

PUBLIC ACCOUNTS COMMITTEE (1977-78)

(SIXTH LOK SABHA)

THIRTY-FIFTH REPORT

PRODUCTION OF POLIO VIRUS VACCINE

**MINISTRY OF HEALTH AND FAMILY WELFARE
(DEPARTMENT OF HEALTH)**

[Action taken by Government on the recommendations of the Public Accounts Committee contained in their 179th Report (Fifth Lok Sabha)]

PRESENTED IN LOK SABHA ON = 6 DEC 1977
LAID IN RAJYA SABHA ON = 6 DEC 1977



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LIST OF MEMBERS OF PUBLIC ACCOUNTS COMMITTEE
(1977-78)

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Shri C. M. Stephen

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Shri T. R. Ghai—*Senior Financial Committee Officer*

*Ceased to be a Member of the Committee on his appointment as Minister of State w. e. f. 14-8-1977.

INTRODUCTION

1. I, the Chairman of the Public Accounts Committee as authorised by the Committee, do present on their behalf this Thirty-Fifth Report on the action taken by Government on the recommendations of the Public Accounts Committee contained in their Hundred and Seventy-Ninth Report (Fifth Lok Sabha) on Production of Polio Virus Vaccine relating to the Ministry of Health and Family Welfare (Department of Health).

2. On 10 August, 1977, an 'Action Taken Sub-Committee' (1977-78) consisting of the following Members, was appointed to scrutinise the replies received from Government in pursuance of the recommendations made by the Committee in their earlier Reports.

1. Shri C. M. Stephen—*Chairman*
 2. Shri Asoke Krishna Dutt—*Convener*
 3. Shri Gauri Shankar Rai
 4. Shri Tulsidas Dasappa
 5. Shri Kanwar Lal Gupta
 6. Shri Zawar Hussain
 7. Shri Vasant Sathe
- } *Members*

3. The Action Taken Sub-Committee of the Public Accounts Committee (1976-77) considered and approved the Report at their sitting held on 20 December, 1976. The Report was adopted by the Public Accounts Committee (1976-77) on 31st December, 1976, but it could not be presented due to dissolution of Lok Sabha on 18 January, 1977. The Action Taken Sub-Committee of the Public Accounts Committee (1977-78) considered and adopted the Report at their sitting held on 18 October, 1977. The Report was finally adopted by the Public Accounts Committee (1977-78) on 16 November, 1977.

4. For facility of reference the conclusions/recommendations of the Committee have been printed in thick type in the body of the Report. For the sake of convenience, the conclusions/recommendations of the Committee have also been appended to the Report in a consolidated form.

5. The Committee place on record their appreciation of the commendable work done by the Action Taken Sub-Committee of the

(vi)

Public Accounts Committee (1976-77) in considering and finalising this Report.

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

NEW DELHI;
November 18, 1977.
Kartika 27, 1899 (S).

C. M. STEPHEN,
Chairman,
Public Accounts Committee.

CHAPTER I

REPORT

1.1. This Report of the Committee deals with the action taken by Government on the Committee's recommendations/observations contained in their 179th Report (Fifth Lok Sabha) on 'Production of Polio Virus Vaccine', commented upon in paragraph 32 of the Report of the Comptroller & Auditor General of India for the year 1972-73, Union Government (Civil), relating to the Ministry of Health & Family Planning (Department of Health).

1.2. The Committee's 179th Report was presented to the Lok Sabha on 31 August 1975 and contained 21 recommendations|observations. Action Taken Notes on all these recommendations|observations have been received from Government and these have been broadly categorised as follows:

- (i) *Recommendations|observations that have been accepted by Government:*
Sl. Nos. 5, 11, 12, 13, 16, 17, 19 and 20.
- (ii) *Recommendations|observations which the Committee do not desire to pursue in the light of the replies received from Government:*
Sl. Nos. 10, 15 and 21.
- (iii) *Recommendations|observations replies to which have not been accepted by the Committee and which require reiteration:*
Sl. Nos. 1, 2, 3, 4, 6, 7, 8, 9, 14 and 18.
- (iv) *Recommendations|observations in respect of which Government have furnished interim replies:*

NIL

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

Performance and achievements of the Polio Vaccine Production Unit (Paragraphs 1.64 to 1.67 and 1.69 to 1.70—Sl. Nos. 1 to 4 and 6 to 7)

1.4. Reviewing the performance and achievements of the Polio Vaccine Production Unit, established in 1964 at the Pasteur Institute, Coonoor, in pursuance of the recommendations of Dr. A. B. Sabin (inventor of the Sabin Strains of the Virus from which the vaccine is made) who had visited India as a World Health Organisation consultant, the Committee, in paragraphs 1.64 and 1.65 of their 179th Report, had been constrained to observe as follows:

"1.64. The Committee are extremely dissatisfied with the performance and achievements of the polio vaccine production unit at the Pasteur Institute, Coonoor on which, as pointed out by Audit, Rs. 21.15 lakhs, excluding foreign aid of Rs. 7.48 lakhs, had been spent upto March 1972. They are concerned to note that as against its annual capacity of 12.50 lakh trivalent doses of vaccine, the unit has been able to produce only 4.61 lakh trivalent doses from December 1966 to May 1973, in a span of about 6½ years. The average annual production, thus, works out to only about 6 per cent of the capacity of the unit. Even conceding that the development of the vaccine is a sophisticated process and the production of contamination-free batches takes time, the present state of affairs at the Institute is far from satisfactory. The Committee apprehend that unless vigorous and concerted efforts are made to improve production and management techniques at the unit, the position may well become irretrievable."

"1.65. In this context, the Committee are of the view that the assessments made by a senior official of the Indian Council of Medical Research and by a team of officers of the Council, the National Institute of Communicable Diseases, Directorate General of Health Services and the Drug Controller, who had been deputed to conduct a detailed study of the shortfalls in production, are of considerable significance and merit serious and immediate attention. The picture that emerges from these two studies is far from complimentary both to the production unit and the Pasteur Institute. The following facts, in particular, bring out the sad state of affairs prevailing in the Institute:

- (a) Lack of cooperation and rapport and a complete breakdown of human and personal relationships between the

personnel of the production unit and the Director of the Institute;

- (b) carelessness on the part of middle level supervisory staff in coordinating the activities of the unit;
- (c) absence of a long range plan of work, non-fixation of targets of production, non-assignment of responsibilities and the absence of frequent and regular checks;
- (d) non-availability of trained middle level staff;
- (e) a complete breakdown of the measures that would ensure sterility in the production chamber; and
- (f) inadequate maintenance of equipment and records."

1.5. In their Action Taken Note dated 31 March 1976, furnished in response to these observations, the Ministry of Health and Family Planning (Department of Health) have stated:

"Government were already aware of the unsatisfactory performance and achievements of the Polio Vaccine Production Unit at the Pasteur Institute, Coonoor. To remedy the defects noticed and to improve the functioning of the Unit, discussions were held in the Directorate General of Health Services and in the Ministry of Health on 23.3.74, 16.7.74, 13.9.74, 1.10.74, 19.10.74, 15.2.75; 20.12.75 and 22.1.76. The recommendations made by a team of officers were also considered. There were inherent difficulties in the Unit as at present constituted. The Polio Vaccine Production Unit, Coonoor, is in fact a Unit of the Pasteur Institute of South India which is a Registered Society. Even though the Indian Council of Medical Research has been financing this Unit as a research project, the actual control of the staff and responsibility for managing the project rested with the Director of the Pasteur Institute who is the Officer-in-Charge of the Unit in addition to his duties. This arrangement was obviously unsatisfactory and led to several problems of indiscipline, inefficiency and also poor production. At one stage it was thought that if the Government of Tamil Nadu could take over the management of the Unit, its performance could be improved considerably. The Government of Tamil Nadu were accordingly requested to take over the Unit, but the State Government, however, regretted their inability to agree to the proposal. The potency of

the vaccine produced at the Unit had become very low and did not pass the neuro-virulence test. The seeds which had been supplied to the Unit by the WHO had also lost much of its potency and if further batches of vaccine are produced out of those seeds, they would not pass the test. The WHO team had made certain recommendations which involve substantial financial outlay. The technical officers, who were consulted in the matter, felt that even if additional inputs in terms of finance, equipment etc., were given to the Unit, it is doubtful whether the Unit would be able to produce good, acceptable and safe vaccine. With the present administrative arrangements and management problems and the proved inefficiency of the staff, it was felt that it would not be worthwhile to spend large sums of money in reviving the Unit in its present form. In the light of the above, the Government of India have decided to close down the Unit.

- (ii) Steps are, however, being taken to develop Polio Vaccine manufacture at the Haffkine Institute, Bombay where necessary infrastructure, expertise and other facilities are available."

