C.P.U. No. 373

COMMITTEE ON PUBLIC UNDERTAKINGS (1978-79)

(SIXTH LOK SABHA)

THIRTY-SEVENTH REPORT

ON

ACTION TAKEN BY GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE EIGHTIETH REPORT OF THE COMMITTEE ON PUBLIC UNDERTAKINGS (FIFTH LOK SABHA)

ON

HINDUSTAN ANTIBIOTICS LIMITED

(Ministry of Chemicals & Fertilizers)

Presented in Lok Sabha on 16-4-1979
Laid in Rajya Sabha on 24-4-1979

LOK SABHA SECRETARIAT
NEW DELHI

April, 1979/Chaitra, 1901(S)

Price : Rs. 9·75

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INTRODUCTION

I, the Chairman, Committee on Public Undertakings having been authorised by the Committee to submit the Report on their behalf, present the Thirty-seventh Report on Action Taken by Government on the recommendations contained in the Eightieth Report of the Committee on Public Undertakingss (Fifth Lok Sabha) on Hindustan Antibiotics Ltd.

2. The Eightieth Report of the Committee on Public Undertakings (1975-76) was presented to Lok Sabha on 19th March, 1976. Replies to all the 79 recommendations contained in the said Report were received in batches from the Ministry of Chemicals and Fertilizers and the last batch was received on 4th October, 1976. Further information in respect of certain recommendations was also called for from the Ministry of 17th January and 14th March, 1977 and the replies to the first batch were received on 25th February, 1977 and replies to the second batch on 9th and 20th May, 1977.

3. As the replies received from the Ministry in respect of certain recommendations required updating, the Ministry were asked on 8th December, 1977 to furnish updated replies with latest information in respect of 35 recommendations and the same were received from the Ministry on 11th January, 1978. Updated information in respect of three recommendations was also received on the 2nd December, 1978.

4. The replies of Government were considered by the Action Taken Sub-Committee of the Committee on Public Undertakings and this Report was adopted by them at their sitting held on the 28th March, 1979. The Report was finally adopted by the Committee on Public Undertakings on the 31st, March 1979.

NEW DELHI;
April 2, 1979.
Chaitra 12, 1901 (*S*).

JYOTIRMOY BOSU,
Chairman,
Committee on Public Undertakings.

CHAPTER I

REPORT

This Report of the Committee deals with the Action Taken by Government on the recommendations contained in the Eightieth Report of the Committee on Public Undertakings on Hindustan Antibiotics Ltd. which was presented to Lok Sabha on the 19th March, 1976.

2. Action Taken notes have been received from Government in respect of all the 79 recommendations contained in the said Report. These have been categorised as follows:—

(i) *Recommendations/observations that have been accepted by Government:*

1—5, 7—13, 15, 16, 19—23, 26—47, 49—55, 57, 58, 60 and 62—79.

(ii) *Recommendations/observations which the Committee do not desire to pursue in view of Government's replies:* 14, 48 and 61.

(iii) *Recommendations/observations in respect of which replies of Government have not been accepted by the Committee:* 6, 17, 18, 24 and 25

(iv) *Recommendations/observations in respect of which final replies of Government are awaited:* 56 and 59.

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

A. Penicillin -Keeping pace with technology

Recommendation No. 6 (Paragraphs 2.28 and 2.29)

4. The Committee recommended that a case study of the production of Penicillin by HAL should be undertaken so as to determine the national loss due to not keeping pace with the technical developments in improving the strains.

5. The Committee also suggested that a Study should be made and a report prepared once a year comparing the output and technology used in the Undertaking with units in the country and if possible with efficient units outside the country, and considered in depth

by the Board of Directors who should give their recommendations for improving efficiency and production.

6. In reply the Ministry have stated that the Company is keeping itself abreast of the developments taking place in technology and making all effort to secure improved technology and strains as and when available. For instance the Company has obtained and introduced improved strain and technology for the manufacture of Streptomycin and Penicillin from M/s. Glaxo (U.K.) and M/s. Toyo Jozo (Japan) respectively and were in the process of introducing improved technology for the manufacture of Vitamin C obtained from M/s. Roche Products*.

7. It has been further stated that a study in respect of Company's output and technology used in the undertaking with the units in the country appears to be not feasible as the results of operation/data in each of other units in the country and outside are not available for comparison. The status of technology of various products of the Company is, however, constantly under review. Comparative statistics of output and technology to the extent available made use of for correct assessment. The Ministry have added that in the above background case study as recommended by the Committee may not be feasible.

8. The Committee are not satisfied with the reply of the Ministry. They do not see any reason why a case study of the manufacture of Penicillin cannot be undertaken so as to determine the national loss due to Hindustan Antibiotics Ltd. not keeping pace with technical developments in improving the strains. This well suits the interest of the multi-nationals in the particular field and therefore requires a deep probe. The Committee would like to reiterate that a case study of the manufacture of penicillin as already recommended by the Committee should be made expeditiously and the results reported to the Committee within three months and reflected in the Annual Report of the Corporation and also the Annual Report of the Administrative Ministry fully.

9. The Committee would also like to reiterate that a study should be made and a report prepared every year comparing the

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* At the time of factual verification, the Hindustan Antibiotics Ltd., substituted this sentence to read as follows:—

"For instance the Company has obtained and partially introduced improved strain and technology for the manufacture of Streptomycin and Penicillin from M/s. Glaxo (U.K.) anti M/s. Toyo Jozo (Japan) respectively and were in the process of rehabilitating the Vitamin C Plant with the free assistance from M/s. Roche Products."

output and technology used in the undertaking with the other units in the country and, if possible, with efficient units outside the country and considered in depth by the Board of Directors who should give their recommendations for improving efficiency and production. This should also be covered adequately and faithfully in the Annual Report of the Undertaking

B. *Streptomycin/Agreement with Mercks and Co.*

Recommendation No. 17 and 18 (Paragraphs 2.105 and 2.106)

10. The Committee recommended that the Ministry should examine critically in consultation with the authorities concerned as to how far the action of Mercks in not informing Hindustan Antibiotics Ltd. about the improved strain of streptomycin was correct with reference to terms of collaboration agreement so that suitable action might be initiated by HAL. The Committee also observed that there was no justification for the delay of four years on the part of HAL in deputing its officers to Mercks & Co. when it was known that Mercks was getting higher titre yield even from 1967 and when the agreement gave the right to the officers of the Company to visit the plants once a year. The Committee deprecated the complacency and negligence on the part of HAL in not keeping itself concurrently informed of the developments and improvements in the strain of streptomycin by Mercks. The Committee recommended that the Government should investigate the matter and fix responsibility for the lapse.

11. In reply, the Ministry have stated that "the Government propose to examine critically in consultation with others concerned, the reasons for the delay on the part of HAL in not deputing its officers to Mercks. Before doing so, it is proposed to get an investigation done by the Board.

12. The Ministry further informed (January, 1978) that the Board of Directors of HAL examined the matter on 3rd March, 1977 and recorded the following minutes:—

> "According to the contract, Mercks & Co. were only required to keep HAL informed of any new improvements made by them in the process of sub-cultures for the production of Streptomycin. In this particular case, according to them no such improvement had been achieved in their own laboratories, but they had purchased an improved strain from Glaxo who had made a break-through in this regard. In view of this, Merck's failure to inform HAL about the improved strain cannot be held to be incorrect in terms of the contract.

Upto the year 1969, Merck's performance in terms of titres achieved showed a slight improvement with fluctuations up and down, but there was no dramatic increase wanting special enquiry, during the same period, there was some decline in the production performance of HAL, but this was stated to be the result of import substitution measures in raw materials. It was only in 1970 that the results obtained by Mercks showed a significant increase in titres obtained in comparison with previous years, and when this was noticed HAL deputed two officers in 1971, in order to find out what improvements had been carried out by Mercks for getting better yields."

13. In regard to keeping itself concurrently informed of the developments and improvements, the Government stated in a further reply as follows:—

"The Board noted that the management of HAL had been endevouring to keep itself abrest of developments in India and abroad by organising symposia, deputing personnel to seminars and symposia in India and abroad, subscribing to over 40 foreign journal in the field of antibiotics and allied subjects. However, the information relating to productivity particularly in the field of antibiotics is highly secretive and is not readily divulged by the firms concerned. It is only as a result of the efforts made by the Company that it was able to locate and obtain improved technology in the case of Penicillin recently."

14. The Committee condemn the negligence on the part of HAL in not keeping itself concurrently informed of the developments and improvements in the strain of streptomycin by Mercks. There could be lot more than meets the eye since Mercks are a very powerful and resourceful multi-national in this field. The Committee would insist that the Ministry of Chemicals and Fertilizers should independently examine critically the action of Mercks in not informing HAL about the improved strain of streptomycin with reference to the terms of the collaboration agreement. The findings of the enquiries should be conveyed to the Committee within three months and the matter should be clearly and fully reflected in the Annual Report.

C. *Vitamin C—selection of technology*

Recommendation Nos. 24 and 25 (Paragraphs 2.164 and 2.165)

15. The Committee observed that they failed to understand as to why the techno-economic evaluation of the project for manufacture of Vitamin C based on the joint report of Hindustan Antibiotics Ltd. and National Chemical Laboratory was not undertaken as envisaged

earlier and a decision was taken by Government without making sure of upscaling the technology/or examining the cost. The Committee desired that this aspect should be investigated and responsibility fixed for the lapse.

16. The Committee stressed that every prudent care should have been taken to have selected the appropriate technology and no efforts should have been spared to critically evaluate the same before taking the investment decision.

17. In their reply, the Government informed the decisions taken at the inter-ministrial meeting held on 14 February and 5 July, 1963 to consider the proposals of HAL for setting up Vitamin C and Hamycin Projects. The decision *inter alia* was "HAL complete pilot plant runs and submit a joint report with NCL to the Government by January 1964". The joint report made a favourable report of the trials of Vitamin C Pilot Plant. "It was then not considered to have a further technical or economic evaluation of the project based on the Joint Report of HAL and NCL. It may also be mentioned that a number of years were lost in making the Pilot Plant trials and seeking Government's approval and in the meantime the private sector company, which was the only monopoly producer was making progress in the manufacture of Vitamin C. It may be mentioned that it was in their eagerness to produce Vitamin C as early as possible that the Company and Government went ahead with the implementation of the Vitamin C for 125 tonnes capacity.

18. It has further been stated that unfortunately the operation of the plant did not yield the desired results on a commercial scale. Government thereafter considered the whole matter afresh and appointed a Task Force to study the problems involved in the matter and report/recommend after thorough examination a suitable course of action to retrieve the Plant.

19. The Committee are not at all convinced with the reply of the Government in regard to the setting up of Vitamin C Plant as the operation of the Plant did not yield the desired results on up-scaling it on a commercial scale. The Committee would reiterate their earlier recommendation that this aspect should be investigated and responsibility fixed for the lapse under advice to the Committee within three months. The Committee apprehend that there are unseen hands of multinationals in this very much.

D. *Withdrawal of batches from market*

Recommendation No. 35 (Paragraphs 2.213 to 215)

20. The Committee noted that a maximum number of batches of potassium penicillin G were withdrawn and the withdrawals were

mainly on account of non-confirmity to specifications. The Committee felt that "withdrawal of batches from market" did not leave a good image of HAL on the public mind. They desired to know how such batches passed the quality control test.

21. The Committee desired that the deficiencies in the products, which resulted in fatal reaction should be thoroughly investigated and deterrent action taken against all those responsible for the delinquency.

22. In their reply, the Government informed that the record of withdrawals of vials from the market was being maintained. The Company constituted a "Complaints Committee," comprising technical experts from Quality Control, Production, R&D and Sales. The Committee examines in depth periodically the nature of complaint and initiates remedial measures. A high powered committee called "Adverse Reaction Committee" is also constituted by analyse in depth the complaints of reactions. As regards investigation into fatal cases, the procedure dealing with the investigation has been explained in detail.

23. The Committee desired to know whether any investigation had been made into fatal cases and what action was taken as a result of such investigation. In their reply Government stated that whenever a fatal case was reported after the use of a HAL product, the Sales Department directed the Regional representative to personally collect further information on the reported incident for carrying out investigation. The procedure dealing with the investigation has been explained, but it has neither been stated clearly that such investigations were done nor the action taken as a result of such investigation been indicated in the reply. The Committee require information should be furnished to them without fail.

E. Utilisation of Services

Recommendation No. 39 (Paragraph 2.240)

24. The Committee recommended that Government/BPE should issue standing directions that measuring control instruments should invariably be provided along with the machines/equipment and should in fact form an integral part of the machines.

In their reply the Government has stated that—

"HAL has already implemented the suggestion. The Committee's recommendation that Government/BPE should

issue standing directions that measuring control instruments should invariably be provided along with the machine/equipment are under consideration."

25. In reply to the Committee's recommendation that Government/Bureau of Public Enterprises should issue standing directions that measuring control instruments should invariably be provided along with the machines/equipment and should in fact form an integral part of the machines, the Government has stated that the matter is under consideration of the Government/BPE. The Committee thoroughly disapprove delay in examining the matter and issue of the necessary instructions which could be a motivated one.

F. *Vialling--Installed Capacity*

Recommendation No. 42 (Paragraph 3.9)

26. The Committee desired that HAL should improve the utilisation of capacity of vialling and bring it to the level of 48,000 vials without further loss of time and money. The Committee were informed that the number of vials filled per shift during the year 1976-77 works out as follows:

	Average vials filled per shift
1976-77	27916
1977-78	26957
1978-79	31730

27. The Committee regret to find that though the installed capacity is 48000 vials per shift, HAL has not been able to achieve capacity utilisation of even 36000 vials per shift which was considered practicable by the Ministry. The Committee would require that Ministry/HAL should critically examine the constraints in the way of achieving installed capacity if necessary in consultation with experts unconnected with the private sector and take concerted measures without delay to improve the capacity utilisation to 36000 vials per shift.

G. *Vialling--Spillage and overage*

Recommendation No. 50 (Paragraph 3.51)

28. The Committee expressed their concern to note that the spillage and overages have always been in excess of standard and cumulative loss on this account during the last eight years was of

the order of Rs. 50.33 lakhs. The Committee stressed that the standards which were fixed in the initial stages should be reviewed by the R&D Wing of the Company in the context of the present stage of equipments and processes and stricter standards evolved for the purpose of assessment of the efficiency of vialling operations.

29. The Government in their reply informed that the Company had fixed an overage of 5 per cent *i.e.* 5 per cent extra by weight of the antibiotic powder than what is declared on the label as dosage, to ensure that no vial would contain less powder than what is declared on the label, and constant efforts were made to restrict it to 5 per cent.

30. The Government also stated in September 1976 that "as recommended by the Committee the R&D Unit of the Company will be called upon to review the standards fixed by the Company in the context of the present stage of equipments and processes and stricter standards evolved for the purpose of assessment of the efficiency of the vialling operations."

