P.A.C. No. 284

PUBLIC ACCOUNTS COMMITTEE 1970-71

(FOURTH LOK SABHA)

HUNDRED AND TWENTY FIFTH REPORT

[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)]

LOK SABHA SECRETARIAT
NEW DELHI

December, 1970 Agrahayana 1892 (Saka)
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(1970-71)

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INTRODUCTION

I, the Chairman of the Public Accounts Committee, as authorised by the Committee, do present on their behalf this 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. The Appropriation Accounts (Civil), 1968-69 and Audit Report (Civil), 1970 were laid on the Table of the House on the 14th April, 1970.

3. The Committee examined Paragraphs relating to the Ministry of Health, Family Planning, Works, Housing and Urban Development (Department of Health) at their sitting held on the 31st July, 1970. The Committee considered and finalised this Report at their sitting held on the 8th December, 1970. Minutes of these sittings form part II* of the Report.

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

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

6. The Committee would also like to express their thanks to the officers of the Ministry of Health, Family Planning, Works, Housing and Urban Development (Department of Health) for the co-operation extended by them in giving information to the Committee.

ATAL BIHARI VAJPAYEE,
Chairman,
Public Accounts Committee.

NEW DELHI;
December 14, 1970.
Agrahayana 23, 1892 (*S*).

*Not printed. (One cyclostyled copy laid on the Table of the House and five copies placed in the Parliament Library).

REPORT

MINISTRY OF HEALTH, FAMILY PLANNING, WORKS, HOUSING AND URBAN DEVELOPMENT

(DEPARTMENT OF HEALTH)

Audit Paragraph

Sub-standard medicines

1.1. The Medical Stores Depot, Karnal purchased 36,000 achromycin (tetracycline Hydrochloride) injections and 34.96 lakhs ferrous sulphate sugar coated tablets costing about Rs. 58,000 and Rs. 13,000 in May/June, 1966 and March/April, 1968 respectively from two firms. The injections were purchased against a D.G.S. & D. rate contract, while the tablets were purchased direct after making rate enquiries from some firms. Out of those purchases, 25,000 injections and 10.50 lakh tablets were supplied by the Depot to Irwin Hospital, New Delhi, and the remaining injections and tablets to various hospitals|dispensaries in the northern zone.

1.2. Out of the 25,000 injections, the Irwin Hospital consumed 20,710 injections during August, 1966 to December, 1967. On 16th December, 1967, the Hospital reported to the Controller of Drugs, Delhi, that reaction had been produced by certain batches of the injections. A drugs inspector examined the unutilised stock with the Hospital on the same day and submitted a report to the Controller of Drugs, Delhi on 19th December, 1967, stating that contents of some of the vials had become discoloured and turned dark brown and, as such, samples from the three batches of injections (available with the hospital at that time) had been taken and sent to the Government Analyst, Calcutta, for analysis. The reports of the Government Analyst, which were received on 29th March|1st April, 1968, showed that the quantity of tetracycline in two batches was "nil", while the third batch contained only traces of tetracycline.

1.3. The Controller of Drugs, Delhi, intimated the results of analysis to the Irwin Hospital on 23rd April, 1968 and also requested the Directorate of Drugs Control Administration, Gujarat (in whose jurisdiction the manufacturing concern is located) for taking necessary action against the firm. The Directorate stated on 7th May, 1968 that samples from the three batches under complaint (in

possession of the manufacturers) and also samples from other batches had been got examined by the Government Analyst, Baroda, and that no defects had been noticed. The Directorate, therefore, did not take any action against the firm. The firm, however, replaced the balance of 4,290 injections still lying with the Irwin Hospital. No investigations have been made to find out how and at what stage the defects developed in the injections 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. The Ministry has, however, stated (February, 1970) that "tetracycline is a highly unstable compound and the fact that on subsequent testing no content of tetracycline was discovered in the injections need not necessarily lead to the conclusion that the tetracycline content was absent in the original preparation. The contents are likely to undergo change due to various factors including transportation and packaging."

1.4. Out of the 10.50 lakh ferrous sulphate tables, the Irwin Hospital utilised 7.07 lakh tablets during May, 1968 to November, 1968 leaving a balance of 3.43* lakh tablets. On 20th November, 1968, the Irwin Hospital reported to the Controller of Drugs, Delhi that the tablets in a majority of the tins were "spotted". On the same day, a drugs inspector examined the unconsumed stock with the Hospital and submitted a report to the Controller of Drugs (on 25th November, 1968), stating that on opening some of the tins out of the existing stock (pertaining to seven manufacturing batches), spotted tablets were found in all the tins and that, as such, a sample from one batch (No. 1562) had been taken and sent to the Government Analyst, Calcutta, for analysis. On 18th January, 1969, the firm was also directed to stop forthwith the manufacture of the ferrous sulphate tablets till further order. The report of the Government Analyst, which was received on 19th April, 1969, showed that dark patches had appeared on most of the tablets and the medicine was not of acceptable quality. While communicating the findings of the Government Analyst (in respect of batch No. 1562) to the Irwin Hospital and the firm on 19th June, 1969, the Controller of Drugs did not make it clear that these findings were applicable to other batches also as the drugs inspector had earlier noticed spotted tablets in all the tins opened by him out of the seven baches available with the Hospital.

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*According to the Hospitals bin card, out of 3.43 lakh tablets 0.51 lakhs tablets were issued after the Drugs Inspector's inspection—0.20 lakh tablets on 22-11-1968 and 0.31 tablets on 29-11-1968.

subjected to any test before acceptance on account of the high reputation of the firm and its inclusion in the list of reliable firms drawn up by the High Powered Committee."