1.6. Dealing, in this context, with the administrative arrangements for the production of the vaccine, the Committee, in paragraphs 1.66 and 1.67 of the Report had gone on to recommend as follows:

"1.66. The Committee attach considerable importance to the recommendation of the study team that the vaccine production unit should be placed under the overall charge of a wholetime officer who would be expected to deal with all the problems relating to premises, personnel, supplies and the production of vaccine. The Committee accordingly recommend that decision on this recommendation should be taken without further delay so as to place the production unit on a firmer footing."

"1.67. The Committee learn that the present Director of the Pasteur Institute, who has vast experience in the field of polio vaccine will be available for only another two or three years. The problem of his replacement, when no longer available, calls for careful thought. It is, therefore, imperative that a sufficient number of persons are trained in the techniques and intricacies of production of

polio vaccine so that production does not suffer in the years to come on account of the non-availability of suitable trained personnel. The Committee desire that urgent steps should be taken to impart necessary training to a sufficient number of middle-level staff who could effectively discharge the responsibility of overseeing the technical aspects of production."

1.7. In paragraphs 1.69 and 1.70 of the Report, the Committee had further recommended:

"1.69. The Committee are of the view that the malady of the vaccine production unit at Coonoor is far more deep-seated than what meets the eye and the two studies emphasise the need for far-reaching changes and remedial measures. The Committee learn with consternation of the lack of cooperation and the complete breakdown of human and personal relationships at the Institute and this should also cause great concern to Government. The Committee desire that the functioning of the unit should be comprehensively and expeditiously reviewed in the light of the analysis already made by the two study teams and urgent steps taken to remove the existing bottlenecks and obstacles and to streamline the production of the vaccine. The Committee note that a meeting had been held on 1st October 1974 to consider the recommendations of the Study Team and would like to be informed of the measures, if any, already taken in pursuance of these recommendations."

"1.70. It is also seen from the ICMR official's report that a team of experts from the World Health Organisation was scheduled to visit the Pasteur Institute at Coonoor in July 1974 to study the technical aspects of vaccine production. The Committee would like to be informed of the findings of this team and the action taken by Government on its recommendations."

1.8. In their Action Taken Notes dated 31 March 1976, relevant to these recommendations/observations, the Department of Health have replied as follows:

Paragraph No. 1.66

"The recommendation of the Study Team for appointment of a whole time officer was considered in one of the meetings

neld in the Directorate General of Health Services. The Director, Pasteur Institute, Coonoor, assured at the meeting that Dr. Vasant Pandit, Assistant Director would be spared completely for looking after the Polio Vaccine Unit of the ICMR. However as already explained in reply to paragraphs 1.64 and 1.65 of the Report in the opinion of the technical officers, no amount of additional inputs in terms of finance, equipment and manpower to the Unit would improve the performance of the Unit with its present administrative arrangement."

Paragraph No. 1.67

"The present Director of the Pasteur Institute who is holding the post of the Officer-in-Charge of the Polio Vaccine Production Unit is due to retire from service of the society in November 1976. Dr. Vasant Pandit, the permanent Assistant Director of the Institute is on deputation to the Polio Production Vaccine Unit. He has been associated with the Unit as a Medical Officer from 2-12-63 and as Research Officer since 1-12-1966. He has been trained in the preparation of live polio vaccine at the Institute of Poliomyelitis and Viral Encephalitis, Moscow on a WHO fellowship. There is also a temporary Research Officer in the Unit since 1-11-1972 who has been associated with the preparation of polio vaccine as medical officer since 8th March 1965. It is agreed that it would be necessary to train other middle level staff in the techniques and intricacies of production of polio vaccine, but as the decision to close down the unit has since been taken, the question of giving training to the existing personnel at the Unit has ceased to be a live issue." Government of India are, however, exploring the possibility of taking over the entire Pasteur Institute including the Polio Vaccine Production Unit provided the society agrees to transfer all its assets and liabilities to them. If the Pasteur Institute is taken over by the Government and the Unit is revived full use of the trained manpower will be possible and further steps to train adequate number of personnel will be taken."

Paragraph No. 1.69

"Keeping in mind the above recommendation and finding the situation irremediable, the Government of India have decided to close down the Unit."

Paragraph No. 1.70

"A team of experts from the WHO visited Coonoor from the 10th to 15th October 1974 and submitted a report to the Director General of Health Services on the 17th December 1974. They also sent copies of the report to the National Institute of Communicable Diseases and to the Director of the Pasteur Institute, Coonoor. The recommendations of the team are given below:

- (1) there is a need for definition of precise work each staff member is to do and a clear indication of their individual responsibilities. It will be advantageous to arrange for all the senior staff to spend two to three months in a production or vaccine control laboratory over the next few years;
- (2) the lift-door opening in the building should be sealed off and made air-tight. All windows in the production area should be closed and air-sealed;
- (3) in the production area the rooms in which the kidney tissue cultures are prepared should be separated by a double-door air lock from the area in which the cultures are infected and harvested. This air-lock could be erected in the corridor between the plus 37 degree C. and the plus 34 degree C. hot rooms;
- (4) the sterile clothing should include trousers as well as the cap, mask, gown, and cotton boots at present supplied so that all outer clothing can be discarded before entry to the production area;
- (5) as rapidly as possible vertical laminar flow cabinets should be installed in the appropriate rooms of the production area and in the control area;
- (6) it is desirable that the viruses and sera are stored in separate containers, preferably in separate rooms;

- (7) the incubator and water bath for the ret marker test are not adequately temperature-controlled; no automatic recorders are fitted and the water bath is too small;
- (8) there is no continuous recording of temperatures on the autoclaves and hot air ovens and indicator capsules are not employed;
- (9) it would be advisable to have a separate cabinet for each type of seed and to institute a suitable system of colour coding;
- (10) a larger water-bath with proper temperature control should be installed, and a better method of trypsinisation for preparing tissue culture cells should be employed;
- (11) considerable improvement in the monkey houses and in the care and handling of monkeys is necessary;
- (12) another matter to be investigated is the consistently low titres of the vaccine lots. The vaccine is prepared on kidney tissue cultures of *M. Radiata* but the yields from this substrate compared with yields from the kidney tissues of *M. Mulatta* and *cercepithecus* have not apparently been compared. These comparisons should be made in Coonoor and Delhi and Dr. Archetti in Rome will test the titres of some of the batches;
- (13) the temperature of the two large cold rooms for storage of vaccine should be kept consistently below -20°C , preferably -25°C to 30°C and a continuous temperature recorder should be fitted;
- (14) a clear policy directive on how much vaccine should be prepared annually over the next several years;
- (15) a firm plan for the uplifting, distribution and use of the vaccine as it is prepared;
- (16) within the Institute, firm management of the production area with clear programming and well defined areas of responsibility for the individual scientists in the senior positions;

- (17) the extension of the Neurovirulence Testing Laboratory at the NICD to undertake other tests on poliomyelitis vaccines, both those from Coonoor and those which are imported;
- (18) frequent contact and exchange of information and views on test procedures between the National Control Laboratory and the Vaccine Production Laboratory.

The copies of the reports were sent by the WHO team to the Director, Pasteur Institute, Coonoor and to the National Institute of Communicable Diseases. The WHO team also discussed this report with the Director General of Health Services and the Director of the Pasteur Institute, Coonoor initiated action on the various recommendations of the WHO's Study Team by calling quotation, by contacting firms for doing necessary additions and alterations to the production area as recommended by the Study Team.

In regard to the other recommendations of the Study Team about the target of production, plan for uplifting of distribution etc., these could be implemented only after the existing defects noticed in the work of the Unit are removed and production schedules brought upto-date. To consider these aspects several meetings were held in the Ministry as well as in the Directorate General of Health Services, but as explained in reply to paragraphs 1.64 and 1.65 of the Report, there had been no improvement in the performance of the Unit, with the result, the decision to close down the Unit had to be taken."

1.9. The Committee are perturbed that instead of attempting to infuse new life into the Polio Vaccine Production Unit at Coonoor, established at considerable expense to reduce the country's dependence on imports of a vital vaccine, and to improve its management and production techniques, Government have apparently chosen the line of defeat and decided to close down the Unit after a decade of its existence and functioning. This decision is stated to have been taken on the advice of the technical officers that no amount of additional inputs in terms of finance, equipment and manpower would improve the performance of the Unit, as constituted at present under the administrative control of the Pasteur Institute, which is a registered society, as well as on account of certain technical problems encountered in the production of good, acceptable and safe

vaccine. The Committee, however find that the two teams of officials of the Indian Council of Medical Research the National Institute of Communicable Diseases, Directorate General of Health Services and the Drug Controller, deputed to conduct a detailed study of the functioning of the Unit and the shortfalls in its production, had not expressed themselves in favour of the dissolution of the Unit but had, on the contrary, suggested remedial measures which could have improved its performance and placed the production on a firmer footing. For instance, a senior official of the Indian Council of Medical Research had given it as his view that the Unit's administrative and technical problems notwithstanding, it could effectively produce, even with its existing staff, several million doses of the vaccine annually if "a few essential steps" were taken. The other study team of officials had also recommended inter alia, remedial measures to be planned and executed on a top priority and that the progress made by the Production Unit should be reviewed annually. The Committee, therefore, cannot appreciate the rationale behind the decision to close down the Unit.