31. On a further enquiry from the Committee, the Government informed as follows:—

"(a) **Overages:** The maximum percentage allowable by the statutory Regulation have been strictly kept in view in our Formulations Department for both the injectable and non-injectable preparations. The norms for overages constitute the product guarantee to the consumer for having a minimum of the effective drug in the given dose form. These are fixed keeping in view the normal variations that are encountered while using equipment and machinery currently in use at HAL and with other formulators. With the introduction of better technology that is being envisaged in the Formulations Plant expansion at HAL, it would be possible to control the overages and reduce the level further, while at the same time assuring dose-level uniformity to the consumer. The R&D and the Production units have had discussions with equipment manufacturers and suppliers on this very question, and hope to achieve improvement in this in their plants."

Actual overages for Penicillin and Streptomycin products for the years 1976-77 and 1977-78 are furnished below:—

	1976-77		1977-78	
	Pen.	STPT	Pen.	STPT
Percentage of actual overage to standard consumption.	7·01	6·99	8·08	7·14

It would be observed from above that actual percentage of overage as compared to standard consumption has shown increased trend both in Penicillin and Streptomycin. This is due to the fact that existing machines in the Formulation Plant have become old and many cases of underages were noticed. Therefore, the machines have been adjusted to higher overage percentage within the pharmacopocial standards prescribed for potency for Penicillin and Streptomycin Products. HAL has also taken procurement action for modernising existing Formulation Plant.

(b) *Spillages*: The wastage due to spillages can be attributed to (1) handling losses, and (2) old and worn-out equipment used in the vialling, tabletting and capsuling operations The vialling machines at HAL are the earlier proto-types and are being replaced with more efficient and faster machines under both the renewals and replacement scheme, as well as in the setting up of the new Formulations II Plant at Pimpri. The present norm for spillage which has been fixed at 5 per cent overall, could not be maintained primarily due to the factor mentioned above. We are confident that with the installation of the newer equipment, it would be possible to drastically bring down the wastage due to spillage. The Production Department has taken several measures to cut down handling losses and constant vigilance will be maintained on this to reduce it still further. The percentage loss due to spillage during 1976-77 and 1977-78.

	1976-77		1977-78	
			(April. 77	Oct. 77)
	Pen.	STPT	Pen.	STPT
Percentage of actual spillage to standard consumption.	5·56	5·19	5·38	5·44

32. Though the percentage of actual spillage to standard consumption both in respect of penicillin and streptomycin has come down from 7.92 per cent and 7.4 per cent in 1974-75 to 5.38 per cent and 5.44 per cent in 1977-78 respectively, the percentage of actual overage to standard consumption both in respect of penicillin and streptomycin has risen from 4.86 per cent and 5.48 per cent in 1974-75 to 8.08 per cent and 7.14 per cent in 1977-78 respectively due to existing machines becoming old. Since in the overage there is an increasing trend, the Committee would reiterate their earlier recommendation that standards, which were fixed in the initial stages should be reviewed by the R and D Wing of the Company in the context of the present stage of equipments and process and stricter

standards evolved for the purpose of assessment of the efficiency of the vialling operations. The outcome of this exercise should be clearly indicated in the Annual Report.

H. Utilisation of capacity of Tabletting and Capsulation

Recommendations S. No. 52 and 53 (Paragraphs 3.65 to 3.68)

33. The Committee were informed that the operable installed capacities of tabletting and capsulation machines were fixed on the basis of actual trials and were lower than mechanical capacity of machines on account of lack of ancillary equipment. The Committee saw no reason as to why such ancillary facilities could not have been provided along with machines so as to utilise the full capacity. The Committee did not see the rationale behind fixing the operable capacity at a reduced figure even after addition of new machines.

34. The Committee also desired that the undertaking/Government should critically examine the constraints, if any, in the marketing of tablets and capsules and the reasons for the under-utilisation of capacities when there is margin of profit in sale of tablets and capsules which would be of direct service to the common man.

35. In their reply the Government stated that as against the installed capacity of 1800 lakh tablets per year, the operable capacity was earlier rated as 1248 lakh tablets per year, and that the Company had taken further measures to increase the operable capacity to installed capacity.

The actual production figures of tabletting and capsules were as below :

(All figures in lakhs)

1974-75	Tablets	149.62	8.31
	Capsules	75.73	52.59
1975-76	Tablets	416.61	23.16
	Capsules	71.48	49.62
1976-77	Tablets	353.66	19.65
	Capsules	258.24	67.19

36. It was further stated that the Company have been considering proposals to increase the market force. The Board of Directors had been examining the constraints and would go deeper into them as regards the marketing of tablets and capsules and the further reasons for the under utilisation of their capacities. With improved availability of bulk for tabletting and capsuling, it was expected that in the current year *i.e.* 1977-78, the utilisation of capacity would be better.

37. The Committee note that though there is an improvement in the percentage utilisation of capacity of tablets from 8.31 per cent in the year 1974-75 to 23.16 per cent in the year 1975-76, there is a decline to 19.65 per cent in the year 1976-77. The percentage utilisa-

tion of capacity in respect of capsules has gone down from 52.59 per cent in the year 1974-75 to 49.62 per cent in the year 1975-76 and gone up to 67.19 per cent in the year 1976-77. In the opinion of the Committee this is not much of an improvement, particularly with the installation of air-conditioning facilities, which were a major constraint earlier. The Committee expect that with higher allocation of bulk for formulations, HAL would show better utilisation of capacity in respect of both tablets and capsules. The results obtained should be shown in the Annual Report.

I. *Captive Consumption of Bulk*

Recommendation No. 54 (Paragraphs 3.69 to 3.71)

38. The Committee are informed that constant efforts are being made by the company to increase the quantum of formulations. In the year 1975-76, the output of filled vials is stated to have gone up by 20 per cent and that of capsules and tablets by 117 per cent over the previous year. It has been stated that the company has approached the Government for further expansion in the formulations capacity and the revised feasibility report entailing an investment of Rs. 4.46 crores is under the consideration of Government.

39. Contrary to these claims, the Committee find from the statistics supplied alongwith the Government replies (Appendix—V) that the percentage of captive consumption of bulk penicillin 'G' has gone down from 37.80 per cent in 1973-74 to 31.24 per cent in 1975-76; in April—June 1976, however, it is reported to have increased to 55.31 per cent. Similarly they also find that the captive consumption of streptomycin bulk has gone down from 59.03 per cent in 1974-75 to 41.25 per cent in April—June 1976. The Committee have also noted that the utilisation of formulations capacity has been much below the installed capacity inas-much-as it was only 23.16 per cent in the case of tablets and 49.62 per cent in the case of capsules in 1975-76.

40. It has been seen from the further information furnished by the Ministry on 1 Dec. 1978 that the percentage of captive consumption of bulk Penicillin 'G' rose to 43.57 per cent in 1976-77 but it showed a sharp decline to 27.69 per cent in 1977-78 (from April to February).

41. The Ministry have also informed (on 1-12-78) that Government have approved the expansion of Formulation capacity of HAL as follows:—

(i) Formulation Plant II involving of Rs. 309.03 lakhs.

(ii) Joint Ventures formulation units in association with State

Governments/State Government Corporations in (a) Karnataka and (b) Maharashtra (near Nagpur)—each involving outlay of Rs. 282.86 lakhs.

42. It has been further stated that with the establishment of these formulation units HAL will be utilising 60 per cent of their production of bulk drugs.

43. The Committee are unable to appreciate as to why the captive consumption of bulk has gone down when there is such a large formulations capacity still unutilised. The Committee would like to reiterate that HAL should investigate the constraints on the optimum utilisation of the existing formulations capacity, take conclusive measures to remove these constraints and ensure that not less than 60 per cent of the production of bulk is utilised for formulation by the company itself as recommended by the Hathi Committee on Drugs and Pharmaceuticals Industry.

44. The Committee are informed that after HAL started basic production of penicillin and streptomycin, the import of these antibiotics was progressively reduced and HAL supplied these bulk antibiotics to the different viallers (formulators) in accordance with the allocations made by Government. They are further informed that whenever the production of bulk drugs is commenced either by Public Sector or Private Sector in the country, the responsibility of supply of bulk drugs to formulators shifts from imports to indigenous producers. This is reported to have happened in the case of HAL also. The Ministry have stated that "since this is the policy of Government, we feel that the question of either not adhering to 'obligation' or fixing the responsibility does not arise."

45. The Committee are not convinced that there was any 'obligation' on HAL to supply bulk drugs to private viallers by keeping its own formulation capacity underutilised even when the bulk sales had been a substantial factor contributing towards losses of the company and when on the contrary the bulk sales had been rather helping the private firms, particularly the foreign firms, to earn huge profits at the expense of the public sector.

J. *Bulk* vis-a-vis *Formulations*

Recommendation No. 55 (Paragraphs 3.84 to 3.91)

46. The Committee noted that major portion of the total production of different products of Hindustan Antibiotics Ltd. was sold in bulk form to private viallers, although sale in vialled formulations was more profitable than sale in bulk. They were unable to appreciate why Company had not been fully utilising its vialling

capacity and why it cancelled orders for formulations and why the Government thought that they "had also an obligation to supply the bulk drug to private vialler." even though the bulk sales had been a substantial factor contributing toward losses which the Company had been sustaining currently.

47. They recommended that Government should thoroughly investigate into the reasons for the under utilisation of formulation capacity.

Indifference to the need to augment the formulation capacity and develop markets for HAL's products, the so-called "obligation" to supply bulk drugs to private viallers and cancellation of orders for formulations in spite of having un-utilised capacity, with a view to fixing responsibility and inform the Committee of the precise action taken in the matter.

The Government in their reply stated as follows:—

"The manufacture of bulk drugs is both capital intensive and technology oriented. Before the public sector projects were set up, the country was mostly dependent on import of bulk drugs and formulating them in India. The Public Sector Projects were set up with the main object to produce some of the essential bulk drugs so as to achieve a measure of self-reliance and to reduce undue dependence of imports. After HAL started basic production of penicillin and streptomycin, the import of these antibiotics was progressively reduced and HAL supplied these bulk antibiotics to different viallers (formulators) in accordance with the allocations made by Government. While allocations of penicillin by the Government was discontinued in 1966, the subsequent distribution to formulators by HAL continued. In 1970, along with the system of canalisation of chemicals including drugs through STC, the system of distribution of bulk drugs which are on the production programme of IDPL also commenced through the IDPL. Streptomycin was one of the drugs imported by STC and distribution through IDPL. It may be mentioned that after a drug is canalised for imports it becomes essential for the Government to ensure supply to non-associated formulators who are licensed for its manufacture and imports are arranged only for such quantity as is necessary to meet the demand. This explains the responsibility of Government or the Public Sector Unit to supply bulk drugs which are not formulated by them to viallers (formulators). The Government through its

mechanism of licensing has over a period of time created formulation capacity for various items. The formulators of such items having installed capacities for those items involving financial investment are entitled to secure the bulk drug in accordance with Import Trade Control Policy in force from time to time. Whenever the production of bulk drug is commenced either by Public Sector or Private Sector, in the country, the responsibility of supply of bulk drugs to formulators shifts from imports to indigenous producers. This has happened in the case of HAL also.

Since this is the policy of Government we feel that the question of either not adhering to "obligation" or fixing the responsibility does not arise.

HAL could not utilise its vialling capacity mainly because of their inability to meet the orders for formulations due to the difficulties encountered in the production of formulation which are indicated below:——

(a) Obsolesence of equipment;

(b) Limited availability of Rubber Stoppers; and

(c) Problems connected with humidity in vialling operations.

There was no desire on the part of the Company to make available their bulk drug to other formulators.

A Committee of Directors is being asked to look into utilisation of vialling capacity/formulation capacity and to submit a report to the Government as soon as a new Board is constituted for 1976-77. As regards indifference to the need to augment formulation capacity the expansion of the Company in various areas has been undertaken in accordance with plan provisions, which in turn are based upon market needs and capability of the company to produce and sell its products. However, the Committee of Directors will be asked to go into this aspect also and to state whether there has been any failure on the part of the Company in this regard.

In a subsequent communication (October, 1976), the Ministry stated as follows:—

"The Board of Directors consisting only of officials has been so far constituted for the year 1976-77 and the point raised by the Committee for being sent to the Managing Director is placing it before the next meeting of the Board of

Directors for constituting a Sub-Committee, to enquire and report to Government through the Board of Directors on the following terms of reference:—

(i) Reasons for under-utilisation of formulation capacity *viz.* vials tablets and capsules in the HAL Plant.

(ii) Fixation of installed capacity that could be attained in regard to the formulations for various categories.

(iii) Whether there was any deliberate under-utilisation of capacity by the company and if so, who is responsible for such under-utilisation.

(iv) Any other matters pertaining to the above.

(v) The Board of Directors will be requested to submit the report within three months.

In a further communication the Ministry informed in January, 1978 that a Sub-Committee of the Board of Directors will be constituted in the next meeting of the Board to enquire and to report to Government through the Board of Directors in respect of the terms of reference indicated in Government's letter No. L-51012(2)/73-DC, dated 11-10-1976.

48. In a further reply, the Ministry informed on 1st December, 1978 that the Sub-Committee of the Board of Directors set up to enquire into the reasons for under-utilisation of formulation capacity has submitted its Report and the Company was making all efforts for improved utilisation of formulation capacity. The Sub-Committee of the Board in its Report have stated that in the case of vialling machine the manufacturers had indicated an absolute capacity of 57,600 vials in an 8 hour shift, on continuous working. Even according to the manufacturers' recommendations, an allowance was required to be provided for scheduled maintenance to the extent of 1.1/3 hours per shift reducing the capacity to 48000 vials per machine/shift. Furthermore, in a normal shift of 8 hours, the actual working time of the personnel was 6½ hours only on account of dress changing, tea and lunch intervals which reduced the utilisation by another 1½ hours *i.e.* by 10,800 vials thus reducing the capacity to 37,200 vials. Further allowance was required to be made for breakdowns, product-changes, multi-does operations, powder characteristics etc. There were other unforeseen technical factors such as power failures, stoppage due to high humidity, not vials etc. besides reasons attributable to personnel such as high rate of absenteeism, with notice as well as without notice. Another reason was the wear and tear of the machinery over the years. Taking all these factors

together, the average achievable vialling capacity worked out to 26,400 vials per machine/per shift. It has also been stated in the Report of the Sub-Committee that "If the Company could tackle both the technical and personnel side, it could be possible to achieve an output of around 36,000 vials per machine/shift."