1.9. The Committee enquired whether these medicines were tested by the manufacturers before despatch or by the hospitals before use. The Drug Controller stated: "According to the Drugs and Cosmetics Act, every manufacturer is expected to maintain his own arrangement for testing the raw materials as well as finished products. In case they do not have their own arrangements they are permitted to get the raw materials and finished goods tested through approved laboratories *i.e.* laboratories appoved by the licensing authorities in the States." He added that in this case the firm had their own testing facilities. The witness further confirmed that the firms keep samples of their products for testing in case of complaints.

1.10. Asked whether adverse effect of the drug was reported by any of the other hospitals|dispensaries to whom supplies from the batches in question were made by the Medical Stores Depot, Karnal, the Drugs Controller, India stated "All this information we have now traced backwards. We have got a full account of the injections which constitute the batch complained of. 3,000 were sent to the Willingdon Hospital, New Delhi they have had no complaints. Safdarjung Hospital received 2000; no complaints. M.S.D. Karnal had received 36,000 vials from.....and had supplied to many hospitals. Medical Store, Karnal had subsequently written to all the hospitals to whom they had supplied stocks of the same batch found in Irwin Hospital—particularly Rajinder Hospital, Patiala, Government Hospital, Rohtak and V. J. Hospital Amritsar. All of them said that they had used the drug within the period of the date of expiry shown on the label and they have had no cause for complaint about the quality. 2665 vials were supplied by ..... to Delhi and about 9,000 vials through the manufactures' distributors in Jaipur. We made intensive enquiries from them also and they have had no complaints."

1.11. To another question the witness replied: "Deterioration could have taken place due to the lack of quality control measures at the level of the manufacturer. They may have not taken proper care in sealing etc. in which case the contents will turn into a lumpy mass. Or once the product leaves the manufacturers and it is exposed for a protracted period to high temperature or is not stored properly under proper conditions, it is likely to change colour and there will be deterioration in potency."

1.12. The witness added: "In order to examine at the manufacturer's end, the Gujarat Drug Controller had an occasion to test the samples and they found the same all right. 3,000 vials of the same batch were used by Willingdon Hospital, New Delhi and they have had no complaint. Similar was the case in regard to Rajinder Hospital, Patiala, Medical College, Rohtak and V. J. Hospital, Amritsar who utilised 7,000 vials. General enquiries made all over the country did not reveal any complaint.....The firm, therefore, could not be held responsible because there was not a single complaint from anywhere else."

1.13. The witness informed the Committee that in order to find out how deterioration took place, an enquiry had been made into the transportation of the injections from the manufacturer to the Medical Stores Depot, Karnal and from there to Irwin Hospital and conditions of storage in the Medical Stores Depot and Irwin Hospital. The report of the Inquiry was awaited. The Committee were subsequently furnished with a copy of the Report of Enquiry.

1.14. The Committee find the following conclusions arrived at by the Enquiry officer:

(i) "Achromycin is required to be kept at a temperature range of 15-25° centigrade well-protected from moisture. It was revealed during our investigation that the item was not stored in this manner but kept in a shaded room situated on the ground floor of a two storeyed building. (in Medical Store Depot, Karnal)."

"Medical Store Depot, Karnal has two cold storage rooms. The first one maintains a temperature of 4-5° centigrade and the second one a temerature of 15.5° centigrade. These special storage rooms though sufficiently large, I was informed, get filled completely at times, leaving little space for extra loading. In my opinion the storage instructions for this drug were not compiled with by the medical Store Depot."

(2) "Almost at the same time when the supplies were despatched to Irwin Hospital, M.S. Depot, Karnal despatched 7,000 vials to three hospitals in Punjab viz. Rajindra Hospital, Patiala, Medical College, Rohtak and V. J. Hospital, Amritsar. Enquiries made (after Irwin Hospital's complaint was received) from these three Institutions revealed that the three Institutions had found the supplies to be quite satisfactory. From this I am inclined to deduce that even-though the drug was not

stored or transported under the ideal conditions, no deterioration took place in the drug upto the time of its delivery at the Irwin Hospital. This is corroborated further by the fact that Irwin Hospital used as much as 20,000 odd vials during the following 17 months without noticing any adverse effect on administration of the drug or detected any change in the colour of the powder or its mobility."

(3) "Having regard to the total cool storage accommodation available in Irwin Hospital, I cannot but reach an inescapable conclusion that the accommodation was not sufficient to keep all the items requiring cool storage (including Achromycin) under prescribed conditions and some of the stocks of Thermalabil Drugs must have been kept in the outer room under ordinary room temperature. At this late stage and particularly having regard to the fact that no register is kept by the hospital for articles kept in the cold storage room, the possibility of Achromycin either wholly or partly having been stocked at ordinary room temperature cannot be ruled out."

(4) "That the deterioration did occure in Achromycin and ferrous Sulphate Tablets whilst in storage at Irwin Hospital, I have no doubt on this point."

"In view of the fact that Irwin Hospital did not have sufficient cool storage accommodation their negligence seems to be apparent in ordering quantities far in excess of their capacity to store them under proper conditions. It was deposed that the demands for the items are compiled by the Store Keeper on the basis of information he received from Doctors incharge of the wards and the ternd of expenditure. As a normal practice a 25 per cent excess is ordered in anticipation of rise in consumption. The annual consumption of Achromycin was stated to be 13,600 ampoules per year. In the indent for Achromycin and other items which was received in M.S. Depot, Karnal in May, 1966, the consumption during the year was indicated as 20,000 vials. This is in excess of its average annual consumption of 13,600 vials mentioned by Shri ....,Pharmacist incharge of Stores in Irwin Hospital. Even allowing for a 25 per cent margin for unforeseen rise, the quantity ordered, *viz.* 25,000 vials, was far in excess of the possible annual off-tak. No basic working

sheets were produced by the Irwin Hospital authorities as to how the demand of 25,000 vials was actually framed and processed through the various stages."

"Having regard to the fact that the cool storage accommodation was inadequate it is a case of over-indenting. It also appears that neither the officer-in-charge of stores nor the Purchase Section which is under the D.M.S. scrutinised the quantity which was indented in relation to the actual off-take figures."