1.10. As regards the Ministry's contention that there were inherent difficulties in the administration of the Unit as at present constituted, the Committee are of the view that it should not have been beyond Government's capabilities to overcome them. In fact, the Committee find from the Action Taken Note furnished in response to their recommendation contained in paragraph 1.67 of their 179th Report that Government are also exploring the possibility of taking over the entire Pasteur Institute including the Polio Vaccine Production Unit, provided the society agrees to transfer all its assets and liabilities to Government. That the Unit should have been closed down even before the final outcome of these efforts is known is something of a paradox. It is also significant that certain steps are stated to have been taken by the Director of the Pasteur Institute, in pursuance of the recommendations of a team of experts from the World Health Organisation, for making necessary additions and alterations to the production area.

1.11. In these circumstances, the Committee find it difficult to reconcile themselves to the closure of the Vaccine Production Unit. It is a pity that after having built-up, over a decade, the necessary infrastructure and expertise for the production of a sophisticated vaccine vital for the well-being of our children, such a decision should have been taken without even giving adequate opportunity to the Unit to rehabilitate itself. As already pointed out, the alleged administrative and technical problems are by no means insurmountable. The Committee cannot countenance the work of a de-

cade being thus virtually frustrated by what, prima facie, appears to be a hasty and ill-conceived decision. They would urge Government to review the decision, particularly in the light of the proposal to take over the Pasteur Institute as well as the other interim measures stated to have been initiated to streamline the functioning of the Unit.

1.12. It is evident that this sorry state of affairs could have been prevented if Government were less complacent and had regularly monitored the functioning of the Unit without waiting for some sort of a crisis to develop. The Health Secretary was frank enough to admit before the Committee that the two study teams of officials had been deputed to review the functioning of the Unit only after Government's attention was drawn by Audit to the prevailing state of affairs. The Committee are convinced that with a closer watch over the Unit's performance and periodic reviews with a view to improving management and production techniques, the Unit would have shown better results. The Committee take a serious view of this default and desire fixation of responsibility therefor.

1.13. Now that steps are being taken to develop Polio Vaccine manufacture at the Haffkine Institute at Bombay by converting it into the Haffkine Bio-Pharmaceutical Corporation Limited and the technical shortcomings of production of the vaccine at the Pasteur Institute have also been identified on the basis of expert studies, the Committee trust that Government will benefit from the experience gained at the latter institute so that there is no repetition of past mistakes. The performance of the Corporation would need also to be closely watched.

Delays in issue of clearance for imports. (Paragraphs 1.71 and 1.72—Sl. Nos. 8 and 9)

1.14. It had been deposed before the Committee by the Director of the Pasteur Institute that the shortfall in production of the vaccine at the Institute was also attributable to delays in the import of African green monkeys and other chemicals and equipment necessary for the preparation and testing of the vaccine. Dealing with this aspect, the Committee, in paragraphs 1.71 and 1.72 of the Report, had recommended:

“1.71. The shortfall in production of the vaccine at the Pasteur Institute has also been attributed by the Director of the Institute to delays in the import of African green monkeys, chemicals and equipment. The Committee have

been informed that while there was a delay of about six months in the issue of clearance by the Director General, Technical Development in respect of the import of 11 monkeys in 1970, necessary clearance had been issued by the Director General, Technical Development after 4 months in respect of a further import of 12 monkeys in 1973. The Committee are concerned over such delays in arranging imports of a vital pre-requisite for the production of the vaccine. The Committee are of the view that it should be possible to streamline the existing procedures for the issue of clearance by the Director General, Technical Development at least in respect of such imports by Central Government departments and organisations for which the justification is beyond doubt. The Committee desire that this should be examined and a suitable simplified procedure evolved."

"1.72. The Committee note that certain changes have been effected in the existing arrangements for sanctioning imports and the Ministry of Health has been empowered to sanction imports, up to an amount of Rs. 75,000, on their own judgment without referring the case to different agencies. The Committee trust that with this arrangement, the bottlenecks in imports would be considerably eliminated. The Committee would like to be informed of the time now taken, after the introduction of the revised procedure, for arranging imports of monkeys and other equipment etc. required by the Vaccine Production Unit"

1.15. The Action Taken Note dated 31 March 1976, furnished by the Department of Health in pursuance of these recommendations is reproduced below:

"As a decision not to continue the Unit at Coonoor in its present form has been taken, the question of importing of the monkeys and other equipment for the Unit at present does not arise."

1.16. The Committee regret that the reply now furnished by the Department of Health is not quite relevant to their specific recommendation, contained in paragraph 1.71 of their 179th Report, that a simplified procedure should be evolved for the issue of clearances by the Director General, Technical Development, in respect of imports by Central Government departments and organisations for which the justification is beyond doubt. Since it is not unlikely that

other Government departments and agencies might also be handicapped by delays in issue of clearances for imports, the Committee reiterate their earlier recommendation in this regard and urge that the existing procedures should be reviewed without further loss of time.

Under-utilisation of the capacity of the Polio Vaccine Testing Division (Paragraph 1.77—Sl. No. 14).

1.17. For conducting the neurovirulence test of the vaccine produced at Coonoor, a testing division had been established in the National Institute of Communicable Diseases, Delhi, in the latter part of 1970. Reviewing the utilisation of the capacity created in the division, the Committee, in paragraph 1.77 of the Report, had recommended as follows:

“It is also a matter of concern to the Committee that the capacity of the testing division (on which, till March 1972, Rs. 14.45 lakhs had been spent, excluding cost of buildings) has been grossly under-utilised so far. The Committee note that only 25 lakh monovalent doses have been tested by the division till 1974 as against 19.2 crore monovalent doses that could have been tested. The under-utilisation of testing capacity has been mainly attributed to the existing limited capacity for production of the vaccine in the country and the delays in the receipt of batches for testing. However, even after streamlining the production at the Pasteur Institute so as to achieve the optimum capacity of 12.50 lakh trivalent doses, the percentage utilisation of the built-in capacity of the testing division would still be only about 15 per cent. The Committee are also doubtful whether, even after the establishment of another production unit at the Haffkine Institute, Bombay, it would be possible to utilise the full capacity of 160 lakh trivalent doses of the testing division. The Committee would like to be informed of the basis on which the existing capacity of the division has been worked out. Government should also examine immediately the feasibility of effecting economy in the expenditure on staff etc. of the testing division.”

1.18. In their Action Taken Note dated 31 March 1976 on the above recommendation, the Ministry of Health & Family Planning (Department of Health) have replied:

“The PAC’s recommendations are appreciated. In view of the decision to close down the Polio Vaccine Unit at Coonoor

there is not enough work with the testing unit. However, the unit has been engaged in testing the imported Polio Vaccine and storage conditions.

The question of closing down the Neuro-virulence Testing Unit is under consideration. Some of the trained staff, however, would be necessary to test the potency of the imported vaccine and other connected matters."

1.19. While the Committee note that the question of closing down the Neurovirulence Testing Unit set up at the National Institute of Communicable Diseases is also under consideration as a sequel to the decision to close down the Polio Vaccine Production Unit at the Pasteur Institute, Coonoor, they find, however, that the Department's reply is silent in regard to the Committee's specific query about the basis on which the present capacity (160 lakh trivalent doses) of the testing division had been worked out. The position in this regard should be clarified forthwith.

1.20. As regards the proposal to close down the testing division, the Committee find from the reply furnished by the Department to their observations contained in paragraph 1.70 of the 179th Report, that the team of experts from the World Health Organisation, visiting India in October 1974, had recommended, *inter alia*, that the Neurovirulence Testing Division at the National Institute of Communicable Diseases should be extended to undertake other tests on poliomyelitis vaccine from Coonoor as well as those imported. It is not clear to the Committee where the vaccine produced by the Haffkine Bio-Pharmaceutical Corporation is proposed to be tested for neurovirulence with the closure of the testing division. They, therefore, fear that adequate thought has not been given to this question and would urge Government to do some rethinking in this regard. The action taken or proposed to be taken on the WHO study team's recommendation should also be intimated to the Committee.

Distribution and marketing arrangements. (Paragraph 1.81—Sl. No. 18).

1.21. The report of the Comptroller & Auditor General of India had pointed out, *inter alia*, that only 1.10 lakh trivalent doses out of 4.61 lakh doses of the vaccine produced by the Unit from December 1966 to May 1973 had been distributed till May 1973 and that as a result of delays in marketing the vaccine, the date of expiry of 0.60 lakh doses was over, necessitating their reiteration and extension of the period of their usability. Commenting on this aspect, in para-

graph 1.81 of their Report, the Committee had recommended as follows:

"The Committee find that on account of the delay in marketing the vaccine, the date of expiry of 0.60 lakh doses was over in July-August 1972 and consequently, these doses had to be retitrated and the period of their usability extended upto April 1975. The Committee would like to know the additional expenditure incurred in retitrating these doses and whether the entire quantity of 0.60 lakh doses has been utilised, now that even the extended period is over. That such a measure was necessary would indicate the need for improving the facilities available for marketing the vaccine and apparently sufficient attention has not been paid to this important aspect. The Committee desire that the adequacy of the existing marketing arrangements should be reviewed and necessary remedial measures taken."