49. The Committee are not convinced that the achievable capacity of vialling machines could be around 26,000 to 27,000 vials. This means that the utilisation of capacity is even less than 50 per cent of the absolute capacity of 57,000 vials in a 8 hour shift. In case, the arguments put forward by the Sub-Committee of the Board accepted it will mean that in a 8 hour shift the machine will work for less than 4 hours. This position is totally unacceptable to the Committee. As recommended earlier in this Report (in paragraph 26), the Committee require that the Ministry/HAL should examine the matter further if necessary in consultation with experts unconnected with the private sector and take concerted measures without delay to improve the utilisation of formulation capacity to at least 36,000 vials per shift immediately and to raise it to 48,000 vials per shift as early as possible. The Committee also require that the norms utilisation of capacity for capsules and tablets should also be fixed and their fulfilment should be watched to ensure that these are achieved in actual practice. The Committee would like that utilisation of formulation capacity for vials, capsules and tablets should also be reflected in the Annual Report of the Undertaking.

K. Pricing Policy

Recommendation No. 56 (Paragraph 4.27 to 4.35)

50. The Committee noted that the cost of production of various bulk drugs and formulation by HAL had more than doubled since 1966-67 in most cases and the cost of production of many items had been higher than the selling prices fixed by the Government. The Committee recommended that the Undertaking should take concerted measures to reduce its cost of production by better utilisation of the capacity, improving its efficiency and controlling rejections and eliminating all wastages.

51. The Committee recommended that the Government might expeditiously examine the various aspect of the pricing of bulk drugs and formulations in the light of the Reports of the Bureau of Industrial Costs and Prices and the assurance given by the Minister in the House about Hathi Committee's recommendations and evolve a pricing policy by which the public sector should play a dominant role in drug industry by making essential drugs available both to the hospitals and the common man at most competitive prices. The

public sector should also have appropriate blend of bulk and formulations so as not to make losses, but generate adequate margin on capital invested to make itself relient and growth oriented.

52. The Government stated in their reply that as a result of implementation of various time bound measures, such as, introduction of new strain technology to increase productivity, utilisation of higher capacities, reduction of wastages, and improvement in efficiencies resulting in lower consumption of raw materials per unit of produtcion, the unit cost of production had come down in the case of Penicillin products as can be seen from the following:—

	Base 1973-74=100			
	1974-75	1975-76	1976-77	1977-78
Penicillin G first crystals	141	128	137	131
Penicillin V first crystals	139	132	89	64
Pottassium Pencillin G Bulk	137	135	131	140
Sodium Penicillin Bulk	134	130	132	150
Procaine Penicillin Bulk	145	141	156	144

53. In the case of Streptomycin, although production was marginally lower in 1975-76, due to 40 per cent power cut, during some months and although the cost of inputs such as wages, furnance oil, power and raw materials had gone up to a considerable extent the cost of production remained the same at the index 117 (1973-74 base 100) in 1975-76 as compared to 1974-75 as a result of implementation of various measures as indiacted above.

54. Based on the recommendation of the Bureau of Industrial Costs and Prices the manufacturers of Penicillin and Streptomycin, which are two major products in the production range of HAL were given price increase for escalation of material costs and other input costs. With a view to make the essential drugs available to the consumer at cheap prices, the question of reduction of excise duty on certain intermediates which are used for the manufacture of essential bulk drugs is stated to be under examination of the Government.

55. The report of the Hathi Committee was also stated to be still under the consideration of Government and decision was likely to be taken soon.

56. The Committee would reiterate that HAL should continue to take concerted measures to reduce its cost of production by better utilisation of the capacity, improving its efficiency and controlling rejections and eliminating all wastages. They would also reiterate that Government may in the light of the reports of the Bureau of Industrial Costs and Prices and the Hathi Committee, evolve a pricing policy by which the public sector may play a dominant role in the drug industry by making essential drugs available to hospitals and the common man as near as possible to the cost price. The Public Sector should also have a appropriate blend of bulk and formulations so as not to incur losses but generate adequate margin on capital invested to make itself-reliant and growth-oriented.

57. The Committee recommend that an early decision should be taken on the issue of reduction of excise duty on certain intermediates used for the manufacture of drugs, with a view to making the essential drugs available to the common man at cheap prices. The Committee should be informed of the outcome within three months and also should be reflected in the Annual Report.

L. *Central Marketing Organisation*

Recommendation No. 59

58. Recalling a recommendation contained in the 40th Report of the Committee on Public Undertakings on "Role and Achievements of Public Undertakings," the Committee recommended that Government should evolve a centralised sales and marketing set up for each type of industries and set up a central marketing organisation for HAL and IDPL. In reply the Government informed that—

> "In pursuance of the recommendation of COPU on IDPL, a Committee was appointed to investigate into the problem of S.I.P. of IDPL. The Committee has submitted the report and in one of the recommendations, it has been suggested that the S.I.P. may be delinked from IDPL. The recommendation if accepted, would involve a reorganisation of IDPL and possibly HAL also. Pending a decision on the overall changes, the matter concerning marketing reorganisation cannot be decided upon in isolation. However, the Board of Directors of HAL have already improvised upon the management that a link up with marketing organisation of Smith Stanistreet & Co., on the one hand and of IDPL on the other should pursued. This is being attended to. The allocation of Streptomycin which is on the production range of both IDPL and HAL

is being issued presently by IDPL. Therefore, an introduction of marketing in a very limited way has been under way for some time.

59. The Committee fail to understand as to why Government have delayed implementation of this very purposeful recommendation which undoubetedly has immensely helped the private sector which are mostly multinations.

6. The Committee would strongly reiterate that the Government should not lose any more time to decide about the set up of a central marketing organisation which would not only be economical but would also lead to greater coordination, evolution of effective sales strategies and development of expertise in the field of sale management and could meet the rivalry of multinational.

61. The Committee further require a probe for fixing responsibility on individual officials for the delay that has taken place. The outcome of this whole exercise should be conveyed to the Committee within three months and should also be reflected in the Annual Report faithfully and fully.

M. *Export through M/s. Unichem*

Recommendation No. 63 (Paragraph 5.56)

62. The Committee desired to know how UNICHEM were selected for exporting the products of HAL and whether any offer of other companies in this regard were considered. The Committee desired that this matter should be investigated.

63. In their reply the Government informed that the Board of Directors had gone into this question and communicated its fiindings to the Committee. (*See pages* 121 *and* 122)

64. The Committee note that the Board of Directors has enquired into various aspects of the arrangement made with M/s. Unichem for exporting the products of HAL. They further note that the Board dhas come to the conclusion that "this arrangement was no doubt somewhat weighted in favour of Unichem" though it has also observed that "the arrangement was on the whole not an unreasonable one." The Committee have serious suspicion about the authenticity of this conclusion and would require the Government to order a probe in which persons connected with drug industry should only be included. The Report of the probe should be sent to this Committee within three months.

N. *Inventory Control*

Recommendation No. 72 (Paragraphs 7.14 and 7.15)

65. The Committee noted that the value of surplus and obsolete stores has increased from Rs. 2.68 lakhs at the end of 1970-71 to Rs. 4.45 lakhs at the end of 1972-73, declined to Rs. 3.51 lakhs at the end of 1973-74 and again increased to Rs. 7.27 lakhs at the end of 1974-75. The Committtee felt that had suitable maxima, minima and ordering levels been laid down and adhered to the undertaking would not have been faced with such surplus and obsolete inventories. The Committee desired that the Government should go into the reasons for a steep rise in the inventory and non-moving items at the end of 1974-75.

66. The Committee stressed the need for timely remedial measures so that inventories were put on most rational and economic basis in the interest of production.

67. In their reply, the Ministry *inter alia* stated as follows:—

> "The fixing up of maxima, and minima and ordering levels in respect of spares will be taken up after completion of the catalogue and implemented by the end of the year (1976). However, as regards raw materials and general stores, maximum and minimum levels are being fixed up and are being operated upon.
>
> In view of the fact that the Company and the Board are keeping a constant vigil over the inventories the levels thereof are under control. Therefore, there does not appear to be any need to investigate the reasons for the steep rise in inventories and non-moving items, earlier. However, Government propose to keep a watch on the situation.
>
> As regards 1974-75, the company is being asked to submit a report giving detailed/codification for the steep rise in inventory."

68. The Ministry have further stated (May, 1977) that the task force had studied the possiblities in reduction of obsolete/surplus inventory specially of Engineering Stores and spares and recommended during January, 1974 liquidation of 2895 items comprising a book value of Rs. 14.14 lakhs. Subsequently, after transferring some of these items for expansion projects and consuming some for maintenance/modification, items worth Rs. 7.27 lakhs were identified for disposal. Stock of surplus inventory as in February 1977 was worth Rs. 6.24 lakhs. It was also stated that the Company would

be taking the problem of disposal of surplus materials on hand immediately.

69. In a further communication the Ministry informed (January, 1978) that the HAL had constituted the following Committees for going into the aspect of disposing surplus material, completing balance of codification work and fixing the maxima and minima norms in respect of stores items—

1 Committee for disposing surplus items.

2 Cell for Codification etc.

3. Committee for reviewing 'A' items of important raw materials.

70. The Committee cannot over-emphasise the importance of keeping inventories within limits in order to avoid blocking of funds and bring down costs of production. They would like to stress again that maxima, minima and ordering levels of all categories of inventories should not only be fixed and thereafter reviewed from time to time in the light of experience, but also observed in actual practice. This may perhaps help the purchasing authorities becoming prosperous.

71. The Committee recommend that vigorous efforts should be made to dispose of the obsolete and surplus items to other public undertakings through the Bureau of Public Enterprises. The Committee would like to reiterate that the inventory position and the outcome of remedial measures taken to bring the inventories within limits should be brought to the notice of the Board periodically to enable to it take such further measures as may be considered necessary. In future major purchase proposals and necessity of making such purchases should be gone into by a Committee consisting of senior executives of the undertaking and the Internal Audit should also be associated with it.

O. *Credit Control*

Recommendation No. 77 (Paragraph 8.38)

72. The Committee did not find any justification for huge outstanding from private viallers to the extent of Rs. 43 lakhs, when the credit system permitted only supplies to them against advance payment. The Committee found that instead of realising the dues of about Rs. 2 crores from the Government departments and private viallers in time, the Undertaking obtained Rs. 2 crore as short term loan for working capital requirement, on which it had to pay interest charges. The Committee recommended a review of the credit

arrangements, streamlining of the billing and recovery system and realisation of outstandings from the appropriate Governments/ Ministries.

73. In their reply the Government informed that the system of billing has been streamlined by the Company. Accordingly, the final bill reached the party alongwith the concerned document within a week before the receipt of the consignment. In regard to Government institutions the Government stated:—

"The Company supplies to over 7000 Government institutions and hospitals all over the country. Some of the supplies are made to the Government institutions through Central Government agencies such as Government Medical stores, against DGS&D contracts. The transit time for the consignments extends upto 30 days depending upon the destination and mode of transport. The State Government institutions have to follow certain procedures which differ from State to State as well as for supplies under DGS&D. In spite of all efforts, it is found that the collection period stands around 90 days which includes about 30 days of transit time. Further measures are being taken such as approaching the various institutions and hospitals through the Company's medical representatives, decentralising despatches by opening depots in various States in order to reduce the transit time and approaching government authorities directly. Collection drives are also launched from time to time particularly after the budget sanctions are available to the Government institutions. DGS&D has been requested to allow 98 per cent payment against proof of despatch and this has been agreed to by the DGS&D for some of the supplies. Based on this analysis, the State Governments are being approached to agree for similar payment system. Some of the Government institutions and hospitals have also defaulted for periods ranging over 1 year and all persuations have proved of no avail. The Company may be constraint to discontinue supplies in extensive case to such defaulting institutions.

As regards collection of outstandings of bulk sales, supplies are made to formulators against payment and this usually takes 7 days from the date of despatch. Of late, the Company has been availing of the Bills Discounting Scheme for sale of bulk drugs as a result of which cash is realised immediately:

It may be mentioned that such delays in payment by the Government institutions and hospitals take place invariably in the case of other formulators who supply drugs to the Government Institutions.

As a result of various measures taken as outlined above the outstandings as on 20th September, 1976 stood at Rs. 187 lakhs which represent approximately 80 days sale.

On an enquiry, the latest position in respect of outstandings was stated to be as follows:—

as on 31-3-1977		Rs. 307.29 lakhs
as on 31-11-1977	..	Rs. 211.56 lakhs
as on 31-3-1978		Rs. 331.46 lakhs
as on 31-3-1979		Rs. 375.00 lakhs

74. The Committee regret to note that there has not been any improvement in the matter of reducing the outstandings due to the Company. The Committee would strongly urge the Corporation to gear up their system in such a way that these outstandings are brought down without undue loss of time. The feasibility of charging interest on outstanding should be examined by the Corporation.

75. An enquiry is needed to reveal the facts behind this unusual position where the amount of outstandings is increasing which is very adversely affecting the operational results of the undertaking. In this matter responsibility should be fixed on the individual officers for taking necessary action under advice to this Committee. The position in regard to outstandings should be reflected in the Annual Report.

CHAPTER II

RECOMMENDATIONS/OBSERVATIONS THAT HAVE BEEN ACCEPTED BY GOVERNMENT

Recommendation No. 1 (Para 2.14)

The Committee regret to note that the installed capacity or the norms of production of Penicillin at different stages have not been indicated in the Project Report. It has been stated that the targets for production of fermentation batches were fixed at lower levels for want of extraction capacities because of an accident in 1967 to the extractor which was replaced only in March, 1970. The Committee regret to note that it took the Company three years to replace the extractor, and the production was allowed to suffer during all these years. The Committee would like the reasons for delay in this regard to be enquired into and responsibility fixed for such excessive delay which resulted in heavy loss in production.

Reply of Government

The matter would be investigated by the Board.

[Min. of C & F O.M. No. 51012/2/75-DC Dt. 30-9-1976]

Further information called for by the Committee

What is the delay?

[L.S.S. O.M. No. 21-PU/76 Dt. 17-1-77]

Further reply of Government

The Board of Directors have taken up consideration but their recommendations are still awaited.

[Min. of C&F O.M. No. 51012/2/75-DC Dt. 24-2-1977]

Further information called for by the Committee

Has the enquiry into the reasons for delay to replace the extractor since been completed? If so, what are the results thereof.

[L.S.S. O.M. No. 21-PU/76 Dt. 8-12-77]

Further reply of Government

The Board of Directors of HAL had examined the matter and the minutes of the meeting held on 3rd March, 1977 are reproduced below —

The Committee has pointed out that it took the Company 3 years to replace the extractors and the Government have asked the Board to investigate the matter. The Board finds that action towards the replacement of the extractors on the grounds of obsolescence was already underway before the accident took place. However, the actual application for the import licence was made only in December, 1967, i.e. seven months after the accident. Thereafter, the formalities relating to the import licence application such as the addressing of enquiries to Indian firms D.G.T.D. clearance, etc., took some time and the import licence was actually received in November, 1968. The indent was then placed on the India Supply Mission, Washington, within a few days. The India Supply Mission, in turn, placed an order in March, 1969 and the equipment was actually received at Pimpri in February, 1970. It will thus be seen that the obtaining of the import licence took a year, and the receipt of the equipment took 14 months thereafter out of which the actual delivery period of the manufacture was 10 months. It cannot be said that the process of obtaining an import licence, placement of order and receipt of equipment have taken unduly long. Even with the special efforts, this period could perhaps not have been reduced very significantly. The delay in this case had occurred at an early stage, i.e., prior to the submission of the import licence application. The Board finds that the process of interdepartmental consultations within the company and the finalisation of the recommendation of the type of equipment to be purchased was pursued in a routine and rather slow manner, without any sense of urgency. Some of this delay could be attributed to the fact that the company was thinking of purchasing a new type of extractor to replace the existing ones, and this required a careful examination of the relative advantages, but it is difficult to avoid the conclusion that the matter was not pursued vigorously enough particularly by the then Superintendent Production and Works Manager. The Board has been informed that the then Superintendent Production and Works Manager are no longer in the service of the Company.