"In my opinion the over-indenting is a matter of group responsibility in which the various people such as Store Keeper, the Doctor incharge of the Stores, the Purchase Section etc. participated."

(5) "The evidence tendered by Sister....revealed that when she gave injections to 2-3 patients, they started developing abscesses. She brought this matter to the notice of the Doctor. After that she checked up the distilled water as well as the sterlization of syringes etc. and gave the injections but same thing happened again. For about a week she was noticing this phenomenon. When she used the same syringes and the same distilled water with other injectibles, no such abscess formation was observed by her. She reported the matter to the Medical Officer and the Store Keeper who ordered that all the supplies should be sent back to the store. She stated that she returned about 20 injections to the Store Keeper. The Store Keeper deposed during his evidence that he flashed message on telephone to all the wards and the Sub-Store to suspend use of the material and return the supplies to the main store. No written complaint was made to the Registrar or the Medical Superintendent either by the Sister or by the Store Keeper. According to the Store Keeper 15-20 cases were mentioned to have developed abscesses. The Irwin Hospital authorities when asked to produce the case sheets of these patients, were not in a position to do so. The Store Keeper however, informed the Delhi Drug Control authorities who sent a Drug Inspector to the Hospital the same day and seized the entire stock after drawing samples. This was on 16-12-1967. No documentary evidence was produced by the

Store Keeper to substantiate the return of Achromycin to the stores either through a depot or a receipt entry in the bin card or in any other document."

"In view of the fact that about three years had elapsed since the incident took place and all the House Physicians who were working in the wards were stated to have left the Institution the question whether the deteriorated Achromycin Injections were actually given to the patients with any adverse effects could not be verified. I am afraid I am unable to reach any definite conclusion in this behalf."

1.15. In a written reply, the Department of Health stated that "the Delhi Administration have stated that they are of the view that the conclusions arrived at by.....about the storage conditions in the Irwin Hospital are not acceptable to the Administration and that they are prepared to accept a further probe in the matter. The objection of Delhi Administration is under consideration."

1.16. During evidence, the Committee drew attention to the fact that the manufacturer replaced the unutilised stock of 4290 injections lying with Irwin Hospital and asked why they did so when, as has been claimed, the responsibility for the defects noticed in the drug did not lie with them. The witness replied that "the statement given by them was that in the interests of commercial goodwill, they replaced the stocks, because they are regular suppliers to all the hospitals.....but what they told us was that without reference to any question of their quality, replacement was made as a gesture of goodwill. They made it very clear to the Hospital authorities that they were doing it as a Commercial gesture and that was without any prejudice to the quality of the product in the defective vials."

1.17. The Committee find from the Report of Enquiry Committee that according to a written statement submitted by the Regional Manager of the firm his local representative who used to visit the Irwin Hospital had complained to him that the stocks "were stored in a place which was adjoined to a boiler room and they had deteriorated and the Irwin Hospital Authorities required replacements." It had been further stated by him that "while I did not go into the details of the nature of storage, however, as a commercial gesture and with a view to the service to Irwin Hospital, the balance of 4,000 and odd vials held by the Irwin Hospital from the subject supplies were replaced by me without receiving the deteriorated vials."

1.18. The Committee asked whether the Drug Controller, Delhi informed the Drug Control Administration, Gujarat about the quality of the injections as soon as he received the Drug Inspector's Report in this regard on 19-12-1967. In a written reply, the Department of Health have stated, "After the receipt of the Drugs Inspector's Report on 19-12-1967, the Drugs Controller, Delhi Administration referred the facts of the case to the Director, Drugs Control Administration, Gujarat on 24th January, 1968 in whose jurisdiction the manufacturer is located for necessary action. This interval could have been shorter. Action is being initiated by Delhi Administration to fix responsibility for the delay."

1.19. The Committee enquired whether the Medical Stores Depot, Karnal, through whose agency supply of the drug was made to the various hospitals|dispensaries in Northern India was informed about the quality of the drug. The Secretary, Department of Health replied, "They were informed, but much later. They were informed on the 11th March, 1968, I do say that it would be desirable to inform also the supply depot in a case like this and not to be content to inform the Drug Controller in whose jurisdiction it is situated."

1.20. The Committee desired to know the reasons for a period of 3 months taken by the Government Analyst, Calcutta in sending the report. The Additional Director General of Health Services admitted that the delay in this case was "on the high side" and added, "If they had given an indication that it is a priority sample, it could have been expedited."

1.21. On being pointed out that the test conducted by the Government Analyst, Calcutta, showed no traces of tetracycline in one batch, the witness replied that "quantitatively it is nothing. But the vial did reveal a trace of the drug in the identification test. I agree with you that it was nil quantitatively."

1.22. During evidence the Committee asked whether the doctors who administered the drug could not have noticed the defect from the physical appearance of the drug. The Additional Director General of Health Services stated as under:

> ".... when the change is slight and the moisture is limited, then it would be rather difficult for a physician to detect that deterioration has taken place. It would depend on the degree of moisture that has gone in and also on the degree of temperature and if there is slight deterioration, it may not be possible to detect. The change will be obvious when there is a marked degree of moisture or

temperature, for then it will form a lump. When the doctor holds it up and finds that the powder is flowing freely and there is no change in colour, he is then sure that no deterioration has taken place. It is, thus, only a question of degree. When it is very marked we will reject it but a slight degree of change will not be possible to detect. In a hospital there are no facilities for testing the potency or toxity or other qualities of a drug."

1.23. In a written reply the Department intimated subsequently that "the doctors|nurses in the ward administering the Achromycin injections could have noticed the disclouration depending on the degree of deterioration."

1.24. The Committee wanted to know the reasons for delay of more than 2½ years in initiating an enquiry into this case after the receipt of the report of Government Analyst. The Secretary to the Department of Health said that "as soon as the audit para came we went into the matter."