1.22. In their Action Taken Note dated 31 March 1976, furnished in pursuance of the above recommendation, the Ministry of Health & Family Planning (Department of Health) have stated:

"51,250 doses of trivalent vaccine from batches No. 11, 13, 14 and 15 and 8,300 doses from batch No. 12 stored at Haffkine Institute, Bombay (i.e. 59,550 doses) had expiry date July-August 1972. These batches were retitrated on 17th April 1973 at the National Institute of Communicable Diseases, Delhi and were found to retain full potency and the expiry date for these batches was extended to 17th April 1975.

These batches were again retitrated at the National Institute of Communicable Diseases, Delhi on 11th October 1974 and the titres of all batches were found to be satisfactory except that for batch 12 which had been stored at Haffkine Institute, Bombay. Samples from batch No. 12 were sent to the National Institute of Communicable Diseases, Delhi by the Haffkine Institute, Bombay, directly. The batch containing 8,300 doses was discarded on 25th March 1975.

Vaccine in batches, 11, 13, 14 and 15 were issued to the Medical Stores Depot, Madras on 17th December 1974 for distribution.

The cost involved in retitrating the virus content in batches of trivalent vaccine will be negligible as the work invol-

ed is very small and the material required for the work is easily available in the testing unit at NICD, Delhi.”

1.23. In paragraph 1.81 of their 179th Report, the Committee had drawn pointed attention to the delay in distribution and marketing of the vaccine, as a result of which 0.60 lakh doses of the vaccine had to be retitrated and certified to be usable beyond their date of expiry and had desired that the adequacy of the existing marketing arrangements should be reviewed and necessary remedial measures taken. The Department's reply is, however, unfortunately silent on the steps taken in this regard. That these batches of vaccine had to be retitrated once again in October 1974, leading to 8,300 doses being discarded on account of having lost their potency, only serves to reinforce the Committee's earlier impression that adequate attention has not been paid to the important aspect of timely marketing and distribution of the vaccine. The Committee are, therefore, constrained to reiterate their earlier recommendation in this regard. An immediate review of the adequacy of the existing arrangements for marketing and distribution of the vaccine is called for.

CHAPTER II

RECOMMENDATIONS/OBSERVATIONS THAT HAVE BEEN ACCEPTED BY GOVERNMENT

Recommendation

In the opinion of the Committee some of the technical problems brought to their notice during their examination are also not entirely insurmountable and are attributable more to negligence and carelessness. For instance, the Committee are surprised to learn that no attempt appears to have ever been made to check whether the germicidal lamps did possess, at a particular time on a particular day, any germicidal activity. Similarly, the electrical appliances are stated to be 'in a mess'. It is, therefore, obvious that effective supervision and prompt remedial measures have been inadequate, if not altogether non-existent. Since the technical aspects of production imperatively call for constant scrutiny the Committee cannot countenance such lapses in the production of a sophisticated vaccine. They desire that responsibility should be fixed for the non-observance of even the basic, elementary requirements of successful production.

[Serial No. 5 (Para No. 1.68) of Appendix II to 179th Report
(Fifth Lok Sabha)].

Action Taken

Government of India appreciate the recommendations of the Committee and in view of the various difficulties and inefficiency of the staff not under the direct control of the ICMR, it has been decided to wind up the Unit and terminate the services of the personnel.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015/8/75-R dated 31-3-76].

Recommendation

The Committee have been informed that the production of vaccine is also liable to be affected by power failures and are surprised to learn that an automatic generator has not been installed so far. Since regular supply of power is one of the important factors for

maintaining production of vaccine at an efficient level and its proper storage, the Committee desire that this deficiency should be made good on a priority basis.

[Serial No. 11 (Para No. 1.74) of Appendix II to 179th Report
(Fifth Lok Sabha)].

Action Taken

There is no doubt that the production of vaccine is likely to be affected by power failures but at the Polio Vaccine Production Unit at Coonoor there was, however, a stand by generator for use on such occasions. Due to the various deficiencies in the working of the Unit already noticed by the P.A.C., the facilities that were available at the Unit were not fully utilised.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015|8|75-R dated 31-3-76].

Recommendation

The Committee are concerned to observe that the approval of the Drug Controller for the preparation of trivalent vaccine from the monovalent doses of vaccine produced at the Institute and tested in foreign countries had been communicated only 5 to 8 months after the receipt of test results. In the opinion of the Committee, this delay was by no means unavoidable. It is surprising that the circulation of the protocols by the Drug Controller to various agencies entrusted with the certification of the vaccine should have taken 5 to 8 months and the reasons advanced by the Ministry for this delay are not at all convincing. The Committee, however, note that the procedure has now been streamlined and that the certification by the Drug Controller would not take more than 2 to 3 weeks. The Committee trust that the revised schedule for the testing of the monovalent doses of the vaccine would be rigidly adhered to and prompt action taken to remedy the situation whenever delays of avoidable magnitude come to notice.

[Serial No. 12 (Para No. 1.75) of Appendix II to 179th Report
(Fifth Lok Sabha)].

Action Taken

As already noted by the P.A.C. the procedure has been streamlined.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015|8|75-R dated 31-3-76].

Recommendation

While the Committee can understand the reasons for the delays involved in the testing of the monovalent doses of vaccine in foreign countries, they are unable to appreciate the delays that have occurred at the testing division, established in the later part of 1970, in the National Institute of Communicable Diseases, New Delhi. The Committee find that the tests in respect of two batches of vaccine received in May, 1971 had been completed only after 11 months in one case and 14 months in another case. Though the time taken for the test has been reduced in respect of two subsequent batches received by the division in January 1973 and February, 1974, the Committee are still unhappy with the performance of the testing division. The Committee would, therefore, like Government to investigate the reasons for the delay in testing the vaccine at the National Institute of Communicable Diseases and take suitable remedial measures to avoid recurrence of such delays. The Committee would like to be apprised of the action taken in this regard.

[Serial No. 13 (Para No. 1.76) of Appendix II to 179th Report (Fifth Lok Sabha)].

Action Taken

The question of the delay referred to by the P.A.C. was considered in consultation with the Director, NICD, Delhi. The Director has replied as follows:—

“The bulk suspensions received in May, 1971 happened to be the first bulk suspensions received for neurovirulence testing in this Institute. It was essential that their neurovirulence was compared with the International reference preparation. The entire procedure of establishing the standards of neurovirulence with the International preparation and the two bulk suspensions took one year. Since the report on neurovirulence testing was to be made for the first time in the country, the protocols of test reports had also to be discussed before being finalised.

Steps have been taken at the National Institute of Communicable Diseases to ensure that there are no delays in reporting on the neurovirulence of any subsequent bulk suspensions received from Pasteur Institute, Coonoor. It is expected that results would be available in 6-8 months period”.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015|8|75-R dated 31-3-76].

Recommendation

Now that the Haffkine Institute, Bombay is also expected to commence production of oral polio vaccine by the end of 1975, the Committee would like the economics of production and distribution of the vaccine at this Institute to be worked out in detail, in case this has not already been done, and intimated. The Committee also trust that the production at this Institute would be geared up and streamlined even in the initial stages in the light of the experience gained at the Pasteur Institute. The Committee expect that in this task there would be no lack of co-ordination, which appears to be feared, between the Institute, the Government of Maharashtra and also, of course, the Central Government. The Committee would be watching the performance of the Haffkine Institute with interest.

[Serial No. 16 (Para No. 1.79) of Appendix II to 17th
Report (Fifth Lok Sabha)]

Action taken

The production wing of the Haffkine Institute, Bombay has been converted into Haffkine Bio-Pharmaceutical Corporation Limited. This Unit has got the requisite expertise and once the seed virus is made available by the WHO, the Unit can start producing polio vaccine. The Government of India also expect that there would be adequate coordination between the Institute, Government of Maharashtra and the Government of India, so that production of vaccine is kept up according to schedule.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015/8/75-R dated 31-3-76]

Recommendation

The Committee note that 1.71 lakh doses of polio vaccine supplied to the Medical Stores Depot, Madras had remained unsold towards the closing months of 1974 and would like to be informed of the present position of the sales at the depot.

[Serial No. 17 (Para No. 1.80) of Appendix II to 17th
Report (Fifth Lok Sabha)]

Action taken

The remaining 1.71 lakh doses of Polio Vaccine in 1974 have since been distributed by the Medical Stores Depot, Madras.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015/8/75-R dated 31-3-76].