Recommendation No. 2 (Para 2.15)

The Committee, however, find that higher output per batch was achieved from 1967-68 onwards and this made up for lesser volume of batches. If it be so, the Committee see no reasons why such

higher output could not be sustained. As in the absence of any norms with regard to the number of batches harvested to the batches seeded, the efficiency of harvesting operations is not susceptible of evaluation, the Committee recommended that the Management should not lose any further time in fixing the norms after a study of such standards obtaining both in India and abroad so that they can evaluate the efficiency of harvesting operations from time to time and take suitable remedial measures to prevent the efficiency going below the norms.

Reply of Government

Norms for evaluating efficiency of harvested batches will be fixed based on the standards obtained through Japanese collaboration for Penicillin. Remedial measures to prevent the efficiency going below the norms include: (i) installation of new system for sterile air; (ii) to bring down contemination; (iii) rigid control on raw material specifications: (iv) mechanising additions of fluids to fermentors; (v) better control on parameters by improving the working of instruments; (vi) training of the personnel; and (vii) better emphasis on preventive maintenance.

Therefore the recommendation that no time be lost in fixing the norms is being carried out. The loss of time in fixing the norms as per Japanese technology would be minimised by adopting the norms as would emerge during the adoptation of the Japanese strain, to conditions obtaining in HAL.

[M/C&F O.M. No. 51012/2/75-DC 30-9-76]

Recommendation No. 3 (Para 2.16)

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

Reply of Government

The norms are already fixed for draining of batches. For both Penicillin G and V, they have been fixed at 3 per cent maximum.

During the last three years, HAL are maintaining the drainings below the norms. Three years data is furnished below:—

Statement showing the Batches Harvested and Drained (1973-74 to June 1976)

No of Batches

PENICILLIN 'G'

Year	Seeded	Harvested	Drained	Percentage of drained to seeded
1973-74	727	706	21	2·9%
1974-75	915	891	24	2·6%
1975-76	611	599	12	1·9%
June 76	145	145	—	—

No. of Batches

PENICILLIN 'V'

Year	Seeded	Harvested	Drained	Percentage of drained to seeded
1973-74	249	241	8	3·2%
1974-75	87	86	1	1·1%
1975-76	325	321	4	1·2%
June 76	53	50	3	5·6%

However, the company would now make a further study of the past data pertaining to the last three years and based thereupon arrive at appropriate norms as suggested by the Committee. A Technical Group from within the company would apprise the data for fixing the norms, if the data reveals that the present norms are not representative of the situation.

[Min. of C & F O.M. No. 51012(2)/75-DC, Dt. 30-9-1976]

Further information called for by the Committee

Has the Technical Group apprised the data? If so, what are their findings?

Further reply of Government

Internal Technical Committee has been constituted by the company for examining the data. The report of the Committee is awaited.

(Min. of C & F, O.M. No. 51012/2/75-DC 24-2-77)

Further information called for by the Committee

Has the Internal Technical Committee completed its examination? If so, what are its findings and whether appropriate norms have been fixed in the light of those findings.

[L.S.S. letter No. 21-PU/76 of 8-12-1977]

Further Reply of Government*

The norms for draining batches in terms of per cent batches drained against the total number of batches seeded was 7 per cent for Streptomycin and 3 per cent for Penicillin. However, due to the tightening of the operational procedure and improved fermentation technology that was established alongside the new strain technology, this percentage of detained batches specially in Streptomycin plant was brought down to below 3 per cent as an average during the year 1973-74 todate. Based on this, the Internal Standards Committee of this Organisation in its February 1977 meeting recommended that the new norms for draining be fixed as follows:

2.5 per cent for Streptomycin

3 per cent for Penicillin

It was also stated that with the introduction of new Penicillin strain and technology alongwith improved sterile air filtration system (the implementation of the Carbon air filtration system as recommended by the Japanese collaborators), it was expected to bring down the drainage percentage even in Penicillin to well below 3 per cent. Today the Carbon air filtration system has not been introduced in the main plant, even though the system in the Pilot Plant has been established.

At present, the Production Dept. alongwith the Costing Dept. is examining the variable cost input for both Penicillin and Streptomycin in arriving at the fermentation titre levels that would be consiedred minimum required, before the batch can be harvested in order to (a) break even with final yield versus variable cost inputs, and (b) maintaining the final product quality keeping in view the good Manufacturing Practices involved. At present, this exercise for fixing the new norms in terms of cost is going on, in view of the new technology, being introduced in both these plants, which has

*Further reply not sent to Audit for vetting.

greatly changed our inputs. Obviously, only after the stabilisation of the new technology, a realistic picture in terms of actual variable cost inputs could be arrived at. The Internal Standards Committee would then fix revised norms for both these fermentations.

Percentage of Drainage of batches for the period April 1977—November 1977 was as under:—

	Batches Seeded	Batches Harvested	Drained	Percentage of drained to seeded.
1. Pen. G	345	337	8	2·32%
2. Pen. V	71	6	2	2·82%

[Min. of C & F, /O.M. No. 51012/2/75- DC, 9.1.78]

Recommendation No. 4 (Para 2.25 and 2.26)

The Committee regret to observe that in spite of the knowledge about the potency of the strain going down no serious attempts appear to have been made from 1962 to 1971 to improve the potency of strain for obtaining better titre yield. They learn that the Company is now negotiating with a Japanese party for a strain which has a yield of 30,000 units/ml. In view of the fact that company has all through this period been importing Penicillin (total foreign exchange outgo on this score being Rs. 1.92 crores from 1966-67 to 1971-72 as mentioned in this report, in the opinion of the Committee, it would have been better and in the national interest if a new strain which is now sought to be imported had been imported much earlier and titre yield and consequently production of Penicillin improved and import of penicillin reduced to that extent. The Committee stress that the Government Undertaking should finalise without further delay the negotiation for import of the best suited and most efficient new Penicillin strain and take suitable measures to maximise the titre yield and the production of penicillin.

Reply of Government

Attempts were continuously made to improve the potency of the strain through R & D efforts of the Company but as this did not yield commendable results, MD, HAL during his tour abroad to look for the best strain and technology was able to locate a suitable party in Japan. Negotiations were accordingly conducted and after approval of Government HAL signed the agreements with M/s. Toyo Jozo of Japan for knowhow and improved strains on the 23rd January, 1976. The improved strains were received thereafter and the Japanese technicians led by their Managing Director arrived at the plant site and commenced working. Promising results are being

achieved and it is expected that with the introduction of the improved strains, and unstallation of additional facilities, the cost of production will be reduced appreciaibly.

[Min. of C & F O.M. No. 51012/2/75-DC, 30-9-76]

Further information called for by the Committee

Please indicate the results of introduction of new strain from Japan in terms of improvement in production and reduction in cost of production.

[L.S.S. letter No. 21-PU/76 of 8-12-1977.]

Further Reply of Government*

The first stage of the Collaboration Agreement for getting a minimum of 50 per cent increase in activity in the main plant with minor modifications was fully achieved even by December 1976. In fact, the actual titres and productivity achieved was much higher than the minimum guaranteed, which could be seen from the following table.

Average titre yield (Units per ml)

	Pen. G	Pen. V.
With Old Strain	9523	5500
With New Strain Min. guaranteed .	14284	14284
April "77 .	15884	19333
May '77	16915	20990
June '77	17334	20283
July '77	17925	18566
Aug. '77	17416	18466
Sept. '77	17485	21033
Oct. '77	16837	16285
Nov. '77	16950	16288
Dec. '77 (expected)	17500	Not in programme.

With regard to the second stage *i.e.* minimum yield of 30,000/U/ml. the implementation programme was to establish it first in the Pilot Plant. This was due to the need to make equipment changes to meet the requirements of new strain and technology, and also for establishing the raw material quality requirements. Penicillin V fermentation

*Further reply not sent to Audit for vetting

which was first taken up in the Pilot Plant, yielded minimum guarantee figures even by October-November of 1976. The Penicillin G establishment which took a little longer, has now been fully established in the Pilot plant and the results obtained are given below:

Pencillin G titres achie[illegible] in HAL Pilot Plant.

Batch No.	Date of Starting	Date of Completion	Age-hrs.	u/ml
77	20-10-77	28-10-77	162·5	30,650
78	20-10-77	28-10-77	178·5	28,050
79	30-10-77	7-11-77	186·0	35,550
80	30-10-77	7-11-77	169·0	33,750
81	9-11 -77	18-11-77	216·5	37,650
82	9-11-77	18-11-77	216·5	41,000
83	19-11 -77	28-11-77	207·5	38,500
84	19-11-77	28-11-77	219·5	33,550

It could be seen that the minimum guaranteed productivity of 30,000 u/ml. of Pen. G or V under 216 hrs. fermentation cycle, has been clearly achieved in our Pilot Plant. Based on the Pilot plant technology, one fermentor in the main plant *viz.* F-15 has been modified, and the table below shows that the minimum guaranteed performance of 30,000 u/ml. under 216 hrs. cycle has been achieved with this system.

Batch No.	Date of completion	Age—hrs.	Titre-u/ml.
9077 . . .	31-10-77	191·5	30,800
9095	12-11-77	192·0	29,250
9110	21-11-77	198·5	31,450
9140	10-12-77	178·0	34,700
9156	20-12-77	198·0	30,800

At present other fermentors are being modified in stages according to the proto-type of F-15. This programme of modification which is likely to be completed during 1978-79, is expected to result in the full rated capacity to be achieved with the new technology.

The benefit of cost reduction would be fully and consistently realised after the total implementation of the second stage of our agreement.

[Min. C & F O.M. No. 51012/2/75-DC of 9-1-78]

Recommendation No. 5 (Para 2.27)

The Committee would also like the Research and Development wing of HAL to keep itself abreast of the developments elsewhere so as to take advantage of any improvements in the technology from time to time.

Reply of Government

The scientists and technologists of HAL in general, and R & D wing in particular, have the following facilities for keeping themselves abreast of the improvements in technology:

1. The organisation has built up a good library, documentation, and information retrieval, patents survey and literature review systems. The library gets more than 350 journals from all over the world in addition to obtaining annual reviews, text books etc., Every encouragement is given to scientists and tecnologists to familiarise themselves with the developments in the field of drugs development and fermentation technology.

2. The scientists and technologists are also deputed to attend national and international conferences, symposia and workshops at which time they have ample opportunities to acquaint themselves with scientific and comtemporary research and development work.

3. Many of the senior scientists of the R. & D. wing are members of National Committee and Research Institutes, and are encouraged to attend meetngs of these Committees. It has been the experience that this is extremely helpful in keeping in touch with the developments in the allied fields that are taking place in our country.

4. Whenever HAL enters into collaborative agreements for know-how and technology transfer with any suitable organisation inside and outside the country, the agreement provides for training of HAL scientists and technologists in the laboratories and plants of the collaborator, as also for inviting scientists and technologists from the respective collaborator to visit HAL plant and give training to HAL staff.

5. Senior scientists of the R & D are given permission to spend period up to two years as visiting scientists in leading laboratories in any part of the world to conduct advanced studies/research in areas of interest to this organisation.

The grant of such special study leave is at times accompanied by providing assistance to the individual scientists from Poona to the place of visit and back.

6. Leading scientists and technologists from other laboratories in India and abroad frequently visit HAL R & D wing and at that time hold seminars and lectures to the scientific and technical staff.

From the above, it will be clearly seen that every opportunity is being provided for the HAL scientists and technologists to keep themselves informed of the latest developments in the field of drug technology.

[Min. of C & F O.M. No. 51012/2/75-DC of 30-9-76]

Recommendation No. 7 (Para 2.32)

The Committee note that the undertaking fixed a standard efficiency of 70 per cent for extraction of first crystals from the fermented broth. The Committee are not sure about the basis on which the percentage of efficiency has been fixed at 70 per cent. The Committee feel that with the introduction of new strain in 1971 the Undertaking should review the performance and fix suitable standards with a view to assessing the performance with reference to such standards. The Committee also note that the Company had been progressively revising the standards of yield of first crystal perharvested batch from 1961—72, the last revision having been made in 1972-73. The actual average yield was however, less than these standards in the case of Penicillin G during 1966-67, 1969-70, 1970-71, 1971-72, 1973-74, and 1974-75 and in case of Penicillin V during 1966-67, 1969-70, 1970-71, 1971-72, 1973-74 and 1974-75. The Committee feel that normally the yield should not be lower than standard yield and recommend that the Undertaking should identify the fatcors depressing the yield so as to take suitable concerted measures for improving the performance. The Committee also recommend that for a realistic assessment of the yield of first crystals, the undertaking should review the percentage of the standard for extraction efficiency and the yield and fix realistic standards for assessing the performance.

Reply of Government

The company has been revising the standards of yield whenever a new strain is developed through R & D and introduced and/or if efficiencies during the period have gone up. The standards are now revised and raised to 1,00,000 mu per fermentor batch (23 kl capacity) as against 85,000 mu fixed earlier, Measures taken include: (i) cooling the broth after filtration; (ii) proper control on Extraction

parameter; (iii) rigid schedule on clearing and decontaminating equipments; (iv) rigid control on temperature at various stages; (v) replacement of obsolete extractors by more efficient extractors; (vi) controlling the fermentation conditions for obtaining higher fermentation efficiency.

The undertaking will no doubt, review the standards after the production has been stabilized with the new Japanese strain.

[Min. of C & F O.M. No. 51012/2/75-DC of 30-9-76.]

Further information called for by the Committee

Has the production with the new Japanese strain been stabilised? If so, has a review of standards been undertaken.

[L.S.S. letter No. 21-PU/76 dt. 8-12-1977.]

Further Reply of Government*

The production of Penicillin V and G in accordance with the new Japanese technology has been stabilised in the main plant with reference to the first stage of the guarantee *viz.* achieving a minimum of 50 per cent increase in productivity over the earlier strain and technology. The standards with reference to raw materials (their quality and consumption rates), standard operating procedures for maintaining operational parameters, the Process Control and Analytical Techniques, the cycle of fermentation, the method of maintaining the spore culture for production purposes, and standards for laboratory testing of raw materials to be purchased for meeting the requirements of the first stage guarantee of the collaboration have been established. The table given below would show that the main plant performance has been consistently obtained.