1.25. The Committee were informed that the Delhi Administration had seriously considered prosecuting the firm, and they sent a Drug Inspector to Karnal to collect the necessary material for launching the prosecution proceedings. They also consulted the Judicial Department of the Administration with regard to what could be done in the matter of prosecution particularly in the light of the observations made by the Drug Controller, Gujrat which went materially in favour of the firm. The Judicial Department's advice was that because the manufacturing firm had supplied the drug to Karnal, they had no fore-knowledge that this drug would subsequently go to Irwin Hospital which comes under the jurisdiction of Drug Controller of Delhi. The Drug Controller of Delhi, could not prosecute the firm for want of jurisdiction."

1.26. According to Audit at one stage the Delhi Administration had decided that either the firm should replace the 20710 vials of injections out of 25000 vials supplied to Irwin Hospital (4290 unutilised vials having been replaced by the manufacturer) or credit for this amount afforded by the Medical Stores Depot, Karnal. In a note furnishd to the Committee the Department of Health explained the position as under:

"The decision of the Irwin Hospital (Delhi Administration) to get balance of 20710 vials replaced by the firm was referred to the supplier. The supplier stated that no question arose with regard to replacement of credit as

the stock had already been consumed. As this quantity of injections were consumed by the Irwin Hospital authorities during the period of 17 months without noticing any adverse effects no further action is proposed by the Government against the firm regarding this quantity."

1.27. In paragraph 2.13 of their Forty-Second Report (1965-66), the Public Accounts Committee were critical of the use of certain time-expired injections in Willingdon Hospital in a routine manner in some cases. The Committee find from the report of the Enquiry Officer that pursuant to the observations of the Committee, the then Director General of Health Services addressed a D.O. letter personally to all the Medical Superintendents of major hospitals in Delhi, including the Irwin Hospital. In this letter (Appendix I) there is particular emphasis laid upon the rational indenting of perishable drugs. He recommended that supplies should be assessed carefully in the light of the average consumption over the past three years and orders should be placed for quantities which are absolutely necessary. He also emphasised the need for staggering deliveries in such a manner that the hospitals do not accumulate stock of time expired drugs. Alternatively, orders could be placed for limited quantities at frequent intervals.

1.28. 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 on 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.

1.29. The Committee deprecate the Irwin Hospital's gross over-indenting of Achromycin injections. Again the past annual offtake 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 incharbe 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.

1.30. 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 Achroymcin must have been 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 outcome.

1.31. 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.

1.32. 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 inspection 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.

1.33. According to the Ministry the doctors/nurses in the ward administering the Achromycin injections could have noticed the dis-

colouration 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 the enquiry was instituted after a lapse of 2½ 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.

1.34. The Committee find that in this 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, Kernal. 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 depot 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.

1.35. 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. May, however, feel that the Central Government could have prosecuted the firm if there was a prima facie case.

1.36. 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.

1.37. 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 through 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 those 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 storage 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.

Supply of Ferrous Sulphate Sugar—coated Tables

1.38. The Committee desired to know the factors that could have led to the deterioration that took place in the ferrous sulphate tablets

noticed by the Irwin Hospital. The Controller of Drugs, India, explained the position in the following terms:—

> "In the ferrous sulphate tablets the active ingredient is ferrous sulphate. The tablet is given a coating of sugar to protect ferrous sulphate from coming into contact with air. That coating is a kind of protection. Otherwise ferrous sulphate comes into contact with air and gets oxidised which is bad. Now if these sugar coated tablets have been kept for a long time during hot months, rainy months etc. the sugar coating will wear off, if they have not been kept properly or made properly. It will wear off at places and whereever sugar coating is worn off spots become visible. The contents may be all right some times."

1.39. On being pointed out that the Government Analyst, Calcutta found the tablets to be of unacceptable quality the witness stated that "in physical appearance alone they were not acceptable, but in regard to contents, he has declared them all right. The content has remained unimpaired and the tablet was not damaged therapeutically". Asked to explain the term "acceptability" from the commercial point of view, the witness stated: "If it was a question of accepting the supply for the first time from this institution, certainly, we would not accept this. He has analysed and said taht from the physical appearance of it, we will not accept it, but the contents are all right." The investigating officer who also investigated into the complaint about the supply of defective tablets has found that "the active ingredient i.e. ferrous sulphate as revealed from the test report did not undergo any deterioration whatsoever."

1.40. In order to find out whether the life of the tablets had expired by the time the defect was noticed, the Committee desired to know their date of manufacture and the date of expiry. They Committee were informed that the date of manufacture of the batches in question was Feb. 68 as per test reports. There was, however, no date of expiry.

1.41. The Committee enquired whether complaints about the tablets being found spotted were received from any of the other 90 indentor hospitals/dispensaries. The Department of Health in a note said that no complaints were received from them. The Committee therefore wanted to know the reasons for the tablets supplied to Irwin Hospital alone being found defective and asked whether the deterioration in the tablets was due to manufacturing defect or faulty storage etc. and who was responsible for the same.

1.42. As regards the question as to whether the deterioration in the tablets was due to manufacturing defect, the Drugs Controller, Delhi informed the Committee that "the manufacturer has stated that the Medical Stores Depot, prior to accepting the goods, had got them tested from the Central Laboratory, Government of India" and "no defects were noticed as per manufacturer's report." The investigating officer has also looked into this aspect and his findings are reproduced below:

> "Against this supply order the firm delivered the stocks in two instalments of 16,60,000 tablets and 18,36,000 tablets in March, 1968. The first lot was accepted on a certificate or warranty furnished by the firm. The reason for accepting the stores in this manner advanced by the depot was that the stores were required urgently and they had no time to send the samples for tests and wait for a test report; their earlier experience of dealing with the firm was that none of their drugs had been found to be substandard. As far as the second lot is concerned samples from all the batches were drawn and got tested by the Central Indian Pharmacopoeia Laboratory, Ghaziabad and the supplies were accepted only after the laboratory had declared all the batches to be up to the standard."