Recommendation

The Committee are concerned to find that there has been no organised effort to rouse public awareness on anti-poliomyelitis in the rural areas. No national programme for immunisation against poliomyelitis has yet been contemplated though epidemics of polio have occurred in the country and relative to need, the efforts so far made are very limited and modest. The Committee consider it important that adequate measures are taken to educate the masses, particularly in the rural areas on polio and the efficacy, of oral polio vaccine which Government should make every possible effort to provide in required quantity and quality. The Committee are of the view that the existing arrangements in this regard are far from adequate and a more earnest and organised effort is called for. The Committee suggest that Government should, *inter alia*, utilise the powerful medium of films and radio so as to make a sustained impact on the rural population.

[Serial No. 19 (Para No. 1.82) of Appendix II to 179th
Report (Fifth Lok Sabha)]

Action Taken

The incidence of polio is mainly in the cities, children living in rural areas generally develop immunity at an early age. It has, therefore, not been considered essential to have a national programme for immunisation against poliomyelitis. However, the Central Health Education Bureau has printed the following publications on Polio and sent these to the State Health Education Bureaux for adaption/translation in the regional language. They are:—

- (i) Infantile Paralysis (English).
- (ii) Bal Pakshaghat (Hindi).
- (iii) Polio Can be Prevented (English)
- (iv) Polio—A crippling diseases of young is preventable—
How? (English).
- (v) Polio Ki Roktham Sambhav Hai (Hindi).

- (vi) 'Bachon ko apang ~~banane~~ vale rog polio se bachav ho sakta hai' Kaise? (Hindi).
- (vii) Get children immunised against Polio (English).
- (vii) Apne Bachon Ko Polo se Bachai (Hindi).

The Radio scripts on 'Immunization and Polio' have been broadcast by different stations as reported by the stations.

A programme of SITE on Polio has been telecast for all the villages in the six states where SITE programmes are beamed.

The Bureau assisted the Municipal Corporation of Delhi in its campaign against Polio by way of providing them folders, hand-bills, posters etc. A small exhibition (table top) developed by the Bureau was displayed in Pataudi district (Haryana) where Bureau's Rural Field Study and Demonstration Centre is situated. This exhibit was also used by the Kalavati Saran Hospital, NDMC and Municipal Corporation of Delhi.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015|8|75-R dated 31-3-76].

Recommendation

The Committee also find that it has been estimated that out of the population of 54.80 crores, according to the 1971 census, 8.20 crore children are in the susceptible group, for whom 24.60 crore doses of trivalent polio vaccine are needed annually, besides for the estimated 1.30 crore new-born, about 3.90 crore doses of trivalent vaccine are also required each year. Yet, the Committee are surprised to find that the Country's annual requirement of polio vaccine has been presently estimated as only 1.20 crore trivalent doses. Apparently, the requirements have been placed at 1.20 crore doses as against the actual estimates of 28.50 crore doses on the basis of the expert view that the vaccine should be made available for immunisation for those who demand it and also used for threatened epidemic. The number of doses actually available in the country (both imported and indigenously produced) has been much less than even in this estimate. The authorities concerned seem to derive comforts from the fact that as the epidemic declines, the public lose their enthusiasm for immunising the children and fail to give the three doses necessary to each child to ensure proper immunising. In the opinion of the Committee this seems to suggest a certain complacency in regard to public indifference not unnatural in Indian conditions, towards serious health hazards. That such a situation has been

allowed to persist only underlines the urgent need to adequately educate the public on the dangers of polio and the measures to combat this acutely infectious disease.

[Serial No. 20 (Para No. 1.83) of Appendix II to 179th Report (Fifth Lok Sabha)]

Action Taken

Action Taken has been reported under Sl. No. 19, Para No. 1.82 of the Report.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015|8|75-R dated 31-3-76].

CHAPTER III

RECOMMENDATIONS|OBSERVATIONS WHICH THE COMMITTEE DO NOT DESIRE TO PURSUE IN THE LIGHT OF THE REPLIES RECEIVED FROM GOVERNMENT

Recommendation

The Committee desire that the possibility of breeding African green monkeys in India in a virusfree form, so as to reduce the dependence on imports, should be explored on a priority basis. The Committee take note of the assurance given by the Secretary, Ministry of Health and Family Planning during evidence that this suggestion would be pursued with the Veterinary Department and would like to be apprised of the progress made in this regard.

[Serial No. 10 (Para No. 1.73) of Appendix II to 179th Report (Fifth Lok Sabha)]

Action Taken

The matter was considered in consultation with the Department of Agriculture who have stated as follows:

“None of the Zoos in our country have a breeding pair of the African Green Monkey. So very little is known about its breeding under Indian conditions. It is felt that it would not be worthwhile breeding these monkeys when the annual demand is expected to be only 12”.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015/8/75-R dated 31-3-76].

Recommendation

It is also significant that while the cost of imported polio vaccine works out to only about 15 paise, the cost of production at the Institute is about 50 paise per dose. Considering the wide disparity in the cost of imported and indigenous vaccine, the Committee desire that urgent steps should be taken to reduce the cost of production by improved techniques. In this connection the Committee have been informed that an exercise in this regard had been carried out by a

Cost Accounts Unit in 1968 and that the review of the cost of production at the Institute is under consideration of the Government. It is deplorable that no action has yet been initiated on the report of the Cost Accounts Unit, even after a lapse of more than six years. The Committee take an extremely serious view of this delay and desire that responsibility should be fixed for the lapse and appropriate action taken under advice to them.

[Serial No. 15 (Para No. 1.78) of Appendix II to 179th Report
(Fifth Lok Sabha)].

Action Taken

The Cost Accounts Unit of the Central Research Institute, Kasauli which went into the cost of production of Polio Vaccine at the Polio Vaccine Production Unit, Coonoor in 1968 worked out the cost more or less on a tentative basis as the normal production level had not been reached at the unit. They stated that with the availability of necessary testing facilities in India and the employment of the full complement of the staff, the production was expected to go up substantially, resulting in the lowering of cost of production progressively. Subsequently, when the question of review of the price of the polio vaccine was considered the Officer-in-Charge of the unit stated that the price of the polio vaccine might be reviewed at a later date as normal level of production, testing, including neurovirulence testing and distribution etc. were not established. For the reasons already explained in reply to paras 1.64 and 1.65 of the Report in spite of several attempts, it was not possible to improve the working of this Unit and to improve the production of the vaccine. The Ministry of Finance, Cost Accounts Branch, who was consulted, also advised that an on the spot study at Coonoor could be undertaken if the normal level of production had been established. Due to the reasons already explained, it was not possible to achieve the normal level of production and consequently the question of review of cost of production could not be taken up.

[Ministry of Health of Family Planning (Department of Health)
O.M. No. G. 25015/8/75-R dated 31-3-76].

Recommendation

The Committee understand that while tap water is free from the virus of poliomyelitis, it is most dangerous to use water available from hand-pumps. While explaining the reasons for not contemplating a national programme for immunisation against polio, the Director General, Health Services had also stated that only by supply-

ing protected water to the entire country, this disease can, to some extent be eradicated and that if this could be ensured, then there would be a national programme. The Committee would like to know the concrete steps taken by Government in this direction.

[Serial No. 21 (Para No. 1.84) of Appendix II to 179th Report
(Fifth Lok Sabha)].

Action Taken

The Ministry of Works and Housing, who were consulted in the matter, have replied as under:—

“There are about 1.53 lakhs problem villages in the country. Upto March, 1974 about 40,000 villages have been covered with protected water supply and the Fifth Five Year Plan expects to cover as many as 80,000 villages with protected water supply through various means including hand-pumps. In this connection, the Committee’s views that ‘it is most dangerous to use water available from hand-pumps’ is not tenable. Presumably, the Committee means to say that there are chances of contamination in case of handpumps. If adequate sanitary measures are adopted to prevent contamination, there is less danger in using water available from handpumps and moreover no such record with us to substantiate the fact that the section using water from properly installed and maintained hand-pumps are affected by Poliomyelitis.

In the light of the magnitude of problem yet to be covered in providing protected water supply to rural communities, it may not be feasible to have piped water supply system in all the 5.57 lakhs villages in the country within a reasonable time limit. Therefore, provision of properly constructed tubewell handpumps in rural areas will have to continue for some more years to come.”

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015/8/75-R dated 31-3-76].

CHAPTER IV

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

Recommendation

The Committee are extremely dissatisfied with the performance and achievements of the polio vaccine production unit at the Pasteur Institute, Coonoor on which, as pointed out by Audit, Rs. 21.15 lakhs, excluding foreign aid of Rs. 7.48 lakhs, had been spent upto March, 1972. They are concerned to note that as against its annual capacity of 12.50 lakh trivalent doses of vaccine, the unit has been able to produce only 4.61 lakh trivalent doses from December 1966 to May 1973, in a span of about 6½ years. The average annual production, thus, works out to only about 6 per cent of the capacity of the unit. Even conceding that the development of the vaccine is a sophisticated process and the production of contamination-free batches takes time, the present state of affairs at the Institute is far from satisfactory. The Committee apprehend that unless vigorous and concert efforts are made to improve production and management techniques at the unit, the position may well become irretrievable.

