestion to enter into firm contracts for the purchase of drugs is stated to be under the consideration of the Government in order to avoid delay in supply by the firms whenever there is scarcity in the market. The Committee would like the Government to come to an early decision in the matter.

[S. No. 17 of Appendix II (Para 1.64) of 125th Report (4th Lok Sabha)].

Action taken

The Ministry of Supply have since agreed to enter into firm contracts *vide* Shri ..... Joint Secretary's D.O. letter No. PI-16(28)|71, dated the 16th June, 1971 (Annexure VII,, page 41).

[Ministry of Health & Family Planning (Department of Health) letter No. F. 12—39|70—H (Pt. II) dated 12-8-1971].

Recommendation

The Committee regret to observe that there was a serious lapse in implementing the decision of the Planning Commission regarding central assistance admissible to the various institutions/hospitals for training nurses under the scheme of integration of public health

with basic course in nursing. Although the assistance approved for the Second Plan period was substantially curtailed by the Planning Commission for the Third Plan period, the Ministry of Health continued to give assistance as per the formula approved for the Second Plan period till the overpayment was brought to notice by the Finance Secretary in October, 1967. According to the Ministry of Health the instructions of the Planning Commission reducing the Scales of assistance for the Third Plan period were not received by them and enquiry held into the matter revealed that the Planning Commission's orders could not be proved to have reached the concerned section in the Ministry of Health. Although at the time of making the budget provisions the files were referred to the Ministry of Finance they failed to detect that the Ministry of Health had not made the provision in accordance with the revised formula approved by the Planning Commission as according to the representative of Finance at that stage no detailed check of individual proposals was contemplated. The Committee would like to know what checks are available now to prevent a mistake of the kind that occurred in this case, either on account of non-receipt of the communication from the Planning Commission or through an oversight. The Committee desire that there should be a second look at the pattern adopted by the various Ministries for the Plan assistance by the Ministry of Finance.

[S. No. 18 of Appendix II (Para 1.76 of 125th Report (4th Lok Sabha)].

Action taken

There are two types of schemes included in the Fourth Plan namely Purely Central Schemes and Centrally Sponsored Schemes. Purely Central Schemes are those for which budget provision is normally made in the grants controlled by the Ministries administering the schemes. For Centrally Sponsored Schemes the budget provision is made in the grants controlled by the Ministry of Finance and assistance is initially given through ways and means advances and regularised at the end of the year by issuing provisional sanction for grants-in-aid followed by final sanction later after the State Governments furnish certified expenditure figures.

With reference to the Committee's query as to what cheeks are now available to prevent a mistake of the kind that occurred in this case either on account of non-receipt of communication from the Planning Commission or through an oversight it may be mentioned that the following checks are available:—

(1) During the 4th Plan period all Centrally Sponsored Schemes are financed by 100 per cent Central grants/loans and as such there is no scope for making over payments.

(2) While formulating budget proposals for the Plan Schemes, the administrative ministry invariably indicates the allocation agreed to by the Planning Commission for the particular scheme.

(3) All sanction letters laying down the pattern invariably indicate that it has the concurrence of the Ministry of Finance.

(4) Where, in exceptional cases, provisions are made in the budget pending finalisation of the pattern, the administrative ministry ensures that no expenditure is incurred until the pattern has been laid down in consultation with the Planning Commission/Ministry of Finance.

(5) At the time of issue of final sanction releasing the Central assistance in respect of Centrally sponsored schemes, the Ministry ensures that the quantum of grants released is based on the approved pattern and the amounts agreed to by the Finance Ministry.

(6) According to the procedure laid down for the release of Central assistance for Centrally Sponsored Schemes copies of the sanction letters and the explanatory notes if any, are invariably sent to the Plan Finance Division.

As regards the second point made out by the Committee that there should be a second look at the pattern adopted by the various ministries of the plan assistance by the Ministry of Finance this is primarily for the Ministry of Finance to look into. It may however be mentioned that this ministry in the Deptt. of Health has already made a detailed scrutiny of the various schemes in operation during the 4th Plan and it has been found that assistance has invariably been released after the pattern/proposal has been accepted by the Planning Commission/Ministry of Finance. There are however a few schemes where the pattern of assistance has yet to be laid down. The Planning Commission/Ministry of Finance will as usual be consulted before final decision on these matters are taken by this Ministry.

[Ministry of Health & Family Planning (Department of Health) letter No. G-25015|45|70—B dated 29-7-1971].

Recommendation

On account of the mistake that occurred in the Ministry of Health over-payment of about Rs. 50 lakhs had been made during the period

1962-63 to 1967-68. The Committee note Government's view that there has been no *malafide* and that as many as 45 voluntary institutions in the country uniformly received assistance on a higher scale during this period. The Ministry of Health have urged that the recovery of over-payments would cause undue hardship to the institutions concerned as they had incurred the expenditure in good faith and in the belief that they were utilising the funds in accordance with the approved pattern and that they should not be penalised.

[S. No. 19 of Appendix II (Para 1.77) of 125th Report (4th Lok Sabha)].

Action taken

The matter has been reconsidered and it has been decided that as the amount had been properly utilised and spent by the Institutions concerned on a *bona-fide* purpose, there could be no question of recovery and the over-payment as pointed out by the Audit should be regularised.