1.43. As regards the receipt, storage and despatch of the tablets by the Medical Stores Depot, Karnal, it has been stated in the report of enquiry that the tables, on receipt by the Depot, "Were examined for physical characteristics in the first lot and laboratory testing for the second lot." They were stored in one of the store rooms as they do not require any special storage conditions and "at the time of despatch from the Depot, no deterioration of the tablets was natice-able."

1.44. According to the enquiry report, no lapse could be found on the part of Irwin Hospital either in the storage of the drug.

1.45. The investigating officer has however attributed the deterioration in the condition of the tablets to "the tendency for sugar coating to peel off or get discoloured or develop spots" in hot humid climate.

1.46. The Committee drew attention to the fact that even after the Drugs Inspector had examined on 20th November, 1968 the stock lying with the hospital and found spotted tablets in all the tins, Irwin Hospital issued some quantities of the tablets on 22-11-1968 and 29-11-1968. The Deputy Director General of Health Services replied that

"they were receiving the indents from the doctors and they were issued. But it is very difficult to find out why they were issued and for what they are issued and nobody is able to say." The Enquiry Officer in his Report has observed:

> "On the basis of the records examined by me it appeared obvious that some Ferrous Sulphate Tablets had been issued to the patients after the dark spots had been observed on the tablets. The Store Keeper was unable to produce any evidence to prove that this was not so. Besides, it was impossible to gather any direct evidence regarding this phenomenon because Ferrous Sulphate Tablets were largely issued from the pharmacy to the out-patients who could not possibly be interrogated.
>
> Since the appearance of the dark spots in sugar coated tablets in hot and humid conditions is not an uncommon phenomenon and the test report had revealed that the active ingredient *e.g.* Ferrous Sulphate was still present in its original strength, I feel that there is no possibility of any adverse effects having been produced by the use of these tablets."

1.47. The Committee pointed out that the Government Analyst, Calcutta took nearly 5 months to communicate his report on the sample sent to him for analysis, while the Drugs Controller, Delhi took 2 months to communicate the report of the Government Analyst to the hospital and the manufacturer and they wanted to know the reasons for these delays. The Department of Health furnished the following reply in a note:

> "The Director Central, Drugs Laboratory who functions as a Government Analyst for Delhi Administration has received the sample of Ferrous sulphate Tablets on 4th December, 1968 and had issued the report on 18th April, 1969. The Central Drugs Laboratory is primarily concerned with the testing of imported samples sent from the ports. As many States do not have testing facilities of their own, the Government of India have made available the facilities of the Central Drugs Laboratory to the State Governments. This has resulted in a considerable pressure of work and consequential delay in submission of reports. To relieve the load on the Central Drugs Laboratory the facilities of the Central Indian Pharmacopoeia Laboratory Ghaziabad, which has recently been set up have been made available to the State Governments and Union Territories

for testing non-schedule C and C(I) drugs. The Delhi Administration has now appointed the Director, Central Indian Pharmacopoeia Laboratory as Government Analyst for non-schedule C and C(I) drugs."

"The report of the Government Analyst was received on the 23rd April, 1969. The Delhi Administration have stated that the opinion of the Government analyst as contained in the Report was conveyed to the Irwin Hospital on telephone on the same day. A copy of the test report was later sent to the Irwin Hospital *vide* the Drugs Controller, Delhi's letter dated the 19th June, 1969. The show cause notice to the firm was cleared by the Asstt. Drugs Controller on 16th May, 1969, and approved by the Drugs Controller on 17th May, 1969. There was delay in office and the final orders were issued on 19th June, 1969. This is stated to be due to shortage of staff in the office."

1.48. The Committee observed that the Drugs Inspector examined the unconsumed stock of the tablets lying with Irwin Hospital on 20th November, 1968 and submitted a report to the Controller of Drugs, Delhi, on 25th November, 1968 stating that spotted tablets were found in all the tins opened by him. The report of the Government Analyst, Calcutta, on the samples sent to him for analysis was received by Government on 19th April. However, it was only on 13th October, 1969 that the Medical Stores Depot, Karnal issued instructions to all the 90 hospitals/dispensaries, to whom they had distributed the tablets, to discontinue further use of the same. The Committee wanted to know when the Medical Stores Depot, Karnal were informed of the report of the Government Analyst that the tablets were not of acceptable quality and the reason for the delay in communicating the findings of the Govt. Analyst to the authorities concerned. The Department of Health furnished the following reply in a note:

"The Assistant Drugs Controller, Delhi Administration, Delhi, informed the Medical Stores Depot, Karnal through his letter dated the 28th November, 1969 (forwarding a copy of the test report) for the first time that Batch No. 1562 had been found to be sub-standard. On the other hand it was the supplier who through his letter dated the 23rd August, 1969, (actually received in the Depot on the 30th August, 1969), informed the Medical Stores Depot, Karnal, that Batch No. 1562 had been declared of unacceptable quality by the Government Analyst and requested that the tablets of the above batch may be recalled back from all the indentors to whom the supplies had been made and

returned to them for replacement. Thus it would be observed that there was no undue delay on the part of the Medical Store Depot, Karnal, as they had to link up the transactions after going through different documents to ascertain the addresses of the parties supplied to each."

1.49. The Committee pointed out that while communicating the finidings of the Government Analyst in respect of the batch from which a sample was sent to him, *viz.* batch No. 1562, to the Irwin Hospital and the manufacturer, the Controller of Drugs did not make it clear that these findings were applicable to other batches also as the Drugs Inspetcor had earlier noticed spotted tablets in all tins opened by him out of the seven batches available with the Hospital. In reply the Department of Health stated as under:

"As mentioned by the Delhi Administration, the Stores Pharmacist of the Irwin Hospital had informed the Drugs Inspector, Delhi Administration on 20th November, 1968 that the Ferrous Sulphate Tablets in the Stores were spotted and that the use of all batches of the drugs had been suspended. From a strict legal point of view, the action of the Drugs Controller has necessarily to be confined to the batch on which the Government Analyst has reported. However, in view of the general complaint made by the Pharmacist, Irwin Hospital. the Delhi Drugs Controller could have advised the Irwin Hospital not to use the remaining batches."