[Serial No. 1, (Para No. 1.64) of Appendix II to 179th Report
(Fifth Lok Sabha)].

Action taken

Government were already aware of the unsatisfactory performance and achievements of the Polio Vaccine Production Unit at the Pasteur Institute, Coonoor. To remedy the defects noticed and to improve the functioning of the unit, discussions were held in the Directorate General of Health Services and in the Ministry of Health on 23-3-74, 16-7-74, 13-9-74, 1-10-1974, 19-10-1974, 15-2-75, 20-12-75 and 22-1-76. The Recommendation made by a team of officers were also considered. There were inherent difficulties in the Unit as at present constituted. The Polio Vaccine Production Unit, Coonoor, is in fact a Unit of the Pasteur Institute of South India which is a Registered Society. Even though the Indian Council of Medical Research has been financing this

Unit as a research Project, the actual control of the staff and responsibility for managing the project rested with the Director of the Pasteur Institute who is the Officer-in-Charge of the Unit in addition to his duties. This arrangement was obviously unsatisfactory and led to several problems of indiscipline, inefficiency and also poor production. At one stage it was thought that if the Government of Tamil Nadu could take over the management of the Unit, its performance could be improved considerably. The Government of Tamil Nadu were accordingly requested to take over the Unit, but the State Government, however, regretted their inability to agree to the proposal. The potency of the vaccine produced at the Unit had become very low and did not pass the neuro-virulence test. The seeds which had been supplied to the Unit by the WHO had also lost much of its potency and if further batches of vaccine are produced out of those seeds, they would not pass the test. The WHO team had made certain recommendations which involve substantial financial outlay. The technical officers, who were consulted in the matter, felt that even if additional inputs in terms of finance, equipment etc. were given to the Unit, it is doubtful whether the Unit would be able to produce good, acceptable and safe vaccine. With the present administrative arrangements and management problems and the proved inefficiency of the staff, it was felt that it would not be worthwhile to spent large sums or money in reviving the Unit in its present form. In the light of the above, the Government of India have decided to close down the Unit.

2. Steps are, however, being taken to develop Polio Vaccine manufacture at the Haffkine Institute, Bombay where necessary infrastructure, expertise and other facilities are available.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015/8475-R. dated 31-3-76]

Recommendation

In this context, the Committee are of the view that the assessments made by a senior official of the Indian Council of Medical Research and by a team of officers of the Council, The National Institute of Communicable Diseases, Directorate General of Health Services and the Drugs Controller, who had been deputed to conduct a detailed study of the shortfalls in production, are of considerable significance and mere serious and immediate attention. The picture that emerges from these two studies is far from complimentary both to the production unit and the Pasteur Institute. The

following facts, in particular, bring out the sad state of affairs prevailing in the Institute:

- (a) Lack of cooperation and support and a complete breakdown of human and personal relationships between the personnel of the production unit and the Director of the Institute;
- (b) carelessness on the part of middle level supervisory staff in coordinating the activities of the unit;
- (c) absence of a long range plan of work, nonfixation of targets of production, non-assignment of responsibilities and the absence of frequent and regular checks;
- (d) non-availability of trained middle level staff;
- (e) a complete breakdown of the measures that would ensure sterility in the production chamber; and
- (f) in adequate maintenance of equipment and records.

[Serial No. 2, (Para No. 1.65) of Appendix II to 179th Report (Fifth Lok Sabha)].

Action Taken

Action taken has been reported under Serial No. 1, Para No. 1.64 of the Report.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015/8/75-R dated 31-3-76]

Recommendation

The Committee attach considerable importance to the recommendation of the study team that the vaccine production unit should be placed under the overall charge of a wholetime officer who would be expected to deal with all the problems relating to premises, personnel, supplies and the production of vaccine. The Committee accordingly recommend that decision on this recommendation should be taken without further delay so as to place the production unit on a firmer footing.

[Serial No. 3 (Para No. 1.66) of Appendix II to 179th Report (Fifth Lok Sabha)].

Action Taken

The recommendation of the Study Team for appointment of a wholetime officer was considered in one of the meetings held in the Directorate General of Health Services. The Director, Pasteur Institute, Coonoor, assured at the meeting that Dr. Vasant Pandit, Assistant Director, would be spared completely for looking after the Polio Vaccine Unit of the ICMR. However, as already explained in reply to paragraphs 1.64 and 1.65 of the Report, in the opinion of the technical officers, no amount of additional inputs in terms of finance, equipment and man-power to the Unit would improve the performance of the Unit with its present administrative arrangement.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015/8/75-R dated 31-3-76]

Recommendation

The Committee learn that the present Director of the Pasteur Institute, who has vast experience in the field of polio vaccine will be available for only another two or three years. The problem of his replacement, when no longer available, calls for careful thought. It is, therefore, imperative that a sufficient number of persons are trained in the techniques and intricacies of production of polio vaccine so that production does not suffer in the years to come on account of the non-availability of suitable trained personnel. The Committee desire that urgent steps should be taken to impart necessary training to a sufficient number of middle-level staff who could effectively discharge the responsibility of overseeing the technical aspects of production.

[Serial No. (Para No. 1.67) of Appendix II to 179th Report
(Fifth Lok Sabha)].

Action Taken

The present Director of the Pasteur Institute who is holding the post of the Officer-in-Charge of the Polio Vaccine Production Unit is due to retire from service of the society in November, 1976. Dr. Vasant Pandit, the permanent Assistant Director of the Institute is on deputation to the Polio Production Vaccine Unit. He has been associated with the Unit as a medical officer from 2-12-63 and as Research Officer since 1-12-1966. He has been trained in the preparation of live polio vaccine at the Institute of Poliomyelitis and Viral Encephalitis, Moscow on a WHO fellowship. There is also a temporary Research Officer in the Unit since 1-11-1972 who has been associated with the preparation of Polio vaccine as medical officer

since 8th March, 1965. It is agreed that it would be necessary to train other middle level staff in the techniques and intricacies of production of polio vaccine, but as the decision to close down the unit has since been taken, the question of giving training to the existing personnel at the Unit has ceased to be a live issue. Govt. of India are, however, exploring the possibility of taking over the entire Pasteur Institute including the Polio Vaccine Production Unit provided the society agrees to transfer all its assets and liabilities to them. If the Pasteur Institute is taken over by the Government and the Unit is revived full use of the trained manpower will be possible and further steps to train adequate number of personnel will be taken.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015/8/75-R dated 31-3-76]

Recommendation

The Committee are of the view that the malady of the vaccine production unit at Coonoor is far more deep-seated than what meets the eye and the two studies emphasis the need for far-reaching changed and remedial measures. The Committee learn with consideration of the lack of cooperation and the complete breakdown of human and personal relationships at the institute and this should also cause great concern to Government. The Committee desire that the functioning of the unit should be comprehensively and expeditiously reviewed in the light of the analysis already made by the two study teams and urgent steps taken to remove the existing bottlenecks and obstacles and to streamline the production of the vaccine. The Committee note that a meeting had been held on 1st October, 1974 to consider the recommendations of the Study Team and would like to be informed of the measures, if any, already taken in pursuance of these recommendations.

[Serial No. 6 (Para No. 1.69) of Appendix II to 179th Report (Fifth Lok Sabha)]

Action Taken

Keeping in mind the above recommendation and finding the situation irremediable, the Government of India have decided to close down the Unit.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015/8/75-R dated 31-3-76]

Recommendation

It is also seen from the ICMR official's report that a team of experts from the World Health Organisation was scheduled to visit the Pasteur Institute at Coonoor in July 1974 to study the technical aspects of vaccine production. The Committee would like to be informed of the findings of this team and the action taken by Government on its recommendations.

[Serial No. 7 (Para No. 1.70) of Appendix II to 179 Report
(Fifth Lok Sabha)]

Action Taken

A team of experts from the WHO visited Coonoor from the 10th to 15th October, 1974 and submitted a report to the Director General of Health Services on the 17th December, 1974. They also sent copies of the report to the National Institute of Communicable diseases and to the Director of the Pasteur Institute, Coonoor. The recommendations of the team are given below:—

- (1) there is a need for definition of precise work each staff member is to do and a clear indication of their individual responsibilities. It will be advantageous to arrange for all the senior staff to spend two to three months in a production of vaccine control laboratory over the next few years;
- (2) the lift-door opening in the building should be sealed off and made air-tight. All windows in the production area should be closed and air-sealed;
- (3) in the production area the rooms in which the kidney tissue cultures are prepared should be separated by a double-door air lock from the area in which the cultures are infected and harvested. This air-lock could be erected in the corridor between the +37°C and the +34°C hot rooms.
- (4) the sterile clothing should include trousers as well as the cap, mask, gown, and cotton boots at present supplied so that all outer clothing can be discarded before entry to the production area;
- (5) as rapidly as possible vertical laminar flow cabinets should be installed in the appropriate rooms of the production area and in the control area;