[Ministry of Health & Family Planning (Department of Health) O.M. No. 13-2|71M.P.T., dated 11th August, 1971]

Recommendation

The Committee would suggest that the matter may be reviewed by Government in consultation with the Planning Commission and the Ministry of Finance, keeping in view the consideration on which the pattern of assistance was scaled down for the Third Plan, the requirement of the nurses to reach the plan targets and the actual progress achieved in this behalf.

[S. No. 20 of Appendix II (Para 1.78) of 125th Report (4th Lok Sabha)]

Action taken

The matter has been reviewed at length in consultation with the Planning Commission and the Ministry of Finance, keeping in view the three considerations suggested by the Committee. The Ministry of Finance and Planning Commission have agreed that Central assistance may be released to the concerned Institutions on the basis of the Second Plan pattern. An amount of Rs. 6.15 lakhs has accordingly been paid to nine voluntary organisations during 1970-71 and a provision of Rs. 18.00 lakhs has been made in the budget estimates for 1971-72.

2. The target for the 3rd Five Year Plan was to qualify 45,000 nurses and this was fully achieved.

3. The pattern of assistance, as laid down by the Planning Commission, for the Second and Third Five Year Plans was as follows:—

	Second Plan pattern	Third plan pattern according to planning Commission's letter No. PC(P)4/2/62, dated the 4th August 1962
Recurring Grant:		
For stipends to trainees and pay and allowances of additional training staff etc.	100%	50%
Non-recurring grant :		
For constructions of school buildings	100% Subject to a maximum of Rs. 50,000/-	75%. Subject to a maximum of Rs 50,000/-
For construction of rostel buildings	100% Subject to a maximum of Rs. 2,000/-per seat in the hostel.	100% Subject to a maximum of Rs. 2,000/-per seat in the hostel for double the number of admission.
For purchase of equipment	100% Subject to a maximum of Rs. 20,000/-.	75% Subject to a maximum of Rs. 20,000/-.

4. If the stipends had been reduced to 50 per cent as proposed for the Third Plan period, the number of nurse trainees would have gone down accordingly as stipend is an attraction for trainees towards the nursing profession. The other reductions in construction of school buildings and purchase of equipment would also had an indirect effect on the training of nurses.

It may be pointed out that during the Second Plan, the voluntary organisations were able to put up only 5 training schools for nurses. With the same pattern of assistance 40 new training institutions came into existence during the Third Plan. Had the scale of assistance been reduced, on the basis of Planning Commission's pattern for the Third Plan most of these institutions would not have come up. The assistance given to these institutions at the rate as followed in the Second Plan period has helped in achieving the Plan target.

5. In the Fourth Plan, the training of nurses has been placed in the State Sector During the intrregnum between the Third and Fourth Plan, the Planning Commission laid down a pattern of assistance under which the State Government was required to give 90 per cent of the total expenditure incurred by the Voluntary Organisations on the training of Para-medical staff including nurses, with

the discretion of going upto 100 per cent. This shows that the Planning Commission themselves had liberalised the pattern previously fixed by them for the Third Plan, bringing it almost on level with the pattern prevalent during the Second Plan and which was inadvertantly followed by this Ministry for the best part of the Third Plan. During the Fourth Plan proper, the question of laying down any pattern of assistance does not arise since training of nurses and other para-medical staff is the responsibility of the State Governments and they are free to give grants on such scale as they consider desirable.

[Ministry of Health & Family Planning (Department of Health) O.M. No. 13-2|71M.P.T., dated 11th August, 1971]

ANNEXURE I

REGISTERED

No. 17-52/70-SII

GOVERNMENT OF INDIA

DIRECTORATE GENERAL OF HEALTH SERVICES

New Delhi, dated the 8th September, 1970.

MEMORANDUM

A set of instructions with regard to the receipt, maintenance and issue of Drug items is sent herewith for strict compliance. The instructions may please be notified in the form of a Depot Order, a copy of which may be sent to this Directorate while acknowledging receipt of this memo.

Sd/-

for Director General of Health Services.

The D.A.D.G. (M.S.),
Govt. Medical Store Depot.
Byculla, Bombay,|Park Town, Madras|
9, Clyde Row, Calcutta|ESI Hospital Campus,
Hyderabad-38.

The Depot Manager,
Govt. Medical Store Depot.
Gauhati/Karnal.

Copy to DG (I) along with a copy of set of instructions

Encl.:—A set of instructions.

Sd/-

for Director General of Health Services.

INSTRUCTIONS

Medical Store Depots:

1. All items which require the cool/cold storage should be placed under the charge of one Pharmacist-*cum*-Clerk who is considered to be the most competent by the officer-in-charge of the Depot. If the work load does not justify the whole time appointment of a man for this purpose he may be given some other life items.

2. Similarly life items which may not require cold storage regardless of the fact whether they are powders, Tablets, Injectibles etc. should be placed under the charge of one Pharmacist-*cum*-Clerk who again may be given additional items if the work load does not justify his full time engagements on these items.

3. A list of items stored on each counter, the prescribed conditions of storage and life should be prominently displayed with each Pharmacist-*cum*-Clerk. This list will be initially prepared by the Store Superintendent and shall be thoroughly scrutinized by the Depot Manager or the D.A.D.G. as the case may be who will attest it with his signatures. Any changes in this list will be likewise attested.