1.50. The Committee wanted to know the position regarding utilisation of the tablets pertaining to the remaining 6 batches subsequent to the instructions issued by the Drugs Controller to Irwin Hospital. The Department of Health stated that "According to the evidence available to Enquiry Officer,.....there is a possibility of some tablets from these batches having been issued to patients in the Irwin Hospital. The exact quantity utilized cannot be stated as no specific records were produced."

1.51. The Committee enquired how many hospitals|dispensaries have furnished information about the unconsumed stock of tablets lying with the indentor hospitals|dispensaries including the Irwin Hospital, the total quantity of the unconsumed tablets and the cost thereof. In a written reply the Department of Health have stated "Ten Hospitals|dispensaries had furnished the information about the unconsumed stock of tablets lying with them. Total quantity involved includidng the stock lying with Irwin Hospital was 3,93,200 tablets, the cost of which is Rs. 1,415.52 (calculated on the basis of purchase price of Rs. 14 per 5,000 tablets plus incidental charges)".

1.52. The Committee were informed that it was not possible to get the defective tablets replaced by the manufacturer as they discontinued the manufacture of this item consequent on the cancellation of their licence.

1.53. The Committee therefore enquired whether the manufacturer accepted that the tablets supplied by them were sub-standard and agreed to reimburse the cost of the same. They also asked how Government's interests were going to be safeguarded in case the manufacturer did not agree to reimburse the cost. In reply the Department of Health stated in a note:—

> "The firm has not accepted the allegation that the tablets supplied by them were sub-standard. They had offered to replace or refund the cost of the unconsumed quantity found to be spotted at the Irwin Hospital and with the other indentors. The Medical Store Depot has already appropriated a sum of Rs. 3,926.52 from their pending bills whereas the total cost of un-consumed quantity works out to Rs. 1,415.52. The firm have, however, protested against excess recovery. This aspect of the matter is under consideration."

1.54. The Committee wanted to know how a licence was issued to the firm and why it was cancelled. It was explained that the licence was granted by the Delhi Administration and that "on receipt of the complaint, the investigation revealed that the firm did not have the requisite technique for making sugar coated tablets and consequently the licence was cancelled."

1.55. In a note subsequently furnished in this regard the Department of Health stated "the firm had the necessary equipment and a competent person having qualifications and experience as laid down under Drugs and Cosmetic Rules to supervise the manufacture of drugs. As the firm had complied with the pre-requisite conditions the licence was granted to the firm to manufacture this drug. The product manufactured by the firm was found not of acceptable quality by the Government Analyst at a later date. In view of the obvious inability of the firm to manufacture the product of acceptable quality due to improper manufacturing techniques adopted, the permission was withdrawn."

1.56. It was further stated that: "the firm was granted licence originally in the year 1951, but at that time it was not permitted to

manufacture tablets. The firm was granted permission to manufacture tablets when the licence was renewed with effect from the 24th December, 1958."

1.57. The Committee enquired whether there was a rate contract of the DGS&D for these tablets. The witness stated that there was no rate contract for these tablets at the time they were purchased in this case and it was enforced after this purchase. Subsequently the Committee were informed that rate contracts for the purchase of ferrous sulphate tablets were introduced on 1st April, 1968. To another question the witness stated: "We are examining the alternative to the rate contract system. Under the rate contract, the rate is fixed for the drug of so many firms. Sometimes it so happens that if it is a drug which is rather scarce in the market, when we go in for purchase, the firm would say that they would not be able to give straightaway but that they would take 10 or 15 days to supply them. If we have a firm contract—firm commitment of quantity—then they cannot postpone the supply against our demand. What we are examining is this, namely, that instead of a rate contract we should put in a firm contract. So and so firm will supply so much of quantity on demand. That suggestion is being considered."

1.58. 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.

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.

1.62. 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 Analyst'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 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.

1.63. 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.

1.64. The Committee were given to understand that the rate contracts for the purchase of ferrous sulphate tablets were introduced only on the 1st 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.

Audit Paragraph

*Integration of Public Health with basic course in nursing**

1.65. With the object of encouraging integration of public health and mid-wifery course and increasing the number of nursing students in various training institutions/hospitals, a scheme of integration of public health with basic course in nursing was started in 1958. The duration of the integrated course was 3½ years, and central assistance was admissible to all institutions/hospitals which could admit at least twelve students in adidtion to the normal annual admissions made by them. Forty-five institutions have been getting central assistance under the scheme. The scale of assistance approved by the Planning Commission was as under:—

	Second Plan period	Third Plan period and for the years 1966-67 and 1967-68
Recurring grant		
For stipends to trainees, pay and allowances of additional training staff, etc.	100 %	50%
Non recurring grant		
For construction of school buildings	100 % Subject to a maximum of Rs. 50,000	75% Subject to a maximum of Rs. 50, 000.
For construction of hostel 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 admissions.
Purchase of equipment	100 % Subject to a maximum of Rs. 20,000.	75 % Subject to a maximum of Rs. 20,000.

1.66. Despite the downward revision of the scale of assistance during the Third Plan, the Ministry continued to make payments to the training institutions/hospitals according to the pattern of assistance prescribed for the Second Plan period. This resulted in overpayment of about Rs. 50 lakhs during 1962-63 to 1967-68. Although the Ministry of Finance had requested (31st October 1967) the Ministry of Health and Family Planning to fix responsibility for the overpayment, this has not been done so far (January, 1970).