Average Titre Yield (units per ml.)

	Pen. G	Pen. V.
1	2	3
With Old Strain	9523	5500
With New Strain min. guaranteed	14284	14284
April '77	15884	19333
May '77	16915	20990
June '77	17334	20283
July '77	17925	18566

*Further reply not sent to Audit for vetting

1	2	3
August '77	17416	18466
Sept 77"	17488	21033
Oct. '77	16837	16285
Nov. '77	16950	16288
Dec. '77 (expected)	17500	Not in programme.

As stated under reply to recommendation No. 4, HAL is at present implementing introduction of the second stage guarantee viz. achieving minimum of 30,000 u/ml. in the main plant. The parameters mentioned above for the second stage are at present being standardised, and would be placed before the Board.

[Min. of C & F O.M. No. 51012/2/75-DC of 9-1-78]

Recommendation No. 8 (Para 2.48)

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

Reply of Government

Government have taken note of this observation made by the Committee, and in fact the company has already been advised that the target of production once fixed before the commencement of the year, during the framing of budget, should not be altered unilateraly by the company and that analysis of production should be made only with reference to the budgetted production fixed before the commencement of the year. A copy of this Ministry's Letter No. L-55013 (3)/76-DC of dated 24-3-1976 is attached. [*See* Appendix I.]

[M/C&F O.M. No. 51012/2/75-DC 30-9-76.]

Recommendation No. 9 (Para 2.49)

The Committee regret to note that the efficiencies actually achieved in the conversion of first crystals into bulk Penicillin (with the addition of potassium, Sodium and Procaine salts) were generally less than the standards efficiencies of 90 per cent, 70 per cent, 80 per cent and 75 per cent fixed by the Management during the period 1966-67 and 1973-74 except in the case of Penicillin V where the percentage of efficiency was more than the standard in 1968-69, 1969-70 and 1972-73, 1973-74 and 1974-75 and Sodium during 174-75 Potassium during 1972-73 and 1973-74. The Committee are informed that less of production in this regard was due to lack of enforcement of protocol laid down for optimum efficiency of production e.g. non-observance of operating para metres like maintenance of optimum temparatures and air pressure in the fermentres caused by lack of facilities like temparature controls, monitoring agents, leakage of steem, non-availability of crucial raw materials, obsolescence of equipment and negligence on the part of employees. The Committee see no reason why the protocols laid down for optimum efficiency of production could not be enforced. The Committee feel that had there been a proper and effective system of control over the different stages of production, it should not have been difficult for the management to have identified the causes of low efficiency and taken concerted measures to realise the protocol standards.

Reply of Government

Government have taken note of the recommendations made, and appropriate instructions are being issued.

(M/C&F O.M. No. 51012|2|75-DC 30-9-76.)

Further information called for by the Committee

Please furnish a copy of the instructions issued in this behalf.

(LSS OM No. 21-PU/76 of 17-1-77).

Further Reply of Government

A copy of this Ministry's letter No. L-51012(2)/75-DC dated 12th October, 1976 addressed to MD—HAL is attached.(*See* Appendix II.)

(M/C&F OM No. 51012|2|75-DC of 24-2-77.)

Recommendation No. 10 (Para 2.50)

The Committee are informed that the matter was gone into in depth and action had been taken to remove the Head of the engineering division and the Head of production and also for replacement of

equipments. The Committee recommend that the management should draw lessons at least now and introduce without any further delay an effective system of management control over the different stages of production so that deficiencies at each stage are identified promptly and suitable remedial measures taken without loss of time and production.

Reply of Government

Effective system of Management Control has been introduced. This includes creation of a new cell for monitoring production and services round the clock; and highlighting shortfalls and deficiencies. These are reviewed daily by Senior Technical Officers and prompt measures are taken to sort out the problems and avoid loss of production. Other measures include systematic plant preventive maintenance, inventory management and establishment of technical cell for debottlenecking and up-gradation of efficiencies, R&D is closely associated for resolving problems and up-grading efficiencies. A constant review is always taken at the highest level.

(M/C&F O.M. No. 51012|2|75-DC 30-9-76.)

Recommendation No. 11 (Para 2.51)

I regard to the replacement of equipment, the Committee are informed that an expenditure of Rs. 20 lakhs has already been incurred and it is proposed to have further replacements for the next three years by spending Rs. 27 lakhs. The Committee are also informed that piecemeal replacement of equipment of improved design, would not provide a substitute for a completely new plant of modern design which would cost Rs. 3 crores and it is not proposed to discard the existing plant and replace. it by a new plant of upto date design. The Committee would like the comparative economics of replacement of equipment in piecemeal *vis-a-vis* wholesale substitutition to be most carefully gone into with particular reference to the new strain proposed to be imported. The Committee would like to be informed of the result of such a study.

Reply of Government

As stated in reply to recommendation No. 4, the company has entered into a technical collaboration agreement with a Japanese firm for the improved strains and technology in the manufacture of Penicillin. The question of equipments *vis-a-vis* the need to replace the existing ones by a new plant of modern design will have to be meshed into the requirements of new technology. Care is being taken to keep the investment as well as the loss of production during

transition period to the minimum. The comparative economics of replacement of equipment in piecemeal vis-a-vis wholesale substitution will be carefully gone into with reference to the new strain and technology being introduced.

(M/C&F O.M. No. 51012|2|75-DC 30-9-76.)

Further information called for by the Committee

Has the comparative economics of replacement of equipment in piecemeal *vis-a-vis* wholesale substitution been gone into with reference to the new strain and technology introduced in collaboration with a Japanese firm? If so please give details thereof indicating therein the cost of equipment replaced/to be replaced.

[L.S.S. letter No. 21-PU/76 of 8-12-77]

Further Reply of Government*

Due to the need for improving production efficiency and lowering cost of production, HAL decided to introduce the new strain and technology into its main plant on a crash basis involving the implementation in two stages. During Stage 1, the strain was introduced into the main plant on a minimum alteration basis, which could be achieved within a very short period of time, and which involved minor changes in the aeration and agitating systems. When this modification was completed in our existing Penicillin plant, the Japanese strain and technology gave a 50 to 100 per cent increase in productivity which gave the full benefit of an immediate reduction in cost of production. For the second stage of technology implementation for achieving the guaranteed 30,000 u|ml. under 216 hrs. of fermentation, it was decided to introduce the plant modifications in stages so that the Penicillin output of HAL was not affected during the course of the change-over. This naturally required that one fermentor at a time was modified and taken into commission subsequently. The performance of the first so modified fermentor *viz.* F-15 has been highly satisfactory in that, it has consistently given the minimum guaranteed yield, as seen from the table below:

Batch No.	Date of completion	Age—hrs.	Titre—u/ml.
9077	31-10-77	191·5	30,800
9095	12-11-77	192·0	29,350
9110	21-11-77	198·5	31,450
9140	10-12-77	178·0	34,700
9156	20-12-77	198·0	30,800

*Further reply not sent to Audit for vetting.

This type of exercise necessarily involves replacement of equipment in a piecemeal manner, and as the technology was established in the Pilot plant, changes were also made in the main plant to suit requirements. Undoubtedly, if the entire plant was modified on a one-time basis, it would have been possible to complete the modification in a shorter period than when done piecemeal. This would have, however, resulted in a total stoppage of Penicillin production by HAL, which would have resulted in this life-saving drug becoming in short supply in the country.

Our existing Penicillin plant started in the year 1954. And has been expanded to the present capacity following an old and technology. The replacement of equipment etc. piecemeal to suit the 30,000 u/ml. technology, while has resulted in achieving the minimum guaranteed yields, has not been conducive to achieving the maximum strain capability and performance that is possible with a more modern plant with better Process control. Already HAL's Pilot Plant has developed the new strain and technology with yields upto 40,000 u/ml. under 200 hrs. of fermentation cycle. The fine Process controls required for consistently achieving such results would not be possible in our existing plant even after the piecemeal or wholesale replacement of equipment. For this purpose, HAL has now submitted a new plant proposal to the Government of India, in which yields ranging from 40,000 to 50,000 u/ml. could be achieved for a total annual production of 500 mmu. of first crystals of Penicillin at an estimated cost of Rs. 900 lacs. If approved, it is expected that this plant would be completed by 31st March, 1981.

(M/C&F O.M. No. 51012|2|75-DC 30-9-76.)

Recommendation No. 12 (Para 2.60)

In the opinion of the Committee targets fixed for production of Penicillin G by the Undertaking represent what can actually be achieved. If so, the Committee see no reason why it should not have been possible to achieve such targets by concerted efforts instead of revising them downwards because of constraints or inefficiency in production.

Reply of Government

Please see reply to Recommendation No. 8.

Suitable instruction have been issued to HAL for maintaining targets once fixed before the year and not to revise them unilaterally.

(M/C&F O.M. No. 51012|2|75-DC 30-9-76.)

Recommendation No. 13 (Para 2.61)

The Committee are informed that shortage of essential raw materials like butyl acetate, phosphoric acid, sulphuric acid and phenyl acetic acid was one of the reasons for shortfall in production of Penicillin during 1973-74 and 1974-75. It has been stated that as a result of the shortage of cash, the suppliers' bills remained outstanding for long due to which requirements of the undertaking received lower priority. The Committee are shocked at this state of affairs in the working of a Public Undertaking where credit worthiness of the Undertaking has become so low as to have affected even the purchase of essential raw materials and production of an essential drug like Penicillin was allowed to suffer on this account. The Committee recommend that this matter should be enquired into and responsibility fixed. The Committee feel that these are matters which should have been gone into by Board of Directors particularly the Managing Director and the Government representative on the Board.

Reply of Government

It may be mentioned at the outset that in the capital and revenue Budget Estimates of HAL submitted by the Managing Director of HAL on 23rd November, 1973 Revised Estimates of the Company for 1973-74 showed a net loss of Rs. 67.16 lakhs while marginal profit of Rs. 5 lakhs was expected during 1974-75. For 1973-74 also the company did not ask for any budgetary support towards working capital for that year stating that Government have been approached for an increase in the selling price of bulk Streptomycin on the basis of the prevailing cost of production based on the then wage and price levels. It was also mentioned that if this was allowed, the company would be able to retrieve its profitability. On this basis for the year in the Revised Estimates for 1973-74 or Budget Estimates for 1974-75 no provision in the Budget was made towards working capital loans.

It was only on 15th December, 1973 that MD, HAL brought to our notice the prevailing difficulties in regard to working capital requirements of the country. The company were obtaining their working capital requirements from the State Bank of India and the Bank had sanctioned an over-draft of Rs. 1 crore. They were also then considering sanction of a further cash credit of Rs. 1 crore against which Rs. 50 lakhs were permitted to be drawn temporarily as over-draft pending formal approval of the Board of SBI. Also that on the basis of their stocks and debtors, they would normally have been eligible for a further credit of approximately Rs. 25 crores over and above Rs. 2 crores referred to above. This also

would have been processed in due course. However, MD, HAL was informed by the SBI on 12-12-1973 that due to restrictions imposed by the RBI on grant of credit they would freeze the cash credit allowed to them at the level of their actual drawings at the end of October, 1973 plus 5 per cent margin. Their actual drawings at the end of October, 1973 against the cash credit allowed by SBI were Rs. 84.81 lakhs. Thus, against a cash credit of Rs. 2 crores out of which Rs. 150 lakhs has already been allowed by the SBI and a further credit of Rs. 50 lakhs being processed, the cash credit of HAL would in future be limited to Rs. 89.05 lakhs only. Since their actual drawings on that date amounted to Rs. 119 lakhs, *i.e.*, an amount of approximate Rs. 32 lakhs has been drawn in excess from the SBI. HAL may also be called upon to release Rs. 114 lakhs being the working capital requirements for the months of December to April 1974 in addition to Rs. 32 lakhs to be refunded to SBI.

Accordingly, the matter was taken up with the Ministry of Finance who however, had stated that this is a difficulty common with all other public undertakings in view of the general policy of Government of imposition of credit squeeze and was of the view that the matter should be taken up with the Banks at a suitable level. Accordingly the Secretary, Department of Banking and State Bank of India were addressed, on 4th February, 1974. This was again followed by another reminder on the 19th February, 1974. Government also noted the huge debtor's position of the company and was of the view that the amount owing to the company by customers for supplies made are substantial and are besides expected to be steadily on the increase. Hence it was felt that the company should take energetic steps to release the outstandings as quickly as possible. Immediately, the company was asked to supply a detailed list of outstanding dues and the matter was taken up by Government with all the concerned authorities, State Governments, public undertakings, on 19th March, 1974. In the meantime the Department of Banking also informed *vide* their letter dated 20th March, 1974 that the State Bank of India to whom the matter was referred by that department had reported that they had earlier requested HAL to restrict drawings on their account to Rs. 85 lakhs because of the credit restrictions as against the outstanding of Rs. 119 lakhs at the end of December, 1973. The Bank had also indicated that in view of the urgent requirements of the Company they have since relaxed the restrictions on the account and permitted HAL to draw to the full extent of the sanctioned limit of Rs. 150 lakhs. Department of Banking also informed us that SBI had informed them that HAL had confirmed to the SBI that this relaxations would meet their requirements fully.

MD, HAL in his letter of 15th May, 1974 confirmed this position and stated that the State Bank of India had not relaxed the cash credit squeeze beyond Rs. 150 lakhs agreed to by them and that in view of the increase in the cost of materials and labour, the cash position of the company had become very critical with the balance of only Rs. 20 lakhs. This matter was examined after obtaining fuller details and was taken up with the SBI on the 4th June, 1974 requesting them to allow cash credit facilities for a further sum of Rs. 100 lakhs. The SBI informed the Ministry in their letter of 18th June, 1974 that though they would appreciate the difficulties of the HAL, their resources position would not permit release of further funds to the company but they pointed out that HAL have been able to negotiate credit facilities from the Bank of Maharashtra and SBI have therefore allowed them to proceed with the necessary arrangements. They also added that the Bank of Maharashtra would be in a position to meet HAL's additional requirements.

MD, HAL also in his letter of 15th July, 1974 informed Government that the Bank of Maharashtra, even though they agreed to the grant of Rs. 50 lakhs, they made available only Rs. 10 lakhs and that the release of further amount may not be possible in view of the credit squeeze. The matter was taken up with the Secretary, Department of Banking on 1-8-1974 who informed in his letter of 17th August, 1974 that the position stated was not entirely correct. He stated that the Bank of Maharashtra had released first instalment of Rs. 10 lakhs even without completion of the formalities regarding documentation. There was, however, some delay in release of further funds because SBI had raised certain points in allowing the creation of *pari passu* charge in favour of Bank of Maharashtra on the securities of HAL. However, the MD, HAL drew the attention of the C & MD of the Bank of Maharashtra to this delay and the Bank immediately agreed to the release of the balance of Rs. 40 lakhs to HAL.