4. In the bin cards whenever the items are brought on charge the name of the manufacturer, batch number, date of manufacture, date of expiry should be invariably shown (if the items are stable the date of manufacture and the date of expiry may be omitted but batch number must be recorded).

5. In the matter of issues of stable/life items the batches which are manufactured earlier or have earlier date of expiry will be issued first than those which have later date of manufacture/date of expiry. Whenever the stock of a particular batch is exhausted a red line will be drawn across the bin card and the batch particulars including date of manufacture and expiry will be indicated before the issues are started from any new batch.

6. The stock verifiers will be instructed to take note of the following and bring to the notice of the D.A.D.G. any lapses:—

(1) If stock holdings are excessive in relation to the turnover particularly of life items:

(2) Storage conditions as given in the lists exhibited at the counters are properly observed by the stock holders;

(3) The manner in which the issue of new batches is started is properly recorded on the bin cards as aforesaid;

(4) Where the items are held in original containers, bottles, tins, cases etc. the stock holders must exercise at least 5 per cent check by opening the containers.

If no lapses are pointed out by the stock verifier it will be taken for granted that the above conditions are fully satisfied.

7. A standard bin card form must contain the following particulars on the top margin: Name of the item, accounting unit, life of the item, VMS No. (on the left hand side), expenditure during the last three individual years and the average expenditure (on the right hand side).

8. A register will be maintained in the following proforma to show all the receipts and issues in respect of each cool/cold storage room whether in the depot or hired out side:—

1. Date
2. V. M. S. Number
3. Item
4. Accounting Unit
5. Quantity
6. R.V. No./Issue Voucher No.

9. The D.A.D.G. will keep in touch with the State Drug Control Authorities and make sure that all gazette notifications which are issued under the Drugs and Cosmetics Act are received by him and are duly implemented. The guard file opened in this behalf will be kept up-to-date and no notification will be filed without specific orders of the D.A.D.G. showing the action taken relative thereto.

10. The officer inspecting the stores on receipt must ensure that under no circumstances he accepts any item which shows a life validity less than the one authorised in the official standards. The statutory standards given in the Drug Act will take precedence over all other standards. Cases of any discrepancies observed in the official standards may be referred to the Drug Controller (India) with a copy to the A.D.G. (Stores).

11. Thermolabile drugs will be verified by each of the officers daily who will be allotted a few items (2 items per day of which

stocks are actually available will do for this purpose) each picked up at random by the D.A.D.G. The same items must not be verified until the whole cycle of life and thermolabile items has been duly completed. Such reports will be collected by the D.A.D.G. and sent to the Directorate at monthly intervals by the officer-in-charge of the Depot alongwith his comments. As in the case of stock verifier, the officer who undertakes verification must point out any lapses, failing which the correctness of storage etc. will be taken for granted.

12. At the time of issue of life items to the hospitals, demands should be scrutinized and supply should be restricted with special reference to actual useful life left and the indented period so that no short-dated drugs are supplied to the hospitals which they are unable to consume during their potency periods. All thermolabile and life items should be despatched by passenger train or Q.T.S. or by road and not by the usual goods train. It should also be watched that such stores do not lie in the despatch section of the depot for any unduly long periods. The responsibility in this behalf should be strictly enjoined upon the officer-in-charge of E. Section who should bring the matter to the notice of the D.A.D.G. In the case of Thermolabile and life items the packing notes should describe not only the number of bottles, containers etc. but the names of the items, VMS Nos., date of manufacture and date of expiry. In addition to the copy of the packing note which is to be deposited in the packing case an extra copy should be supplied alongwith the P.W. Bill|Road receipt etc. with case Nos. clearly marked to the indentor.

13. Separately orders have been issued that the D.A.D.G. will certify to this Directorate regarding the proper storage of Thermolabile under the prescribed conditions. Wherever the cool|cold storage accommodation within the Depot falls short and the necessity of additional accommodation is inescapable the Directorate will be only too willing to sanction extra expenditure on hiring cold storage space out side. For this purpose competitive quotations must, however, be called either through limited tenders if the cold storage institutions in the town are known or through an advertised tender.

14. Frequently delays have been experienced in the testing of samples sent to Medical Store Depot Unit at C.D.L., Calcutta. The Directorate proposes in due course to establish a ful-fledged biological laboratory at Madras and it is hoped that all such delays will be eliminated. However, since the unit at Calcutta is at present unable to handle the total work load and it may take time to establish the Biological Laboratory at Madras, with a view to avoid delay the Depots are free to utilise the services of State Government laboratories for which they may be remunerated at their standard rates.

While the acceptance of stores without testing is not entirely barred in the case of really reliable and reputable firms, occasional testing must be resorted to even after the purchases have been effected. In the matter of purchases standard formulae for provisioning and local purchases will apply. Under these instructions discretion has been allowed to the officer-in-charge in respect of life items to regulate their purchase consistent with their off take trends. It may please be noted that what is required is that the depots should organise proper storage of all drugs particularly perishables and the mere fact that the above conditions are being imposed should not deter them from acquiring their requirements and thereby fail in compliance of indentors' demands which is the primary aim of the Depots.