[Paragraph 73 of Audit Report (Civil), 1970].

* The case was referred to the Ministry on 14th October, 1969, their final comments are still awaited (February, 1970).

1.67. The Committee asked how the scale of assistance was reduced by the Planning Commission for the Third Plan period and why the decision of the Planning Commission was not acted upon by the Ministry of Health. The Secretary of the Department of Health stated:

"I happened to be in the Planning Commission at that time. We were quite confident of reaching what we call the self generating economy, I mean reaching the take-off stage at the end of Third Plan Period and we have reasons to believe so. And we took some decisions on this basis. This was one of them, namely, that we should reduce the grant portion. We needed more money for various purposes. Then, on 4th August, 1962, the Planning Commission issued instructions according to which there were variations in grants.....Before these instructions were issued there was a meeting held by my predecessor where all were represented and the view taken was that the grant should not be reduced and 100 per cent should be maintained and that decision was conveyed to State Governments. Between 1st April, 1961 and 4th August, 1962 instructions for 100 per cent grant were issued. So, everyone assumed on the 100 per cent grant. This letter dated 4th August, 1962 unfortunately is not found on the file and no one says I had seen the face of it. I do want to refer to the atmosphere prevailing then in the country when so many concessions were being given by the Government specifically because of the Chinese Aggression to producing more nurses and doctors. Nurses and doctors being the most scarce commodity nobody thought we would reduce the 100 percent grant and everyone who was operating—my officials, the State Government officials, the Planning Commission and the Finance Ministry—wherever the file went everyone okayed on the basis of 100 per cent grant.

"Later on when this was brought to our notice we tried to find out whether we could recover this amount. We found it is not possible. Then we tried to find how we slipped up but we could not find.

"We have not been able to find where this circular is. The file has gone everywhere and they have assumed 100 per cent grant."

1.68. In a written reply, the Department of Health have stated:

> "An enquiry was also ordered by this Ministry for fixing responsibility for omitting to revise the pattern as subsequently approved by the Planning Commission. After a thorough enquiry of all the concerned documents, the Enquiry Officer has pronounced that no malafide is there; that the Planning Commission's orders could not be proved to have reached the concerned Section in the Ministry."

1.69. Asked how the omission escaped the notice of Finance, the representative of the Ministry of Finance stated:

> "When the Budget files came to us for making provision for the next year, two or three files were brought to my notice in which the Health Ministry had indicated the pattern for the Second Five Year Plan. That pattern was not checked up by the Ministry of Finance also and they said it seems like this. It was not examined at that time. It was not a detailed examination of an individual proposal or a sanction. They only said, all right, we agree to so much of amount. Beyond that I have not come across an individual case for being sanctioned by the Health Ministry which has come to the Finance Ministry.....

> "Normally this should not happen because I find from the file itself that there is a mention that the Planning Commission direction of August 1962 was communicated to the Director General of Health Services. Normally, of course, we rely on the Health Ministry."

1.70. The Committee enquired when the excess payment came to notice first. The Secretary to the Department of Health replied: "On 31st October, 1967 when the Finance Secretary pointed out that this was not in accordance with the instructions issued by the Planning Commission in 1962." Asked whether the Planning Commission was then approached to revise their decision, the Secretary, Department of Health stated, "Actually they had revised the decision also-after 1967, of course".

1.71. The Committee enquired how the excess payment was proposed to be regularised. In a written reply the Department of Health have stated:

> "It would cause extreme hardship on the Institutions if the technical over-payment made to these voluntary organisations is recovered, as their financial position is not very sound. These institutions depend on Government grants and they have been agitating that they should be paid the arrears due to them upto the year 1968-69 in accordance with the pattern approved for the Second Plan period. A budget provision of Rs 24 lakhs has been made in the current year on an *ad hoc* basis for providing this assistance.
>
> Government have also recognised the need for continuing this assistance in the Fourth Plan period though the Scheme has been transferred to the State sector under which State Governments may give assistance to these voluntary organisations to the extent of 90 per cent and within the overall Central assistance of 90 per cent, State Governments may give 100 percent assistance without making a reference to the Central Government. Since this is a very important activity and there is still a great demand for nurses in order to maintain the norm laid down, viz. 1 nurse for 5 beds in the general hospitals and 1:3 in teaching hospitals, there is need for continuing this activity. The Public Accounts Committee may, therefore, please agree to continue the pattern of assistance which was in force during the Second Plan period, in the Third Plan as well and to agree to regularising the over-payments made so far. In so far as the voluntary organisations are concerned, they incurred expenditure in good faith and in the belief that they were utilising the funds in accordance with the approved pattern. They should not be penalised."

1.72. The Committee have been informed by the Ministry of Health that of the 45 institutions receiving Central assistance under this scheme, 44 were being run by private voluntary agencies and one by Municipal Committee/Corporation. The total expenditure incurred on the scheme from 1960-65 to 1967-68 amounted to Rs 100.93 lakhs.

1.73. The Committee wanted to know how far the assistance given to these institutions under the scheme was actually utilised for its implementation and how it was ensured that this was actually being done. The Department of Health stated in note as follows:—

> "The assistance given is fully utilised by the grantee institutions. This is checked by seeing the audited statement of accounts and utilisation certificates duly signed by Chartered Accountants and by perusal of progress reports. The utilisation certificates in respect of the grants sanctioned in this regard are forwarded to the Accountant General concerned. These utilisation certificates are also scrutinised by the audit when the accounts of the Directorate General of Health Services are audited."

1.74. The Committee wanted to know whether any evaluation of the scheme has been made during the past 12 years of its existence. In a written note furnished to the Committee, the Department of Health have stated as under:

> "While no formal evaluation of the scheme has been done, however, quarterly Progress Reports, detailed Audited Statement of Accounts, Local Inspections and Inspection Reports of the Accountant Generals have been received and scrutinised. This was considered sufficient.