These steps also did not improve the cash position of the company and the abnormal increase in the cost of the inputs and the fact that the selling price of the antibiotics had not been increased by Government due to the cost examination by BICP, the MD, HAL again requested Government to make available cash credit facilities. This was examined further in consultation with the Ministry of Finance and a sum of Rs. 200 lakhs was provided by means of a supplementary grant in October, 1974. The Government released Rs. 100 lakhs on 29-10-1974, Rs. 25 lakhs on 23-12-1974, Rs. 25 lakhs on 13-1-1975 and Rs. 50 lakhs on 27-2-1975.

It will be seen from the above that the company and Government had taken all steps that were necessary to provide financial assistance to the company to meet the working capital requirements on account of increase in outputs etc., but it was due to the policy of the Government to impose the credit squeeze that there was a set-back on the availability of the working capital of the company.

Nearly, 98 per cent of the formulations manufactured by the company are sold to Government hospitals and institutions who pay, in most cases in about 90 days and there are cases where this period exceeded one year. While this is the position about the debtors, in the case of suppliers, most of the bills have to be paid within 7 to 30 days of the receipt of raw materials. In the case of furnace oil, which amounts to about 30 per cent of the total raw material purchases, the Company has to pay in Advance. This situation has put a very severe strain on the Company's financial resources. The situation has been crefully reviewed by the Board of Directors of HAL who decided to discontinue the production of one of the major lines of production *viz.*: Streptomycin Sulphate as is was incurring heavy losses due to un-economic price fixed by the Government. However, the Government desired that the production should be continued in the larger national interest. The working capital requirements were partly met from the loan obtained from the Government.

With the various measures taken by the Company, including introduction of a high yielding strain and technology in the case of streptomycin and subsequently in the case of Penicillin, the position regarding the working capital has eased to some extent. The Company has also taken measures to expedite collection from various Government Hospitals and Institutions.

As a result of this the operations of the company are expected to become viable during 1976-77 and the credit worthiness of the company is expected to improve correspondingly.

The Government Director kept the Ministry informed as regards the functioning of the company as also its short-comings inadequacies and problems. This was done after every meeting of the Board of Directors that he attended and reported the position thereafter.

[M/C&F OM No. 51012/2/75—DC of 30-9-76]

Recommendation No. 15 (Paras 2.63 & 2.64)

The Committee are surprised to note that it was only in May, 1971, *i.e.* 16 years after the commissioning of the Plant that the

Management took serious note of shortfall due to break-down of machinery and introduced a scheme of maintenance of the plant and machinery. The Committee cannot but view it as an instance of gross negligence on the part of Management that they operated the plant for 16 years without any regular system of preventive maintenance. The Committee also find that frequent break-down of production equipments were reported to be due to considerable shortcoming in the working of engineering department which do not appear to have been investigated. The Committee recommend that the entire matter regarding lack of preventive maintenance for such a long time should be investigated immediately with a view to fix responsibility for the lapse.

The Committee also regret to note that even after introduction of the system of preventive maintenance in 1971 the preventive maintenance schedule has not been implemented fully during the period 1971 to 1975. The Committee are not convinced by the reasons advanced for non-implementation of the maintenance schedules which, as the undertaking has confessed affected production. The Committee cannot but deprecate the negligence shown by the Management first in not introducing any regular preventive maintenance schedules for 16 years and thereafter not implementing the schedules regularly. They recommend that the reasons for non-implementation of the maintenance schedules since 1971 should also be investigated with a view to fix responsibility and adequate measures taken to ensure that at least in future the schedules for maintenance of the plant and equipment are adhered to. The Committee also recommend that Government/Board of Directors would ensure that preventive maintenance protocols are inbuilt into the system right from the inception and such protocols are actually adhered to.

Recommendation No. 21 (Para 2.110)

The Committee are also informed that prior to 1971, there had been no system of planned preventive maintenance for the plant and equipment with the result that there were frequent breakdowns which affected the availability of services. The planned preventive maintenance is reported to have been introduced since 1971. The Committee deprecate the neglect of so vital a plant for over 9 years and strongly reitrate, as already recommended in this chapter, that a thorough investigation into this matter may be held expeditiously and responsibility fixed for not introducing a schedule of preventive maintenance right from the beginning. They would further recommend that the Corporation should take all possible measures

to ensure that at least now the preventive maintenance schedule is strictly followed for all plant and machinery so that they can be kept in good running condition.

Reply of Government

Recognising the imperative necessity to reduce incidence of plant break-downs, a system of planned preventive Maintenance was introduced for the whole plant during 1971. Nearly 25 Senior supervisory personnel of maintenance and Production departments were trained in Preventive Maintenance as a result of which implementation of the developed system became immediate. Status of implementation of these schedules is being monitored by weekly review and as a result, implementation of schedules has improved progressively during the last 4 years.

	MECH			ELEC			INSTS		
	No. of Equipments			No. of Equipments			No. of Equipments		
	SCHD	ATTD	IMPL%	SCHD	ATTD	IMPL%	SCHD	ATTD	IMPL%
1972	52	41	79	38	28	74	31	12	39
1973	87	70	80	70	61	87	48	25	52
1974	88	68	77	91	84	92	48	33	69
1975	103	85	83	103	98	95	72	53	74

As a result of progressive improvement in the implementation of preventive maintenance schedules, incidence of plant break-down and its adverse impact on production has been brought down significantly.

It may also be mentioned that a Sub-Committee of the Board of Directors of the Company had already investigated the matter and on the basis of this the company had removed the then Chief Engineer from service during October, 1974.

The progress on plant maintenance schedule is reported to the Board at each of its meetings. The recommendation of the Committee that preventive maintenance protocols are inbuilt into the system right from the inception and such protocols are adhered to has been noted for necessary action by the Company in respect of any future programme going to be taken up by them.

[M/C&F OM No. 51012/2/75-DC of 30-9-1976]

Recommendation No. 16 (Paras 2.103 and 2.104)

The percentage of drained batches to seeded batches has widely varied from 6.3 per cent in 1970-71 to 1.3 per cent in 1974-75. The Committee regret to note that no norms have so far been laid down by the Management with regard to the harvesting of seeded batches with the result that the efficiency of harvesting operations could not be properly evaluated. The Committee recommend that the undertaking should, after keeping in view the equipment, the technology, operating conditions etc. and after a study of the norms obtaining with the collaborator for such operations, fix appropriate norms for harvesting so as to evaluate the efficiency of harvesting operations from time to time and take suitable remedial measures to keep the drainage within limits.

Reply of Government

The norm fixed for draining in respect of Streptomycin was 7.1 per cent. The percentage of trained batches to seed batches in 1975-76 was 2.1 per cent and is well within the norm. Based on the recent experience, the Company is examining the question of revising the norm downwards, keeping in view the equipment, technology operating conditions, etc. as suggested by the Committee.

[Min. of C and F O.M. No. 51012/2/75 Dc. 30-9-76]

Further information called for by the Committee

Has the revised norms been fixed to keep the drainage within limits?

[L.S.S. letter No. 21-PU/76 of 8-12-77]

Further Reply of Government*

The norms for draining batches in terms of percent batches drained against the total number of batches seeded was 7 per cent for Streptomycin and 3 per cent for Penicillin. However, due to the tightening up of the operational procedures and improved formentation technology that was established alongside the new strain technology, this percentage of drained batches specially in Streptomycin plant was brought down to below 3 per cent as an average during the years 1973-74 todate. Based on this, the Internal Standards Committee of this organisation in its February 1977 meeting recommended that the new norms for draining be fixed as follows:

2.5 per cent for Streptomycin

3 per cent for Penicillin

* It was also stated that with the introduction of new Penicillin strain and technology along with improved sterile air filtration sys-

*Further reply not sent to Audit for vetting.

terms (the implementation of the Carbon air filtration system as recommended by the Japanese collaborators), it was expected to bring down the drainage percentage even in Penicillin to well below 3 per cent. Today the Carbon air filtration system has not been introduced in the main plant, even though the system in the Pilot plant has been established.

At present, the Production deptt. along with the Costing deptt. is examining the variable cost input for both. Penicillin and Streptomycin, in arriving at the fermentation titre levels that would be considered minimum required, before the batch can be harvested in order to, (a) break even with final yield versus variable cost inputs, and (b) maintaining the final product quality keeping in view the good manufacturing practices involved. At present this exercise of fixing the new norms in terms of cost is going on in view of the new technologies being introduced in both these plants, which has greatly changed our inputs. Obviously, only after the stabilisation of the new technology, a realistic picture in terms of actual variable cost inputs could be arrived at. The Internal Standards Committee would then fix revised norms for both these fermentations.

(Min. of C & F O.M. 51012|2|75-DC 9-1-78)

Recommendation No. 19 (Paras 2.107 and 2.108)

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

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

Reply of Government

The improved strain and the associated technology for any antibiotic manufacture can be obtained only from such parties who would agreed to offer the technology as is available with them.

The measures taken to get the maximum yield from the new strain include:—

1. Introduction of three stage fermentation in place of two stage fermentation;
2. Addition of Mannosidase Enzyme to reduce the Streptomycin 'B' content in the broth.

As a result of the above measures, the titre yield has gone up from 14,450 u/ml. in 1974-75 to 15,786 u/ml. in 1975-76 and the average efficiency of recovery has gone up from 77.6 per cent to 78.2 per cent.

Measures under implementation include:

1. Installation of 200 H. P. motor and agitator in place of existing 125 H. P. motor and agitator.
2. Installation of equipments for controller eddition of carbohydrates and Nitrogen sources.

These measures are expected to improve the output and reduce the cost of production. After implementation of these measures and based on the above performance the Standard of titre yield has been revised to 16,000 u/ml.

[Min. of C&F O.M. 51012(2)/75-DC dt. 30-9-1976]

Recommendation No. 20 (Para 2.109)

The Committee are informed that because of stoppage of import of soyabean meal used for production of streptomycin, there was shortage in supply till the quality of soyabean meal fit for use in antibiotics industry was established in the country. The Committee feel that the undertaking should have taken timely action to identify suitable indigenous quality and built up sufficient stock when it was known that import of soyabean was to be stopped, although the problem is however now reported to have been solved. Similarly, the problem of dextrose, which also effected production is stated to have been solved with the replacement of dextrose by starch which is easily available. The Committee recommend that now, when HAL has located sources of good quality raw materials within the country, it should make long term arrangements for their timely supply and storage of raw materials may not affect the production of this vital drug hereafter. The Committee would also like HAL to review the production performance of streptomycin with reference to new strain and revised the standard efficiency and capacity so that evaluation of production could be done in a meaningful way.

Reply of Government

The Company is taking steps to make long term arrangements for timely supply and storage of good quality raw materials. It is also constantly reviewing the performance of Streptomycin operations with reference to the strain and revising the standard efficiency and capacity, so that evaluation of production can be done. In fact, the present production of Streptomycin is of the order of 7.5 tonnes per month which is the installed capacity of the plant. The company would undertake review of production performance of Streptomycin w.r.t. new strain and assess standard efficiency and capacity with a view to evaluate production in a meaningful way after this strain has been tried sufficiently for long time say 1 year. Since 1 year of commercial exploitation of Streptomycin has been completed, therefore review is now proposed to be undertaken.

[Min. of C and F O.M. No. 51012/2/75 Dc. 30-9-76.]

Further information called for by the Committee

Has the proposed review of the production performance of streptomycin with reference to new strain been undertaken and standard of efficiency and capacity revised?

[LSS. letter No. 21-PU/76 of 8-12-1977.]

Further Reply of Government*

During the year 1973-74 by using the Merck strain the average Streptomycin titre was 6560 u/ml. By introduction of Glaxo strain in 1974 the titre was improved as follows:—

Year	Units per ML
1974-75	14549 U/ml
1975-76	15786 U/ml
1976-77	13593 U/ml
Latest average in Oct./Nov. 1977	15000 U/ml.

As a result of introduction of Glaxo strain and technology, production of Streptomycin reached a level of 85.95 Tons in the year 1976-77, with 184 batches as against 83.15 tons in 310 batches with Merck Technology. Revised efficiencies and capacity are as under:—

	With Merk Strain	With Glaxo Strain
1. Annual capacity	Tons 80—90	Tons 80—90
2. C.C.C. per batch (extracted)	320 kg.	525
3. Conversion efficiency c.c.c. to Streptomycin Sulphate.	85%	85%

*Further reply not sent to Audit for vetting.

Fermentor capacity rendered surplus due to use of new strain is proposed to be utilised by suitable expensions in other areas of aperations. A project for production of additional 75 tonnes p.a. which takes this into consideration has been approved and expansion has commenced.

[Min. of C and F O.M. No. 51012/2/75 DC. 9-1-78.]

Recommendation No. 22 (Para 2.132 to 2.134)

The Committee do not see the rationale behind the decision to increase the capacity of Hamycin Plant from 15 kgs. to 50 kgs even before the pilot plant was set up and results of pilot plant study were known. While the Committeee commend the development of the drug by the R&D wing of the undertaking they feel that HAL should have set up the 15 kgs. plant as originally envisaged on a pilot basis, and after testing the product, stablising it in consultation with the ICMR/IMA and Federal Drug Administration of USA, established the demand for the product after a proper demand survey and only thereafter gone in for production on a large scale. The Committee regret to note that the undertaking went on increasing the capacity to 250 kgs. and even set up the plant with 250 kgs. capacity at a cost of Rs. 65 lakhs in November, 1968 merely on the basis of a demand from USA which was only "anticipated" but was not even got verified. The Committee fail to understand as to why the demand of the product could not have been assesssed and firmed up even in the earlier stages before going in for increase of capacity and why the approval of the Federal Drug Administration of USA which is now considered necessary for the systematic use of Hamycin could not have been obtained.

Reply of Government

The recommendation of the Committee has been noted. It may, however, be mentioned that Hamycin was a new antibiotic developed through the company's own R&D efforts, and that this antibiotic belongs to the group of polyene-group of antibiotics. Even though the company established the plant for 250 kgs. capacity based on the anticipated demand particularly in the USA, still further expansion to 1000 kgs. was suggested by Lt. Gen. B. M. Rao, Hony. Consultant to the Minister of Defence. In his letter to the Planning Commission in February, 1974 he stated that this drug had been found to be extremely useful for the treatment of all kinds of skin infections as ointment and nail and scalp infections. It was also mentioned by him that its activity is several times more than any other anti-fungal antibiotic known then. Hamycin was also said to be the most effective in oral treatment for eliminating fungal diseases of the lungs for which no cure was

available then, US Government Laboratories, it was stated, were also planning to use Hamycin on human patiens Lt. Gen. Rao also added that pulmonary condiciasis which complicates pulmonary tuberculosis cases can be effectively cured by oral hamycin thus increasing the chance of arrest of the disease. He felt that such large scale need of this valuable antibiotic would require an expansion of the plant capacity from 50 kgs. to 1000 kgs.