15. In the event of any drug reported to be sub-standard by any of the indentors, news should be flashed to all the Depots and the D.G.A. F.M.S. under registered cover and all the indentors who have received supply of that drug should be told to suspend the issue. The supply should be got tested at one of the authorised laboratories, either our own or the State laboratories. If the test report reveals article to be of standard quality, the ban on usage should be withdrawn. On the other hand if the test report reveals the item to be defective in any respect a report should be made to the State Drug Controller in which the Depot is situated in the case the item has been manufactured within the State. If the supplies have been manufactured by a party situated in another State the complaint should be sent to D.C. (I) alongwith a copy of the test report under intimation to the A.D.G. (Stores) by name. In the former case the State Drug Controller will take the necessary action and in the latter case the Drug Controller (India) will take the necessary action.

Sub-standard stock of the drug must not be returned to the supplier without prior intimation, under registered A.D. to the State Drug Controller or the Drug Controller (India) as the case may be.

16. In respect of local purchases, as soon as it is established that a Sub-Standard drug has been supplied by the manufacturer a claim should be made against him and recovery straightway enforced in case any of his bills are pending with the Depot. In regard to purchases made through the D.G.S. & D. the Purchase Officer should be immediately informed of the incident with a simultaneous request to the Pay & Accounts Officer under Registered Acknowledgement Due to enforce the pecuniary liability against the firm.

ANNEXURE II

No. 17-52/70-SII

DIRECTORATE GENERAL OF HEALTH SERVICES

New Delhi, the 23rd April, 1971.

MEMORANDUM

In continuation of this Directorate Memo No. 17-52/70-SII dated 8th September, 1970 the following further instructions are issued for strict compliance.

The fact of a drug having been found substandard by a Medical Store Depot should be reported to the DGAFMS and other depots on the very date this matter comes to their notice. In the case of their own depot, since they have to ascertain issue voucher Nos. and then the addresses of the receipients from two different documents, M.S. Depots may take another 24 hours, if necessary, but the information should be communicated latest by the following day after collection of particulars regarding the names and addresses of the recepients even by making staff sit over time.

The CGHS, M.S. Pepot, should also be advised alongwith the DGAFMS and other depots. It should be enjoined as personal duty upon the Officer-in-charge of Drugs section to take the necessary action in this behalf and the Officer-in-charge of the depot should himself carefully watch that no delay takes place. Samples for test should also be sent from the depot the same day or latest by following day.

If no counter samples are available in the depot the reporting indentor and one or two other who have been supplied big quantities should be asked to send samples (the quantity of which may be indicated along with instructions that sealed containers as received from the contractors in tact should be sent) immediately under intimation to this Directorate. This should be followed up on a vigorous basis. Telegraphically and through D.O. letters. Copies of communications should be endorsed to their administrative Officer invariably. Similarly testing of samples at laboratory should be expedited on a TOP PRIORITY basis. Cases of undue delay, 10 days in receipt of samples 20 days in testing of non-biologicals and 60 days in the case of Biologicals should be reported by name to the DADG (ST), in Directorate who will similarly take prompt action for further follow up with the higher authorities.

The procedure prescribed for recording details of batch Nos. etc. and for reporting testing etc. in the event of complaints should be

adopted *mutatis mutandis* for all drugs and miscellaneous items having a direct action on human body e.g. surgical aligatures, Surgeons gloves etc.

It is noticed that reports regarding stock verification in pursuance to instructions issued vide para 11 of set of instructions sent with this Directorate Memo No. 17-52/70-SII dated 8th September, 1970 are not sent regularly to this office. These may please be sent regularly in future.

Further, please note that if a firm is convicted in court of law for violating the Drug Act, it should be straightaway removed from the list of approved suppliers.

Please acknowledge receipt.

Sd/-

for Director General of Health Services.

To

The D.A.D.G. (MS),
Govt. Medical Store Depot,
Bombay|Madras|Calcutta|Hyderabad|Karnal
The Depot Manager,
Govt. Medical Store Depot,
Gauhati-2 (Assam).
Copy to File No. 15-4/71-SI.

ANNEXURE III

DRUGS CONTROLLER (INDIA) D.O. No. 29-17|71-D

DIRECTORATE GENERAL OF HEALTH SERVICES

New Delhi, 22nd June, 1971.

Dear Dr./Shri

All State Drugs Controllers

The Public Accounts Committee 1970-71 of the Fourth Lok Sabha, in its 125th Report has, among other things, dealt with two drug items. The first one relates to the supply of Injection of Tetracycline Hydrochloride supplied by M/s..... through Government Medical Store Depot Karnal. The stocks in question had become discoloured before the date of expiry had crossed and side-effects

such as the development of abscess formation in certain cases in which the drug was used were reported.

The second item relates to the supply of Ferrous Sulphate tablets which had become spotted because of the peeling off the sugar quoting. The Public Accounts Committee recommendations reads:—

> "Para 1.62 The Committee are distressed to learn that the defect noticed in the tablets in November, 1968 was not intimated to the Medical Stores Depot, Karnal by the Irwin Hospital/Drugs Controller, Delhi until November 1969 although the Government Analysts's report had been received in April, 1969. Strangely enough it was the firm which first reported the matter to the Depot in August, 1969 and it took 2 months for the Depot to instruct all the institutions to whom they had distributed the tablets to discontinue their further use. The Committee strongly deprecate the gross delay of about a year in issuing instructions to indentor hospitals regarding the defective nature of supplies. As suggested earlier in the report any defect noticed to the supplying medical stores depot who should arrange to inform all the depots and hospitals with a view to promptly suspending further use".