- (6) it is desirable that the viruses and sera are stored in separate containers, preferably in separate rooms;
- (7) the incubator and water bath for the rot marker test are not adequately temperature-controlled; no automatic recorders are fitted and the water bath is too small;
- (8) there is no continuous recording of temperatures on the autoclaves and hot air ovens and indicator capsules are not employed;
- (9) it would be advisable to have a separate cabinet for each type of seed and to institute a suitable system of colour coding;
- (10) a larger water-bath with proper temperature control should be installed, and a better method of trypsinisation for preparing tissue culture cells should be employed;
- (11) considerable improvement in the monkey houses and in the care and handling of monkeys is necessary;
- (12) another matter to be investigated is the consistently low titres of the vaccine lots. The vaccine is prepared on kidney tissue cultures of *M. radiata* but the yields from this substrate compared with yields from the kidney tissues of *M. mulatta* and *ceropithecus* have not apparently been compared. These comparisons should be made in Coonoor and Delhi and Dr. Archetti in Rome will test the titres of some of the batches.
- (13) the temperature of the two large cold rooms for storage of vaccine should be kept consistently below -20°C , preferably -25°C , to -30°C and a continuous temperature recorder should be fitted.
- (14) a clear policy directive on how much vaccine should be prepared annually over the next several years;
- (15) a firm plan for the uplifting, distribution and use of the vaccine as it is prepared;
- (16) within the Institute, firm management of the production area with clear programming and well defined areas of responsibility for the individual scientists in the senior positions;
- (17) the extension of the Neurovirulence Testing Laboratory at the NICD to undertake other tests on poliomyelitis vac-

cines, both those from Coonoor and those which are imported;

- (18) frequent contact and exchange of information, and views on test procedures between the National Control Laboratory and the Vaccine Production Laboratory.

The copies of the reports were sent by the WHO team to the Director, Pasteur Institute, Coonoor and to the National Institute of Communicable Diseases. The WHO team also discussed this report with the Director-General of Health Services and the Director of the Pasteur Institute, Coonoor initiated action on the various recommendations of the WHO's Study Team by calling quotation, by contacting firms for doing necessary additions and alterations to the production area as recommended by the Study Team.

In regard to the other recommendations of the Study Team about the target of production, plan for uplifting of distribution etc., these could be implemented only after the existing defects noticed in the work of the Unit are removed and production schedules brought up-to-date. To consider these aspects several meetings were held in the Ministry as well as in the Directorate General of Health Services, but as explained in reply to paragraphs 1.64 and 1.65 of the Report, there had been no improvement in the performance of the Unit, with the result, the decision to close down the Unit had to be taken.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015/8/75-R dated 31-3-76]

Recommendation

The shortfall in production of the vaccine at the Pasteur Institute has also been attributed by the Director of the Institute to delays in the import of African green monkeys, chemicals and equipment. The Committee have been informed that while there was a delay of about six months in the issue of clearance by the Director General, Technical Development in respect of the import of 11 monkeys in 1970, necessary clearance had been issued by the Director General, Technical Development after 4 months in respect of a further import of 12 monkeys in 1973. The Committee are concerned over such delays in arranging imports of a vital pre-requisite for the production of the vaccine. The Committee are of the view that it should be possible to streamline the existing procedures for the issue of clearances by the Director General, Technical Development at least in respect of such imports by Central Government

departments and organisations for which the justification is beyond doubt. The Committee desire that this should be examined and a suitable, simplified procedure evolved.

[Serial No. 8 (Para No. 1.71) of Appendix II to 179th Report
(Fifth Lok Sabha)]

Action Taken

As a decision not to continue the Unit at Coonoor in its present form has been taken, the question of importing of the monkeys and other equipment for the Unit at present does not arise.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015/8/75-R dated 31-3-76]

Recommendation

The Committee note that certain changes have been effected in the existing arrangements for sanctioning imports and the Ministry of Health has been empowered to sanction imports, up to an amount of Rs. 75,000, on their own judgement without referring the case to different agencies. The Committee trust that with this arrangement, the bottlenecks in imports would be considerably eliminated. The Committee would like to be informed of the time now taken after the introduction of the revised procedure, for arranging imports of monkeys and other equipment etc. required by the Vaccine Production Unit.

[Serial No. 9 (Para No. 1.72) of Appendix II to 179th Report
(Fifth Lok Sabha)]

Action Taken

Action taken has been reported under Sl. No. 8, Para No. 1.71 of the Report.

[Ministry of Health & Family Planning (Department of Health)
O.M. No. G. 25015/8/75-R dated 31-3-76]

Recommendation

It is also a matter of concern to the Committee that the capacity of the testing division (on which, till March 1972, Rs. 14.45 lakhs had been spent, excluding cost of buildings) has been grossly under-utilised so far. The Committee note that only 25 lakh monovalent doses have been tested by the division till 1974 against 19.2 crore-

monovalent doses that could have been tested. The under-utilisation of testing capacity has been mainly attributed to the existing limited capacity for production of the vaccine in the country and the delays in the receipt of batches for testing. However, even after streamlining the production at the Pasteur Instituté so as to achieve the optimum capacity of 12.50 lakhs trivalent doses, the percentage utilisation of the built-in capacity of the testing division would still be only about 15 per cent. The Committee are also doubtful whether, even after the establishment of another production unit at the Haffkine Institute, Bombay, it would be possible to utilise the full capacity of 160 lakh trivalent doses of the testing division. The Committee would like to be informed of the basis on which the existing capacity of the division has been worked out. Government should also examine immediately the feasibility of effecting economy in the expenditure on staff etc. of the testing division.

[Serial No. 14 (Para No. 1.77) of Appendix II to 179th Report
(Fifth Lok Sābha)]

Action Taken

The P.A.C's recommendations are appreciated. In view of the decision to close down the Polio Vaccine Unit at Coonoor there is not enough work with the testing unit. However, the Unit has been engaged in testing the imported Polio Vaccine and storage conditions.

The question of closing down the Neuro-virulence Testing Unit is under consideration. Some of the trained staff, however, would be necessary to test the potency of the imported vaccine and other connected matters.

[Ministry of Health and Family Planning (Department of
Health) O.M. No. G. 25015/8/75-R dated 31-3-76]

Recommendation

The Committee find that on account of the delay in marketing the vaccine, the date of expiry of 0.60 lakh doses was over in July-August 1972 and consequently, these doses had to be retitrated and the period of their unability, extended upto April 1975. The Committee would like to know the additional expenditure incurred in retitrating these doses and whether the entire quantity of 0.60 lakhs doses had been utilised, now that even the extended period is over. That such a measure was necessary would indicate the need for im-

proving the facilities available for marketing the vaccine and apparently sufficient attention has not been paid to this important aspect. The Committee desire that the adequacy of the existing marketing arrangements should be reviewed and necessary remedial measures taken.

[Serial No. 18 (Para No. 1.81) of Appendix II to 179th Report
(Fifth Lok Sabha)].

Action Taken

51,250 doses of trivalent vaccine from batches No. 11, 13, 14 and 15 and 8,300 doses from batch No. 12 stored at Haffkine Institute, Bombay (*i.e.* 59,550 doses) had expiry date July-August, 1972. These batches were retitrated on 17-4-1973 at the National Institute of Communicable Diseases, Delhi, and were found to retain full potency and the expiry date for these batches were extended to 17-4-1975.

These batches were again retitrated at the National Institute of Communicable Diseases, Delhi on 11-10-1974 and the titres of all batches were found to be satisfactory except that for batch 12 which had been stored at Haffkin Institute, Bombay. Samples from batch No. 12 were sent to the National Institute of Communicable Diseases, Delhi, by the Haffkine Institute, Bombay, directly. The batch containing 8,300 doses was discarded on 25-3-1975.

Vaccine in batches, 11, 13, 14 and 15 were issued to the Medical Stores Depot, Madras on 17-12-1974 for distribution.

The cost involved in retitrating the virus content in batches of trivalent vaccine will be negligible as the work involved is very small and the material required for the work is easily available in the testing at N.I.C.D., Delhi.

[Ministry of Health and Family Planning (Department of Health) O.M. No. G. 25015/8/75-R dated 31-3-1976]

proving the facilities available for marketing the vaccine and apparently sufficient attention has not been paid to this important aspect. The Committee desires that the existing technology of the existing

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

Serial No. 18 (Para No. 1.81) of Appendix II to 170th Report
(Fifth Lok Sabha)] **NIL**

Action Taken

51250 doses of trivalent vaccine from batches No. 11, 13, 14 and 15 and 8300 doses from batch No. 12 stored at Haffkine Institute, Bombay (i.e. 59550 doses) had expiry date July-August, 1972. These batches were retested on 17.1.1973 at the National Institute of Communicable Diseases, Delhi and were found to retain full potency and the expiry date for these batches were extended to 17-4-1973.

These batches were again retested at the National Institute of Communicable Diseases, Delhi on 11-10-1974 and the titres of all batches were found to be satisfactory except that for batch 12 which was stored at Haffkine Institute, Bombay.

New Delhi, 27 November 18, 1977
Kartika 27, 1899 (S)
C. M. STEPHEN, Chairman,
Public Accounts Committee.