It will be seen from the above that on the fact of the advice received from an expert in the field, the action taken by HAL could not be considered as not correct. Further events, however, proved that a proper evaluation of technology should have been made before embarking on setting up a plant with 250 kgs. capacity. It may, be obsorved here that sometime Government may need to take some calculated risks to develop and support the indigenous technology and this is a cost which the country might have to bear for a risk of this nature. When a new product is introduced, the market needs to be explored very quickly as in the case of drugs the rate of obseloscence is very high. In this context, inaccurate estimation of demand pattern for a totally new product may in some cases be inescapable. If sufficient capacity was not built up and demand of a high order developed, the criticism about short supply would have had to be faced.

[Min. of C and F O.M. No. 51012/2/75-DC. 30-9-76.]

Recommendation No. 23 (Paras 2.135 and 2.136)

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

The Committte also recommend that the undertaking should find the best alternative use to which the plant and machinery could be put. The Committee suggest that Ministry/Undertaking should derive a lesson from this experiment and ensure that when-

ever investments are made for manufacture of experimental drugs in future, the plant and machinery are such as could be used for more than one product.

Reply of Government

The Board of Directors have appointed a sub-committtee to go into the entire question of Hamycin and their report is awaited. On receipt of the sub-committee of the Board of Directors a view by the Board of Directors would be possible regarding the need for fixing the responsibility for the lapses.

Existing equipment and machinery in Hamycin plant are being utilised continuously for (i) Recovery and extraction of Pen. V as a separate stream. (This obviated the loss of production during transition); (ii) processing of Aureofungin; (iii) Processing of Enzyme for Streptomycin plant; (iv) processing of trial batches taken up in pilot plant where adequate facilities for recovery of products are not available; (v) Recovery of Penicillin from salvages. It is also being used to cope up with the production of Penicillin in case of difficulties arising in the Main Plant.

Further information called for by the Committee

When is the sub-committte of the Board of Directors expected to given its report? What are the terms of reference.

Further reply of Government

A sub-committee of the Board was appointed to go into this (Hamycin Project) with particulars reference to the Utilities of this Plant. The sub-committee had discussion with the concerned department and had asked for certain data on production and sale of Hamycin as also the data about quality, stability, and toxicity of the drug which was submitted to it. The sub-committee also discussed in detail various aspects connected with the Hamycin Plant and was to submit its report. In the meantime, there have been changes in the constitution of the Board of Directors of HAL, and none of the sub-committee members except Dr. S. S. Gothaskar continues on the Board. The Board, therefore, has reconsituted the sub-committee to examine the issue on the basis of the data already furnished to the previous sub-committee and to submit its report to the Board soon. The data submitted to the earlier sub-committee has already been furnished to the re-constituted sub-committee which is likely to meet soon and submit its report to the Board.

[Min. of C&F O.M. 51012/2/75-DC 24-2-77]

Further information called for by the Committee

Has the sub-committee of the Board completed investigations into Hamycin project? If so, what the result thereof.

[LSS letter No. 21-PU/76 dated 8th Dec. 1977]

Further Reply of Government*

The Board's Sub-Committee after holding discussions with HAL's R&D, Production and Marketing staff, came to the conclusion that Hamycin was an effective drug in the treatment of topical fungal diseases of man, and on the issue of the safety and efficacy of the drug the sub-committee was satisfied. At the same time, it noted that due to the limited shelf-life of this antibiotic, a careful assessment of the market potential should be made and a plant suitable for the manufacture of adequate quantities to meet market demand at regular intervals of manufacture, should be put, up, provided it is both economic and feasible. The Sub-Committee also came to the conclusion that production capacity to the second antifungal antibiotic developed by HAL, *viz* Aureofungin which has been shown to be highly effective in controlling certain important diseases of major agricultural plants, as also for its newly established use in preventing mould deterioration of Poultry and other animal feeds (this has been established in collaboration with M/s. Toyo, Jozo, Japan and it appears that there could be a substantial Export market of Aureofungin for feed protection purposes as indicated by HAL Japanese collaborators) should also be included in the proposal for an optimum sized manufacturing unit, in which both Hamycin and Aureofungin could be produced.

The feasibility and preliminary project report for the establishment of such a unit is currently under preparation for submission to the Board.

(Min. of C & F OM 51012/2/75 DC 9-1-78)

Recommendation No. 26 (Para 2.166)

The Task Force has also recommended that the two problems require immediate attention for improving overall efficiency and suggested that the management of HAL should immediately explore the possibility of obtaining better technology either locally or imported which will ensure better return on the investment already made with the minimal additional inputs and HAL should immediately explore the possibility of maximum utilisation of the plant already installed by constituting a joint working group comprising the scientists of HAL, NCL and also National Research Development Corporation to go into the details of the technology and the

*Further reply not sent to Audit for vetting.

design of the plant in order to assess the techno-economic viability of the entire project afresh. The Committee feel that HAL should have evaluated in depth the NCL technology at the pilot plant stage in consultation with Indian Council of medical Research, NRDC and other experts in the field especially when even at the pilot plant stage according to the Secretary doubts were expressed. The Committee feel that the pilot plant studies were not carefully done before setting up a plant for large scale production. The Committee recomend that HAL should without any further delay, take concerted measures to overcome the immediate problems affecting the production.

Reply of Government

The Government had appointed a Task Force headed by Brig. B. J. Shahaney, DGTD to look into the problems of Vitamin C. The Task Force having examined the various issues involved, appointed a Working Group comprising of representatives from NCL, HAL and NRDC to go into the problems in depth and make recommendations. The Task Force also suggested that HAL should explore the possibility of taking alternative technology. The Working Group has since submitted its report to the Task Force.

HAL contacted M/s. Sarabhai Chemicals, Jayant Vitamins, E. Merck, of Germany, Takeda of Japan and Roche. While M/s. E. Merck and Takeda regretted their inability, M/s. Roch Products of India expressed their willingness to offer their services to rehabilitate the Vitamin C plant of HAL and after assessing the installed facilities have stated that the plant with a reasonable investment of Rs. 79 lakhs, would be in a position to produce the rated capacity of 125 tonnes of Vitamin C, a year, at a cost close to the selling price fixed by Government.

The report of the Working Group and that of M/s. Roch products have been examined by the Task Force and the final report of the Task Force is awaited.

[Min. of C & F O.M. No. L-51012/275-DC dated the 30-9-76]

Further information called for by the Committee

When is the Task Force expected to give its final report?

Further reply of Government

The Task Force has sent an advance copy of its final report which is under consideration of Government and decision will be taken as early as possible.

(Min. of C&F 51012(2)/75-DC dated the 24-2-77)

Further information called for by the Committee

Has a decision on the report of the Task Force been taken? If so, what is the latest position in this regard

[LSS letter No. 21-PU/76 dated 8th December, 1977]

Further Reply of Government*

Pending the finalisation of the Feasibility Report by the sub-committee, the Board desired that Feasibility Report be submitted to the Government of India with a remark that the final recommendations of the Board would be forwarded in due course. The Feasibility Report was submitted to the Government on 23rd August, 1977. The sub committee met on 3rd September, 1977 (New Delhi) and on 16th September, 1977 (at Pimpri) and desired additional data in respect of cost required to establish increased capacity at 160 Tonnes P. A. The same has been submitted to the sub committee.

The Board noted the minutes of the meeting of the sub-committee on Vitamin C, of 3-9-77 and 16-9-77 keeping in view that in any complex chemical manufacturing or fermentation plant, due to fluctuations in productivity caused by use of complex organic raw materials as well as factors such as high levels of wear and tear and corrosion due to the use of corrosive raw materials and extreme reaction conditions, it would not be possible to achieve and consistently maintain the actual plant capacity at the production or rated capacity. Generally, the actual production capacity would be in the vicinity of 80 to 85 per cent of the name-plate capacity of such manufacturing units. The sub-committee had, therefore, recommended having due regard to the addition marginal capital cost which did not significantly affect the overall status of the project, an additional expenditure of Rs. 18.60 lakhs (in addition to Rs. 77 lakhs—thus making a total Rs. 95.60 lakhs) in order that against the name-plate capacity of 160 tons per annum, a minimum production of 125 tons per annum would be assured. The Board has since approved this recommendation and has directed that M/s. Roch Products India Ltd. be kept in constant consultation.

[Min of C & F O.M. 51012/2/75-DC 9-1-1978]

Recommendation No. 27 (Para 2.167)

The Committee do not understand as to why, when IDPL another Public Sector Undertaking under the same Ministry is also producing Vitamin C, the assistance of that Public Undertaking could not be taken for revamping the plant. The Committee recommend that a careful evaluation of the available technologies

*Further reply not sent to Audit for vetting.

should be made and the appropriate technology selected so that the plant is capable of operation on an economic basis. The Committee need hardly stress that it should be endeavour of the Public Sector Undertakings dealing with drugs to ensure that essential drugs of assured quality including those for prevention of diseases are made available at most competitive prices and in adequate quantities.

Reply of Government

The IDPL are producing Vitamin B-1, B-2, Folic Acid etc. but not Vitamin C. They are only formulating Vitamin C.

As already mentioned in reply to recommendation No. 26 introduction of appropriate technology is under consideration.

[M/C&F OM 51012/2/75-DC 30-9-76]

Further information called for by the Committee

Has any instructions been issued in this regard?

[LSS OM 21-PO/76 17-1-1977]

Further reply of Government

The Task Force set up by Government to go into the problems of Vitamin C Plant have unanimously come to the conclusion that HAL should go ahead with the revamping/rehabilitation of the Plant with the technological assistance offered by M/s. Roche. The company has been asked to submit a Feasibility Report accordingly for approval by the Government.

It is the declared objective of the Government to ensure production of essential drugs and their availability inadequate quantities at reasonable prices. The Public Sector Undertakings are already playing a significant role towards this objective. Fair selling price of each bulk drug and formulation is fixed by the Government under the Drugs (Prices Control) Order 1970, on the basis of approved norms stipulated in this order. No further instruction in this respect are called for.

[M/C&F OM 51012/2/75-DC 29-2-77]

Further information called for by the Committee

What is the latest position with regard to revamping/rehabilitation of the Vitamin C Plant?

[LSS letter No. 21-PU/76 of 8-12-77]

Further Reply of Government*

The Task Force set up to go into the problems of Vitamin C Plant has submitted their report to Government recommending that HAL should go ahead with the assistance offered by M/s. Roche Products Limited. This recommendation has been agreed to by the Government and HAL has submitted feasibility report on revamping existing Vitamin C Plant for achieving its rated capacity of 125 T. per annum.

The total cost of rehabilitation is estimated at Rs. 77 lakhs. The Government of India had originally sanctioned an expenditure of Rs. 163 Lakhs out of which company has spent Rs. 138 lakhs leaving thereby Rs. 25 lakhs as balance on the original sanction. Additional sanction would be for Rs. 52 lakhs, making total additional expenditure of Rs. 77 lakhs. With this investment it is expected that the Vitamin C Plant would start working from August 1978 with rated capacity of 125 tonnes per annum.

The Board noted the minutes of the meeting of the Sub-committee on Vitamin C, of 3-9-77 and 16-9-77 keeping in view that in any complex chemical manufacturing or fermentation plant, due to fluctuation in productivity caused by use of complex organic raw materials as well as factors such as high levels of wear and tear and corrosion due to the use of corrosive raw materials and extreme reaction conditions, it would not be possible to achieve and consistently maintain the actual plant capacity at the production or rated capacity. Generally, the actual production capacity would be in the vicinity of 80 to 85 per cent of the name-plate capacity of such manufacturing units. The Sub-committee had, therefore, recommended having due regard to the additional marginal capital cost which did not significantly affect the overall status of the project, an additional expenditure of Rs. 18.60 lakhs (in addition to Rs. 77 lakhs—thus making total Rs. 95.60 lakhs) in order that with the name-plate capacity of 160 tons per annum, a minimum production of 125 tons per annum would be assured. The Board has since approved this recommendation and has directed that M/s. Roche Products India Ltd. be kept in constant consultation.

[M/C & F OM/51012/2/75-DC 9-1-1978]

Recommendation No. 28 (Para 2.179 and 2.180)

The Committee feel that both the Ministry of Petroleum Chemicals and Fertilizers and HAL should have taken the assistance of the Ministry of Agriculture and the ICAR for testing the product Aureofungin a product developed by its own R&D efforts in the field establishing its efficiency and popularising and standardising it as a pesticide before taking up production on a large scale. If it is

*Further reply not sent to Audit for vetting.

established as a pesticide or even as an antibiotic for agricultural products, the Committee feel that the undertaking should have passed on the know how to another public undertaking dealing with the pesticides or to the Ministry concerned for further processing and development. The Committee regret to note that, instead, the company went on manufacturing the product though on a moderate scale without obtaining any firm commitment of indents from the State Government and produced 1250 kgs. till the end of March, 1975 at a cost of Rs. 39 lakhs. The Committee see no justification for the company to have gone on with the production during 1972-73, 1973-74 and 1974-75 when there was already an accumulation of stock in 1971-72 and the shelf life of products was only two years especially when there were no firm indents/commitments from the State Government.

The Committee find that the off-take of the product has not even been 50 per cent of the production to the end of 1974-75 and even the stocks lying with the company are not usable with the result that the company has been put to a loss of over Rs. 20 lakhs calculated on the basis of total cost of production. The Committee would like that the entire matter should be thoroughly investigated with a view to fixing responsibility for the loss.

Reply of Government

Government accepts the recommendation and propose to implement it by calling upon the Board of Directors to examine the matter and submit a report to Government.

[Min. of C&F 51012(2)/75-DC 30-9-77]

Further information called for by the Committee

What concrete action has been taken in this regard?

Further Reply of Government

The Board has taken up the examination of the recommendation made by the Committee and their report is awaited.

[Min. of C&F 51012/2/75-DC 24-2-1977]

Further information called for by the Committee

Has the Board completed its examination of the production of Aureofungin and a decision taken in the matter?

[LSS. O.M. No. 21-PU/76 dated 8th December 1977]

Further Reply of Government

The matter was considered by the Board of HAL and minutes of the meeting held on 3rd March 1977 are reproduced below:—

The Company has made the following submission to the Board:

"Aureofungin, a highly potent antifungal antibiotic was discovered by the Research Laboratories of HAL. It has been shown to

be active at extremely low concentrations against a wide variety of fungi including several major plant pathagens. This antifungal antibiotic was tested widely in different agricultural research stations round the country against several plant diseases including paddy blight, sugarcane redrat, diseases of grapes, coconut, areeanut, rubber and others. Its efficacy against plant diseases under field conditions was not only established but was confirmed by several independent workers in India and this is evidenced by the number of original research papers that have been published so far.

As is well known the establishment and introduction of new antibiotic either for human and agricultural uses into the market is an extremely long, difficult and expensive process. While conceding the fact that this organisation has not so far sold very large quantities of this antibiotic in the market, it should also be appreciated that with the limited R & D facilities the company has for conducting field trials and demonstration plots etc. as also the limited marketing force, it has been difficult to successfully introduce this compound in the market. The company is making efforts to establish this compound.