In view of the above recommendation it is suggested that the Drugs Inspectors in your State may please be instructed to adopt the following procedure in those cases where the samples sent by him for test are reported to be not of standard quality and where it is necessary to prevent the use of the drug inquestion:—

(i) The Drugs Inspector may ascertain from the hospital/sales establishment/institution/dispensary from where the sample was drawn as to whether the supply was made by a dealer or Medical Store Depot of the State or Central Government.

(ii) In case the supply was made by the State or Central Medical Store Depot, the Drugs Inspector, in addition to corresponding with the Drug Licensing authority of the State in which the manufacturing firm is located, shall also write to the State or Central Medical Stores Depot which had supplied the drug so that the latter in turn may write to all the parties involved for the withdrawal of the drug in question.

(iii) A copy of the letter sent by the Drugs Inspector under para (ii) above may be sent to the Drugs Controller (India)

and the Assistant Director General (Stores) in the Directorate General of Health Services for similar action.

A copy of the instruction issued to the Drugs Inspectors in your State may please be forwarded to us for information.

Yours faithfully,

Sd/-

All State Drugs Controllers.

Copy forwarded to the Zonal officers, Central Drugs Standard Control Organisation, Assistant Director General (Stores), Directorate General of Health Services and the Medical Store Depots for information and necessary action.

ANNEXURE IV

IMMEDIATE.
REGISTERED A.D.
CONFIDENTIAL

No. 17-27|70-SII

DIRECTORATE GENERAL OF HEALTH SERVICES

New Delhi, Dated the 14-5-1970.

MEMORANDUM

SUBJECT:—*Condition of storage in regard to biological and other special products specified in Schedule C&C(I) to the Drugs Rules,* 1946.

There has been an objection regarding the supply of ACHROMYCIN made to the Irwin Hospital for the Medical Store Depot, Karnal. After the hospital had consumed a large quantity of the material the local Drug Control authorities found the remaining vials in their possession to be of sub-standard quality. An extract from the relevant P.A.C. Report is reproduced below:—

"No investigations have been made to find out how and at what stage the defects developed in the injection with the Irwin Hospital nor has any enquiry been made from the other hospitals/dispensaries about the results of such injections received by them from the Medical Stores Depot, Karnal."

In view of the foregoing it has become imperative that in storage conditions for drugs and other allied items as prescribed in the official standards i.e. in the different pharmaceopeias and under the Drugs and Cosmetics Act, 1940 and rules made thereunder as published from time to time are strictly adhered to by the Medical Store Depots. In this connection the Drugs Controller (India) issued a special circular vide his No. 5-56|61-DC, dated 23rd April, 1963 to all the State Drug Controllers on the conditions of storage with regard to the biological and special products specified in Schedule C&CI to the Drugs Rules, 1945 and requested them that the storage conditions should be published in the State Gazetters. One copy of his letter with enclosure is sent herewith. In the light of the foregoing you are requested to please obtain a copy of the Gazette issued by the State Drug Control authorities pursuent to circular referred to above and any other notifications which might have been issued by them on the subject.

The storage conditions obtaining in your Depot should examined carefully vis-a-vis the legal standards as published in the Drugs and Cosmetics Act and Rules made thereunder and in the official Pharmacopoeias to ensure that there is no violation in this regard, possibly you are storing a large quantity of drugs in cold storage pursuant to the Army Lists in your possession. While such lists need to be followed with a view to preserve quality of the drugs, the former must take precedence over such lists. If you find after a careful assessment installation of refrigerators, extra cold storage space etc., specific proposals may please be submitted to this Directorate. The possibility of hiring cold storage space for the storage of small-pox vaccine which occupies considerable accommodation in same of the Depots may also please be explored, if the cold storage facilities are deficient.

It may please be impressed upon your Superintendent and Officer-in-charge of the Drugs Section that the proper storage of drugs according to legal and pharmacopeias standards is strictly their personal responsibility and in the event of any loss being discovered due to non-complence of the provisions they are liable to be held responsible.

It is also requested that the DADG/Depot Manager of the depots, as the case may be kindly undertake frequent inspection of the conditions under which the items are stored and furnish a quarterly

certificate to the effect that the prescribed storage conditions are being duly followed.

Please acknowledge receipt.

Sd/-

for Director General of Health Services.

To

Dr. S. K. Guha,
DADG(MS), MSD, Bombay.
Shri K. Gangayya,
DADG, Madras.
Shri W. A. D'cruz,
D.M. Calcutta.
Shri P. R. Haryal,
DADG, Hyderabad.
Shri A. K. Ghosh,
D.M. Gauhati.
Shri H. K. Tewari,
D.M. Karnal.
Copy to Guard file.
Copy to manual file.

Copy to Assistant Chemist. It will be her responsibility to watch for the receipts of certificates prescribed in the last para. She may enter this in her calendar of remarks.

Sd/-

for Director General of Health Services.

ANNEXURE V
No. 17-27|70-SII

DIRECTORATE GENERAL OF HEALTH SERVICES
New Delhi, 31st October, 1970.