Vaccine in batches 11, 13, 14 and 15 were issued to the Medical Stores Depot, Madras on 17-12-1974 for distribution.

The cost involved in retesting the virus content in batches of trivalent vaccine will be negligible as the work involved is very small and the material required for the work is easily available in the testing at N.I.C.D. Delhi.

[Ministry of Health and Family Planning (Department of Health) O.M. No. 62301/58/75-76 dated 31-3-1978]

Appendix

Conclusions/Recommendations

Sl. No.	Para No.	Ministry concerned	Conclusions/Recommendations
1	2	3	4
1	1.9	Health & Family Planning (Department of Health)	The Committee are perturbed that instead of attempting to infuse new life in the Polio Vaccine Production Unit at Coonoor, established at considerable expense to reduce the country's dependence on imports of a vital vaccine, and to improve its management and production techniques, Government have apparently chosen the line of defeat and decided to close down the Unit after a decade of its existence and functioning. This decision is stated to have been taken on the advice of the technical officers that no amount of additional inputs in terms of finance, equipment and manpower would improve the performance of the Unit, as constituted at present under the administrative control of the Pasteur Institute, which is a registered society, as well as on account of certain technical problems encountered in the production of good, acceptable and safe

vaccine. The Committee, however, find that the two teams of officials of the Indian Council of Medical Research, the National Institute of Communicable Diseases, Directorate General of Health Services and the Drug Controller, deputed to conduct a detailed study of the functioning of the Unit and the shortfalls in its production, had not expressed themselves in favour of the dissolution of the Unit but had on the contrary, suggested remedial measures which could have improved its performance and place the production on a firmer footing. For instance, a senior official of the Indian Council of Medical Research had given it as his view that the Unit's administrative and technical problems notwithstanding, it could effectively produce, even with its existing staff, several million doses of the vaccine annually if "a few essential steps" were taken. The other study team of officials had also recommended, *inter alia*, remedial measures to be planned and executed on a top priority and that the progress made by the Production Unit should be reviewed annually. The Committee, therefore, cannot appreciate the rationale behind the decision to close down the Unit.

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I.10

Health & Family Planning
(Department of Health)

As regards the Ministry's contention that there were inherent difficulties in the administration of the Unit as at present constituted, the Committee are of the view that it should not have been beyond Government's capabilities to overcome them. In fact, the Committee find from the Action Taken Note furnished in response

to their recommendation contained in paragraph 1.67 of their 179th Report that Government are also exploring the possibility of taking over the entire Pasteur Institute including the Polio Vaccine Production Unit, provided the society agrees to transfer all its assets and liabilities to Government. That the Unit should have been closed down even before the final outcome of these efforts is known is something of a paradox. It is also significant that certain steps are stated to have been taken by the Director of the Pasteur Institute, in pursuance of the recommendations of a team of experts from the World Health Organisation, for making necessary additions and alterations to the production area.

3

I.II

—do—

In these circumstances, the Committee find it difficult to reconcile themselves to the closure of the Vaccine Production Unit. It is a pity that after having built-up, over a decade, the necessary infrastructure and expertise for the production of a sophisticated vaccine vital for the well-being of our children, such a decision should have been taken without even giving adequate opportunity to the Unit to rehabilitate itself. As already pointed out, the alleged administrative and technical problems are by no means insurmountable. The Committee cannot countenance the work of a decade being thus virtually frustrated by what, *prima facie*, appears to be a hasty and ill-conceived decision. They would urge Government to review the decision, particularly in the light of the proposal to take over the Pasteur Institute as well as the other interim measures stated to have been initiated to streamline the functioning of the Unit.

41

- 4 1.12 **Health & Family Planning
(Department of Health)** It is evident that this sorry state of affairs could have been prevented if Government were less complacent and had regularly monitored the functioning of the Unit without waiting for some sort of a crisis to develop. The Health Secretary was frank enough to admit before the Committee that the two study teams of officials had been deputed to review the functioning of the Unit only after Government's attention was drawn by Audit to the prevailing state of affairs. The Committee are convinced that with a closer watch over the Unit's performance and periodic reviews with a view to improving management and production techniques, the Unit would have shown better results. The Committee take a serious view of this default and desire fixation of responsibility therefor. 42
- 5 1.13 —do— Now that steps are being taken to develop Polio Vaccine manufacture at the Haffkine Institute at Bombay by converting it into the Haffkine Bio-Pharmaceutical Corporation Limited and the technical shortcomings of production of the vaccine at the Pasteur Institute have also been identified on the basis of expert studies, the Committee trust that Government will benefit from the experience gained at the latter institute so that there is no repetition of past mistakes. The performance of the Corporation would need also to be closely watched.
- 6 1.16 —do— The Committee regret that the reply now furnished by the Department of Health is not quite relevant to their specific recom-

mentation, contained in paragraph 1.71 of their 179th Report, that a simplified procedure should be evolved for the issue of clearances by the Director General, Technical Development, in respect of imports by Central Government departments and organisations for which the justification is beyond doubt. Since it is not unlikely that other Government departments and agencies might also be handicapped by delays in issue of clearances for imports, the Committee reiterate their earlier recommendation in this regard and urge that the existing procedures should be reviewed without further loss of time.

7 1.19

—do—

While the Committee note that the question of closing down the Neurovirulence Testing Unit set up at the National Institute of Communicable Diseases is also under consideration as a sequel to the decision to close down the Polio Vaccine Production Unit at the Pasteur Institute, Coonoor, they find, however; that the Department's reply is silent in regard to the Committee's specific query about the basis on which the present capacity (160 lakh trivalent doses) of the testing division had been worked out. The position in this regard should be clarified forthwith.

43

8 1.20

—do—

As regards the proposal to close down the testing division, the Committee find from the reply furnished by the Department to their observations contained in paragraph 1.70 of the 179th Report, that the team of experts from the World Health Organisation, visiting India in October 1974, had recommended, *inter alia*, that the Neurovirulence Testing Division at the National Institute of Communi-

cable Diseases should be extended to undertake other tests on poliomyelitis vaccines from Coonoor as well as those imported. It is not clear to the Committee where the vaccine produced by the Haffkine Bio-Pharmaceutical Corporation is proposed to be tested for neurovirulence with the closure of the testing division. They, therefore, fear that adequate thought has not been given to this question and would urge Government to do some rethinking in this regard. The action taken or proposed to be taken on the WHO study team's recommendation should also be intimated to the Committee.

44

**Health & Family Planning
(Department of Health)**

In paragraph 1.81 of their 179th Report, the Committee had drawn pointed attention to the delay in distribution and marketing of the vaccine, as a result of which 0.60 lakh doses of the vaccine had to be reitrated and certified to be usable beyond their date of expiry and had desired that the adequacy of the existing marketing arrangements should be reviewed and necessary remedial measures taken. The Department's reply is, however, unfortunately silent on the steps taken in this regard. That these batches of vaccine had to be reitrated once again in October 1974, leading to 8,300 doses being discarded on account of having lost their potency, only serves to reinforce the Committee's earlier impression that adequate attention has not been paid to the important aspect of timely marketing and

distribution of the vaccine. The Committee are, therefore, constrained to reiterate their earlier recommendation in this regard. An immediate review of the adequacy of the existing arrangements for marketing and distribution of the vaccine is called for.

Sl. No.	Name of Agent	Agency No.	Sl. No.	Name of Agent	Agency No.
DELHI.			33.	Oxford Book & Stationery Company, Scindia House, Connaught Place, New Delhi-1.	68
24.	Jain Book Agency, Connaught Place, New Delhi.	11			
25.	Sat Narain & Sons, 3141, Mohd. Ali Bazar, Mori Gate, Delhi.	3	34.	People's Publishing House, Rani Jhansi Road, New Delhi.	76
26.	Atma Ram & Sons, Kashmere Gate, Delhi-6.	9	35.	The United Book Agency, 48, Amrit Kaur Market, Pahar Ganj, New Delhi.	88
27.	J. M. Jaina & Brothers, Mori Gate, Delhi.	11	36.	Hird Book House, 82, Janpath, New Delhi.	95
28.	The Central News Agency, 23/90, Connaught Place, New Delhi.	15	37.	Bookwell, 4, Sant Naran-kari Colory, Kingsway Camp, Delhi-9.	96
29.	The English Book Store, 7-L, Connaught Circus, New Delhi.	20	MANIPUR		
30.	Lakshmi Book Store, 42, Municipal Market, Janpath, New Delhi.	23	38.	Shri N. Chaoba Singh, News Agent, Ramlal Paul High School Annexe, Imphal.	77
31.	Bahree Brothers, 188 Lajpatrai Market, Delhi-6.	27	AGENTS IN FOREIGN COUNTRIES		
32.	Jayana Book Depot, Chaparwala Kuan, Karol-Bagh, New Delhi.	66	39.	The Secretary, Establishment Department, The High Commission of India India House, Aldwych, LONDON, W. C.-2.	59

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