> "No specific target was fixed for Training of Nurses in Voluntary institutions. However, during the Second Plan period, only five voluntary institutions were in receipt of financial assistance and the number of nurses turned out during that period by these organisations was only 180. On the other hand, during the Third Plan period and over the years 1967-68 and 1968-69 (seven years in all) it was possible to increase the number of nurses to 4,100. The number of institutions which received grants during this period was 45. The overall target fixed for the Third Plan was very successfully achieved. The number of registered nurses on 31st March, 1966 was 57,621 against the target of 45,000. During the Emergency, the number of admissions in the Nursing Colleges was increased by 25 per cent. This additional target was also achieved by the end of Third Plan Period. The number of registered nurses as on 31st March, 1968 was 66,620."

1.75. As regards the per capita cost of the training under the scheme, the Secretary, Department of Health, stated: "The expenditure per nurse comes to Rs. 4,748 in 3½ years. I personally think that if the Government has to do it, it would cost much more. It would come to about Rs. 10,000."

1.76. 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 intergation 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 over payment 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.

1.77. 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 overpayments 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.

1.78. 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.

NEW DELHI;
December 14, 1970.
Agrahayana 23, 1892 (*S*).

ATAL BIHARI VAJPAYEE,
Chairman,
Public Accounts Committee.

APPENDIX I

(*Vide* paragraph 1.27)

Copy of D.O. letter No. 1-39|66-D|DC dated the 11th May, 1968 from the Director General of Health Services to the Medical Superintendents of all major hospitals in Delhi.

The use of time-expired drugs by certain hospitals and destruction of substantial quantities of time-expired drugs by some hospitals had been brought to our notice recently. Questions about these have figured in the Parliament and the Public Accounts Committee of the Parliament had made adverse observations on those undesirable features.

The question has been examined and it is felt that with regard to biological and other drugs which have a life period assigned to them is necessary that their requirements should be assessed carefully in the light of their average consumption over the past three years and that orders should be placed for such drugs in quantities which are absolutely necessary. While placing orders, manufactures should be requested to phase their deliveries in such a manner as to ensure their consumption in hospitals before they become time expired. If however, such arrangements are not possible, orders for such drugs should be placed in limited quantities and at frequent intervals so that there may not be any occasion to write off stocks on the ground that these had become time-expired.

The stores attached to hospitals must be placed under the charge of a competent Pharmacist who should preferably be a graduate in Pharmacy and who should be responsible for assessing the requirements of drugs including thermo-labile drugs and drugs which have life-periods, their issue from the store maintenance of proper storage conditions, review of stocks with reference to their life-periods and maintenance of a special register recording the receipt and issue of drugs which are perishable and which bear dates of expiry of potency.

The Pharmacist-in-charge of the Stores, should carry out fortnightly inspections of the stocks and ensure that drugs whose dates of expiry are about to be crossed are used sufficiently in advance of such dates. If in his opinion, these drugs are not likely to be

used before expiry of potency, every effort should be made by the Pharmacist to obtain, if possible, from the manufacturers replacement supplies in exchange. In case he notices visu signs of deterioration in any drugs, the local Drugs Inspector should be sent for and asked to take samples and send them for test. Pending the receipt of test reports, the stocks should be frozen and no issue should be made from them.

It is requested that the points set for the above may be specially borne in mind and the Hospitals Stores reorganised as to give no room for the criticism that drugs which had become time expired were used in hospitals or issued to patients and that stocks of time expired drugs had been written of causing financial loss to the State.

It will be appreciated if action taken in this matter is intimated to us in due course.

APPENDIX II

Summary of main Conclusions/Recommendations

S. No.	Para No.	Ministry/Department concerned	Conclusions/Recommendations
1	2	3	4
1	1·28	Ministry of Health, Family Planning, Works, Housing and Urban Development (Department of Health)	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 on 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.
2	1·29	Do.	The Committee deprecate the Irwin Hospital's gross over-indenting of Achromycin injections. Against the past annual offtake 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.
31	1·30	Do.	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 been 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 outcome.

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4	1·31	Ministry of Health, Family Planning, Works, Housing and Urban Development (Department of Health)	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.
5	1·32	Do.	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 inspection 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.
6	1·33	Do.	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 2½ 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.
7	1·34	Do.	The Committee find that in this case there was a delay of one month in reporting the deterioration of the drug to the Drug Control Administration, Gujrat 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

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			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 depot 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.
8	1·35	Ministry of Health, Family Planning, Works Housing and Urban Development (Department of Health)	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.
9	1·36	Do.	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.
10	1·37	Do.	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 requiremetns 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

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			on a to p 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.
11	1·58	Ministry of Health, Family Planning, Works, Housing and Urban Development (Department of Health)	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.
12	1·59	Do.	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.
13	1·60	Do.	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.
14	1·61	Do.	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.
15	1.62	Do.	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 Analyst's report had been received in April, 1969. Strangely enough it was the firm which

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			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 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.
16	1·63	Ministry of Health, Family Planning, Works, Housing and Urban Development (Department of Health)	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.
17	1·64	Do.	The Committee were given to understand that the rate contracts for the purchase of ferrous sulphate tablets were introduced only on the 1st 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.

18	1·76	Ministry of Health, Family Planning, Works, Housing and Urban Development (Department of Health)/ Ministry of Finance	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

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			the various ministries for the Plan assistance by the Ministry of Finance.
19	1·77	Ministry of Health, Family Planning, Works, Housing and Urban Development (Department of Health)/ Planning Commission/ Ministry of Finance	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 *mala fide* 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 overpayments 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.
20	1·78	Do.	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.

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26.	Atma Ram & Sons, Kashmere Gate, Delhi-6.	9
27	J. M. Jaina & Brothers, Mori Gate, Delhi.	11
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39.	The Secretary, Establishment Department, The High Commission of India, India House, Aldwych, LONDON W.C.—2.	59

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