MEMORANDUM

SUBJECT:—*Conditions of storage in regard to biological and other special product specified in schedules C&C (I) to the Drugs Rules* 1945.

In continuation of this Dte. letter No. 17-27/70-SII dated the 12th May, 1970 on the subject mentioned above, you are further requested to examine available facilities for cold storage in the depot and

in the event of your cold storage accommodation falling short of Depots' requirements, you should arrange to hire cold storage facilities commercially offered in your area until permanent arrangements are made in this behalf.

Such proposals for hiring cold storage accommodation should be sent with full justification in terms of volume of stores colding such storage with certificates that your own arrangements are inadequate and that accommodation you propose to hire is the cheapest available taking into account the distance from the depots and consequent expenditure on movement of stores to and from with a view to achieve competative rate.

You may advertise your requirements in the press, contact Government departments (both Central & State) who may have a surplus capacity and also the various local refregeration companies.

Sd/-

for Director General of Health Services.

To

The D.A.D.G.(MS),
(1—5) Govt. Medical Store Depot,
Bombay/Calcutta/Karnal/Madras/Hyderabad.

Copy to:—The D.A.D.G.(MS).GMSD, Calcutta with reference to his letter No. RS/TCI/Storage/3848 dated 31-8-1970.

(6) The Depot Manager,
Govt. Medical Store Depot,
P.O. Pahabari, Goshalla Godown,
Gauhati (Assam).

ANNEXURE VI

OFFICE OF THE DIRECTORATE HEALTH SERVICES, DELHI ADMN, 15-ALIPORE ROAD, DELHI-6.

No. F. 1(23)/71-DHS—Dated the 1971.

Administrative order No. 1

An instance has been reported where a Drug Inspector while inspecting the stores of one of the local Hospital discovered that several batches of a particular drug were showing physical changes. However, he took sample only of one batch instead of taking sample of all the batches. This is not correct and should be avoided. All

officers concerned will please ensure, that in future, in case of suspension, sample should be taken of all the suspected batches for test.

Sd/-

Director Health Services, Delhi.

No. 1(23)/71-DHS/1194 Dated the 9th March, 1971.

Distribution:—

Deputy Director of Health Services.

Assistant Drugs Controller I.

Assistant Drugs Controller II.

All Drugs Inspectors.

Office Order Register File.

Administrative Officer.

ANNEXURE VII

D.O. No. PI-16(28)/71.

Joint Secretary, Government of India
Ministry of Supply, New Delhi.
16th June, 1971.

My dear,

Please refer to your D.O. letter No. F.16-4/70-D dated 29/30-3-71 about the working of the Medical Store Organisation *vis-a-vis* the rate contract system of purchases. We wish you has sent us some instances to show how the procedure of rate contracts had proved unsatisfactory so far as the Medical Store Depots were concerned. However, we have no objection to covering your requirements of stable items through A/Ts with a programme of a staggered deliveries if and when requested. Similarly, running contracts could be concluded for perishable items, as suggested by you. The running contracts are for obvious reasons operated by the DGS&D centrally so that they can keep a watch on the quantities purchased and the tolerances allowed not being exceeded. You would, therefore, have to provide your annual demands and indicate the phased deliveries ahead of your requirements, in specific quantities. These details in respect of various items can be worked out by you and firm consolidated indents placed on the DGS & D.

So far as the BHC 50 per cent W.D.P. is concerned, I may mentioned that the reason why we prefered a regular indent was because

the requirements of your Ministry added upto 2,730 M/Tonnes valued at Rs. 52,00,000 approximately, while in the rate contract there was a monetary limit of Rs. 25,000 only. Moreover, it had come to our notice that the price trend for BHC 50 per cent W.D.P. was slightly on the lower side and for such a large requirements as yours, better prices that those of the rate contract could be obtained. In fact, it has been possible to purchase your requirements with considerable saving to Government.

Yours sincerely,
Sd/-

Shri.....
Joint Secretary,
Ministry of Health,
New Delhi.

CHAPTER III

RECOMMENDATIONS/OBSERVATIONS WHICH THE COMMITTEE DO NOT DESIRE TO PURSUE IN VIEW OF THE REPLIES OF GOVERNMENT

Recommendation

The Enquiry Officer has come to the "inescapable conclusion" that cold storage accommodation at the Irwin Hospital was inadequate to keep all the items of medicines requiring cold storage and according to him some stocks of Achromycin must have kept under ordinary room temperature. The Committee note that Delhi Administration have not accepted the conclusions of the Enquiry Officer about the storage conditions in the Irwin Hospital and that they are prepared to accept a further probe in the matter. The objection of the Delhi Administration is stated to be under consideration of the Ministry. The Committee would like to be apprised of the out-come. [Sr. No. 3 of Appendix II (Para 1.30) of 125th Report (4th Lok Sabha)]

Action Taken

The Delhi Administration have objected to the conclusions drawn by Dr. J. K. Thanawala following his enquiry at the Irwin Hospital that there is a reason to believe that there was negligence on the part of the staff of the Hospital regarding the storage of Achromycin. The Delhi Administration have stated that the Enquiry Officer had not recorded the statement of officers of the Drug Control Department who had inspected this drug under actual storage conditions in the Irwin Hospital. They have also forwarded extracts of the report of the Drug Inspector, Delhi, wherein it had been stated that the entire stock of Achromycin intramuscular injection was stored in an air-conditioned apartment of the hospital store.

The Drugs Controller (India) had also, on the basis of his own independent inquiry, come to the conclusion that the Hospital had adequate storage facilities for storing tetracycline hydrochloride injection.

It has to be stated, however, that the inspection arranged by Drugs Controller (India) was done at a much later date and it is not pos-

sible to conclude as to what was the storage situation at the time under consideration.

A fresh probe as suggested by the Delhi Administration at this stage after four years of the event *may not* yield any useful results.

[Ministry of Health and Family Planning (Department of Health) letter No. 12-39/70-H (Pt.II) dated 12-8-1971]

CHAPTER IV

RECOMMENDATIONS/OBSERVATIONS REPLIES TO WHICH HAVE NOT BEEN ACCEPTED BY THE COMMITTEE AND WHICH REQUIRE REITERATION

Recommendation

The Committee find that the DGHS had in a communication addressed to all the Medical Superintendents of major hospitals in Delhi including the Irwin Hospital as far back as in May, 1966 stated *inter alia* that the stores attached to the hospitals must be placed under the charge of a competent pharmacist who should be responsible for the maintenance of proper storage conditions. He added that the pharmacist-in-charge of the stores should carry out fortnightly inspections of the stocks and that in case he noticed visual signs of deterioration in any drugs, the stocks should be frozen, sending the samples for testing through the local Drugs Inspector. In view of what has happened in this case the Committee have to take the view that these instructions have not been fully followed by the Irwin Hospital. The Committee would like to know whether the responsibility of the person in charge of stores in regard to improper storage conditions and failure to detect the visible deterioration of the drug in this case was examined.

[S. No. 5 of Appendix II (Para 1.32) of 125th Report (4th Lok Sabha)]

Action Taken

The hospital authorities are fully aware of the instructions issued by the Directorate General of Health Services. The senior-most Pharmacist of the Institutions Group is Incharge of the Irwin Hospital Pharmacy. He is a qualified Pharmacist. Besides, the Senior Medical Officer is Incharge of the Medicine Stores and it is his duty to see that the instructions are followed.

At a meeting of State Drug Controllers held in February, 1971, a specific recommendation was made that an adequately qualified pharmacist, preferably a graduate in Pharmacy, should be appointed to supervise the working of the Hospital Store and Pharmacy in all hospitals with 200 or more beds. Instructions have been issued to the State authorities to tighten the quality control measures over the activities of the Hospital Stores and Hospital Pharmacies.

These instructions, among other things, call for proper supervision and inspection by a qualified and competent person (Annexure).

The question of fixing responsibility for unsatisfactory storage does not arise in view of the satisfactory reports both the Drug Controller of India and the Drug Inspector, Delhi Administration.

[Ministry of Health and Family Planning (Department of Health) letter No. 12-39/70-H(Pt. II) dated 12-8-1971]

ANNEXURE

Copy of D. O. No. F.3-13/70-D dated the 17th June, 1971 sent to all State/Union Territories Health Ministers by the Deputy Minister for Health and Family Planning.

Dear

At a recent meeting of the Drugs Standard Control Officers from the Centre and States, the question of exercising stringent control over the quality of drugs used by the hospitals was considered. It was felt that the conditions under which drug formulations are processed by hospitals for the use of their patients, the functioning of hospitals stores and the operation of sterile service in hospitals needed close surveillance and a number of measures were suggested which are contained in the attached note.

May I therefore suggest that the Superintendents of Hospitals in your State be advised to avail themselves of the assistance of the State Drugs Control authorities in organising the Hospital Stores, Hospital Pharmacy and dispensing and sterile service establishments on the lines recommended by the Drug Control authorities. In particular, the hospital authorities should invite more frequent inspection of their hospitals by the officers/inspectors of the State and Central Government and extend to them all assistance, Mutual cooperation between Drugs Control authorities and hospital authorities would contribute a great deal towards improvements of hospital services in the country.

I shall be glad to know in due course the action taken in the matter.

Yours sincerely,
Sd/-

MINISTRY OF HEALTH & F. P.

(DEPARTMENT OF HEALTH)

SUBJECT:—*Quality control on drugs.*

At a recent meeting of the Drugs Standard Control Officers from the Centre and the States, the question of exercising stringent control over the quality of drugs used by hospitals was considered. The Drug Control authorities felt that the conditions under which drug formulations are processed by hospitals for the use of their patients, the functioning of hospital stores and the operation of sterile service in hospitals needed close surveillance with a view to ensuring that patients in hospitals receive drugs of good quality.

The following decisions were taken at the meeting:—

(a) If drugs are manufactured for use of patients by hospitals in hospitals pharmacies, the conditions of manufacture should be stringently controlled in the same manner as private manufacturers of similar items are controlled.

(b) Facilities for sterilisation services in hospitals should be frequently inspected by the Central and State Drugs Inspectors.

(c) The manner in which drugs are ordered, stored and issued by the hospitals should also be subjected to frequent checks so as to ensure that purchases are made in phased instalments to obviate financial loss to hospitals; that drugs which require special storage conditions are stored properly and that drugs which bear a date of expiry are issued or turned over by arrangement with manufacturers in such a manner that hospitals are not saddled with any time expired stocks.

(d) The responsibility for ensuring 'good manufacturing practices' including sterilisation facilities in hospitals and management of hospitals stores should be fixed on special members of the staff in hospitals who would also be made to maintain the necessary registers and records.

(e) In hospitals with 200 beds and above, a Chief Pharmacist who should be at least a graduate in pharmacy should be appointed and given gazetted status with an appropriate salary scale. The Chief Pharmacist should have a thorough

background knowledge of drugs, their substitute, storage conditions etc. and should be able to assist the hospitals administration in maintaining the quality of drugs supplied to patients. The Committee also recommended that similar facilities should be made available in smaller hospitals.

Recommendation

The Committee note that the Delhi Administration had at one stage seriously considered the question of prosecuting the firm but they were advised by the Judicial Department of the Delhi Administration against it on the ground that the Drug Controller, Delhi could not prosecute the firm for want of jurisdiction as the drug in question was supplied by the firm to the Medical Stores Depot, Karnal. The Committee would suggest that the Delhi Administration might take the opinion of the Ministry of Law in the matter for future guidance. They, however, feel that the Central Government could have prosecuted the firm if there was a *prima facie* case.

[S. No. 8 of Appendix II (Para 1.35) of 125th Report (4th Lok Sabha)]

Action Taken

There was no *prima facie* case to show that the manufacturing firm was responsible for the defect in Achromycin injection. The fact that supplies from the same batches used by other hospitals and institutions did *not* produce any adverse reaction or had *not* been reported to have changed colour and the fact that the investigations carried out by the Director, Drug Control Administration, Gujarat on the record samples from the same batch maintained by the manufacturing firm did not reveal any deficiencies, gave sufficient indication that the cause for the defects noticed by the Irwin Hospital authorities had to be established by checking on the conditions of storage of the drug from the point it left the manufacturer's premises.

[Ministry of Health and Family Planning (Department of Health) letter No. F. 12-39/70-H (Pt. II) dated 12-8-1971]

CHAPTER V

RECOMMENDATIONS/OBSERVATIONS IN RESPECT OF WHICH GOVERNMENT HAVE FURNISHED INTERIM REPLIES

Nil

NEW DELHI;
February 22, 1972
Phalguna 3, 1893 (*S*).

ERA SEZHIYAN,
Chairman,
Public Accounts Committee.

APPENDIX

Summary of main Conclusions/Recommendations

Sl. No.	Para No.	Ministry/Department concerned	Recommendations/conclusions
(1)	(2)	(3)	(4)
1	1.7	Ministry of Health & Family Planning (Department of Health)	The Committee note that although the annual average consumption of Achromycin injections according to the information given to the Enquiry officer was 13,600 vials, the actual consumption during 1965-66 was 18,750. However, the fact remained that as against the quantity of 25,000 vials of the injections indented for one year (1966-67) only 20,710 vials were consumed in 16 months between August, 1966 and December, 1967. The Committee would, therefore, like Government to examine whether the present system of provisioning of medicines on the basis of 25 per cent over the previous year's consumption needs revision in the light of this experience.
2	1.10	Do.	The Committee desired to know whether the responsibility of the person in charge of stores in regard to improper storage conditions and failure to detect the visible deterioration of the drug in this case was examined. The Ministry in their reply have merely stated that the question of fixing responsibility for unsatisfactory

			storage does not arise in view of the satisfactory reports of both the Drug Controller of India and the Drug Inspector, Delhi Administration. As some vials of Achromycin injections were stated to have become discoloured and turned dark brown, by the Drug Inspector who examined the stock and submitted a report on the 19th December, 1967, the Committee fail to understand how the person incharge of the stores did not notice the discolouration earlier if he had carried out the fortnightly inspections of stocks regularly as required. The Committee would, therefore, like to reiterate that the failure in this regard should be investigated and responsibility fixed.
3	1.13	Do.	The Committee suggest that the question of jurisdiction of Delhi Administration for launching prosecution against manufacturers of drugs for supply of defective medicines through Medical Stores Depots located outside Delhi should be examined in consultation with the Ministry of Law for future guidance. The Committee wish that this had been done earlier as they had specifically raised this point in their 125th Report (Fourth Lok Sabha).
4	1.16	Do.	The Committee are surprised that the earlier issues of the Ferrous Sulphate Tablets pertaining to the period prior to 20th November, 1967 were irregularly entered in the bin cards after the inspection by the Drug Inspector. The Committee suggest that responsibility for not maintaining the bin cards properly should be fixed.

(1)	(2)	(3)	(4)
5	1.19	Ministry of Health and Family Planning (Department of Health)	The Committee note that manufacturers of Ferrous Sulphate Tablets have been advised to adopt film or shellac coating for the tablets instead of sugar-coating; or, in the event of the tablets being sugar-coated, show a cautionary note that the tablets should not be used if they are discoloured or spotted. The Committee would, however, suggest that it should be examined whether instead of sugar-coating, film or shellac coating of the tablets should not be made obligatory to avoid health hazards due to peeling off of sugar-coating.
6	1.22	Ministry of Finance	The Committee wish to reiterate that their earlier recommendation that there should be a second look by the Ministry of Finance at the pattern adopted by the various Ministries for Plan assistance should be examined by the Ministry of Finance.

GMGIPND—LS II—3148 LS—2-3-72—1250.