Considered against the above background, the company had to retain this item in its line of production eventhough the material produced in earlier years had not been sold out because continuity of supply of non-time-expired stock had to be maintained till the poduct was established firmly in the market and regular production could commence on the basis of actual/forecast demand. Thus between 1966 and 1976 a total quantity of 1.303 tonnes were produced to support the marketing in the introduction of this new item. However, since the market did not respond quickly and the financial position of the company also did not permit further expenditure on this new item, it was decided to discontinue the production of this item.

The year-wise details of the quantity produced are furnished below:

	Kgs.
1966-67	733·62
1967-68	37·35
1968-69	Nil
1969-70	Nil
1970-71	43·32

1971-72	25·90
1972-73	106·85
1973-74	44·95
1974-75	258·655
1975-76	49·44 (Processed Qty)
1976-77	Nil

The Board notes that the Committee has made two points, (a) that the manufacture of this Product was not undertaken against firm indents, and (b) that even though the Company has unsold stocks of this product at the end of 1971-72, further production of fresh batches was continued by the Company in subsequent years. In regard to the first point, the Company has pointed out that when a new product is to be introduced it is not possible to plan production against advance indents and that the normal practice is to make to a survey of the demand prospects in the country and plan production on that basis. Further, in this particular case, it was explained that the demand was contingent on the incidence of a particular fungal disease and that production had to be planned in advance of such a contingency and not after it had occurred. It has also been explained that the production was always planned in consultation with the Ministry of Agriculture, State Governments etc. and with reference to the indications given by them of the probable demand. The Board finds this explanation quite reasonable.

As regards the second point, the Board finds that the quantity which was on hand at the close of 1971-72 was time expired and that efforts to re-process the time-expired product were not successful. At the same time, the demand for the product arose and the quantities produced in subsequent years have also been sold. There are no stocks of the product at present.

Coming to the question of up-dating the figures of loss, the total cost of production up to 1975-76 was Rs. 39.84 and the total realisation were Rs. 14.99 lakhs and on this basis, the total loss on this operation could be said to be Rs. 24.85 lakhs. However, it has to be borne in mind that the manufacture of this product was undertaken with the available equipment, man-power and other facilities and no extra investment or man-power was involved. The cost of production mentioned above included the element of depreciation, overheads etc. on a notional allocation, but even if the manufacture of this product had not been undertaken, those costs would have been incurred. Excluding such unavoidable costs and computing the loss on a marginal cost basis, the loss on this operation would be only

Rs. 11.39 lakhs. As this was incurred in the development and marketing of a new product, it would be more reasonable to treat this as promotional expenditure rather than as a financial loss. The Board ventures to submit that there can be no guarantee that such developmental and promotional efforts will always be successful, and that any approach in terms of fixing responsibility for the losses likely to have a deleterious effect on R & D activities.

[Min. of C&F 51012/2/75-DC dated 9-1-78]

Recommendation No. 29 (Para 2.193)

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

Reply of Government

The observation made by the Committee has been noted.

All proposals from the Public Sector units are considered and approved only after Government satisfied themselves of the demand pattern for such products. There is, however, a risk of obsolescence in the field of drugs with the development of more efficacious and less toxic chemotherapeutic agents.

[M/C&F OM 51012/2/75-DC dated 30-9-76]

Recommendation No. 30 (Paras 2.194 and 2.195)

The Committee also note that the Board approved in December 1969 setting up of a plant for the manufacture of 5,000 kgs. of semi-synthetic Penicillin per annum at an estimated cost of Rs. 50 lakhs during the Fourth Five Year Plan. According to management, the plant would be commissioned by June, 1976. The Committee also note that in the mean time manufacture of semi-synthetic penicillin capsules was started, in November, 1971, and out of 17.52 lakhs cap-

sules manufactured 14.67 lakhs were sold upto March 31, 1975, 0.80 lakhs were scrapped (produced in May 1972) leaving of a balance of 1.05 lakhs in stock. The low volume of sale was stated to be done to inherent difficulties in introducing a new formulation in the market.

The Committee feel that the undertaking should have made intensive efforts for marketing this new drug. Now that the plant would be commissioned by June, 1976, the Committee recommend that the undertaking should intensify its efforts to develop the market for the product and also take steps to get the problems regarding efficacy and shelf life of the product resolved. The Committee would also like to reiterate that in the sphere of drugs particularly the new drugs, it is always advisable to take up production on a pilot basis before going in for production on a commercial scale.

Reply of Government

In the group of semi-synthetic Penicillin, HAL have taken up the product—Ampicillin as the first item for production. Ampicillin is a well established drug and a number of manufacturers have already been marketing the finished formulations based on the imported bulk drug. HAL, no doubt, should have taken up the marketing of ampicillin capsules with more vigour, but there would be no problem for them in disposing the bulk Ampicillin going to be produced by them to the other formulators and this in turn would save the foreign exchange spent on its import to that extent. Besides the production of the bulk Ampicillin, HAL would also be consuming a part thereof for converting the same into finished dosage form in capsules, as per demand.

[M/C&F O.M. No. 51012|2|75-DC dt. 30-9-76].

Recommendation No. 31 (Para 2.196)

The Committee are informed that the preliminary feasibility reports show that the projects for Industrial Enzmes and Aminoglycosidic antibiotics will be financially feasible while that of Erythromycin would not be financially feasible on the basis of technology available with the undertaking at present and therefore efforts are being made to obtain improved technology before the project is processed further. The Committee would like that a thorough study of the technologies if any available in India for the manufacture of these products should first be made before considering import of any foreign technology and the feasibility and economic viability

of the projects should be critically examined before taking up the projects. In case selection of foreign technology is inevitable, the Committee would like that the undertaking should select the best technology capable of producing the drugs at most economic prices. The Committee also caution that the earlier mistakes of taking up manufacture of Hamycin, Aureofungin etc. should not be repeated while taking up manufacture of the new drugs and every care should be taken to ensure that the drugs produced will be efficacious, stable and have a viable market for them.

Reply of Government

HAL have submitted a feasibility report for the manufacture of Industrial Enzymes with a capacity of 20 tonnes based on their own technology.

The company has also submitted feasibility report for the manufacture of 19 tonnes of Erythromycin in a new plant to be set up for the purpose, involving an outlay of Rs. 4.16 crores based on imported technology. They are still negotiating for foreign technology. This proposal has been circulated to various Ministries for initial comments.

The recommendation of the Committee has been noted. Approval of Government will be granted only after a thorough examination of all the aspects concerning demand, technology, cost of production, profitability etc.

[M/C&F OM 51012/2/75-DC 30-9-76]

Further information called for by the Committee

What is the latest position with regard to manufacture of industrial enzymes, Aminoglycosidic Antibiotics and Erythromycin.

[LSS letter No. 21-PU/76 of 8-12-1977]

Further Reply of Government*

1. Industrial Enzymes:

The Company has developed the manufacturing know-how for several industrial enzymes meant both for captive use as well as for outside sales. Already the organisation is manuacturing few of these enzymes required for its own captive use. Example, Penicillinacylase for manufacture of 6-APA, L-Mannosidase for converting Streptomycin B to A, Amloglucosidase for converting Starch to Dextrose. The others enzymes that have been developed and ready for manufacture are Lipase, Glucose Oxidase and Penicillinase. The

*Further reply not sent to Audit for vetting

Government has approval the manufacture of all these enzymes at HAL and at present, the company is preparing the techno-economic and feasibility reports for submission to PIB of Government of India.

2. Aminoglycosidic Antibiotics:

The items included under this category are (a) Gentamycin and (b) Neomycin. The Company is in the last stages of negotiations with M/s. Medimpex and Chinoin of Hungary for technical collaboration and manufacturing know-how. This project which has already been approved by the PIB, on receiving the final clearance from Government, would be set up at HAL. The Company, with plans to begin with formulating Gentamycin Sulphate imported from Hungary, would be beginning its basic manufacture within the next two years.

(b) **Neomycin:** The Company developed its strain and know-how for Neomycin, but it could not go into full scale production due to certain technical difficulties. It has since improved its strain yields further, and this is at present undergoing feasibility studies.

3. Erythromycin:

In its Fifth Plan product profile, HAL had included the manufacture of different salts of Erythromycin by fermentation. However, during the discussions in November-December 1976 with the Government of India, it was finally decided that Erythromycin bulk would be manufactured by IDPL Plant at Rishikesh and not by HAL. HAL would, however, formulate Erythromycin and introduce to the market the sub-divided products such as Erythromycin strearate film-coated tablets, and Erythromycin pediatric syrup. In fact, HAL introduced the Erythromycin film-coated tablets during November 1977.

[M/C&F O.M. 51012/2/75-DC dt. 9-1-78]

Recommendation No. 32 (Para 2.209)

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

Reply of Government

Every effort is being made to keep the rejections of the bulk products manufactured by the company at as low as possible. The reject percentage for bulk Penicillin and Streptomycin during the years 1974-75, 1975-76 and April—September, 1976 is shown below:—

	1974-75 %	1975-76 %	1976-77 %
Streptomycin	5·46	6·47	6·38 (April-Sept.)
Penicillin			(April-Aug.)
Procaine Benzyl	1·93	2·25	3·19
Benzyl Sodium	0·819	1·90	Nil
Benzyl Potassium	3·90	Nil	Nil
V. Potassium	6·76	3·02	Nil

Every endeavour is being made to ensure that the rejects are further brought down.

[M/C&F O.M. 51012/2/75-DC dt. 30-9-76]

Further information called for by the Committee

What is the percentage of rejects to total production in the case of Penicillin bulk in 1976-77?

[LSS O.M. No. 21-PU/76 dt. 8-12-77]

Reply of Government*

Percentage of rejects for the year 1976-77 is as follows:—

	1976-77 %
Streptomycin	5·18
Penicillin	
Procaine Benzyl	1·79
Benzyl Sodium	0·18
Benzyl Potassium	Nil
V. Potassium	0·84

[M/C&F O.M. 51012/2/75-DC dt. 9-1-78]

*Further reply not sent to Audit for vetting.

Recommendation No. 33 (Para 2.210)

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

Reply of Government

Record of rejection of capsules has since been maintained and rejections of capsules during 1975-76 is 1.23 per cent.

[M/C&F O.M. 51012/2/75-DC dt. 30-9-76]

Further information called for by the Committee

What has been the rate of rejection in 1976-77?

[LSS O.M. No. 21-PU/76 dt. 8-12-77]

Further Reply of Government

Rate of rejection of capsules during the year 1976-77 works out to 0.19 per cent.

For the period April 1977 to November 1977 the rate of rejection of capsules was 2.52 per cent. This was mainly due to 8.6 lakhs capsules held back as the bulk used was subsequently declared as rejected. After the rejected capsules are reprocessed, the percentage of rejection of capsules is likely to be reduced.

[M/C&F O.M. 51012/2/75-DC dt. 9-1-78]

Recommendation No. 34 (Paras 2.211 and 2.212)

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

Reply of Government

Month-wise product-wise details of capsules and tablets withdrawals from the market are being maintained by the Company. Similarly, the percentage of rejection to the total production is also maintained regularly. As pointed out by the Committee, these two figures will be merged in order to indicate the overall percentage of rejections.

[Min. (C&F) O.M. No. 51012/2/75-DC dt. 30-9-1976]

Further information called for by the Committee

Have the reasons for rejections been analysed in depth and deficiencies identified? If so, what corrective measures have been adopted?

[LSS O.M. No. 21-PU/76 dt. 17-1-1977]

Further Repy of Government

Reasons for rejections have been analysed and the deficiencies have been identified by the Company. These are (a) For Penicillin products:—Moisture pickup, the product having lost its potency below the pharmacepoeial requirements. This has been overcome by introduction of butyl rubber stoppers in Penicillin products. The stability study has revealed that on use of butyl rubber stoppers, the stability of the product has improved very considerably, (b) For Streptomycin products:—The withdrawals have been mainly due to the moisture pick up which is in proportion is very much less than the Penicillin products and this has not adversely affected the potency. Remedial measures for preventing moisture pick up are being examined on the lines of Penicillin products. Corrective actions are to be taken after analysing reasons for deficiency.

[M(C&F) 51012(2)/75-DC dt. 24-2-1977]

Further information called for by the Committee

Have the corrective measures in regard to vialling of Streptomycin been finalised and introduced with a view to bring down rejections?

[L.S.S. O.M. No. 21-PU/76 dt. 8-12-1977]

Further Reply of Government*

The following corrective measure in regard to vialling of Streptomycin has been taken to prevent moisture pick up.

In order to ensure the minimum moisture at the time of filling, rubber stoppers, before use, are now dried in high vacuum. Evaluation of results of this measure can only be assessed after 24 months.

Another corrective measure proposed to bring down the rejection is use of Butyl Rubber Stopper for this product. This will to be considered if the percentage of rejects does not come down, after examining the cost of Butyl Rubber Stoppers and their availability etc. in details.

[M/C&F O.M. No. 51013(2)/75-DC dt. 9-1-1978]

*Further reply not sent to Audit for vetting.

Recommendation No. 35 (Paras 2.213 to 2.215)

In the opinion of the Committee it should not be difficult for the undertaking to have a sample test check of batches if any lying unsold for more than six months to ensure that the efficacy of such batches remains intact before they are actually sent to the market. The Committee feel that 'withdrawals from market' do not leave a good image of a public undertaking on the public mind. The Committee find that a maximum number of batches of potassium penicillin G were withdrawn and they pertained to the period October 1965 to March, 1966, April 1967 to September 1967 and October 1967 to March 1968 and the withdrawals were mainly on account of non-confirmity to specifications. The Committee fail to understand how such batches which did not conform to specifications passed the quality control tests.

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

Reply of Government

The record of withdrawals of vials from the market is being maintained. The company constituted a "Complaints Committee" comprising of technical experts from Quality Control, Production, R&D and Sales. The Committee examines in depth periodically the nature of complaint and the test results of the reference formulations as well as those involved in the complaint and initiates remedial measures promptly.

A high powered committee called "Adverse Reaction Committee" is also constituted consisting of senior scientists from R&D, Quality Control, Company's Chief Medical Officer to analyse in depth the complaints of reactions with a view to taking expeditious remedial measures. Senior technical representatives of the company from

one or more departments are deputed to make on-the-spot investigation regarding the adverse reaction, and discuss with the senior officials and Doctors concerned. Invariably, in each and every case of complaint, concerned Drugs Control Administration draws independently samples from the batch and thoroughly tests them. Practically, in each case, the results of the test carried out by the Drugs Control Administration indicate that the concerned product conforms to the prescribed standards. From these and from the on-the-spot investigations of our representatives, it appears that in most of the cases reactions are of allergic nature and in some cases, due to faulty administration of the drug. It is for this purpose that the Drugs Controller of India has issued a directive to all the Government hospitals and institutions in the country to constitute a Local Investigation Committee soon after a reaction has been observed.

It is also seen that very often, deterioration takes place due to improper storage and handling of the product at the consuming point. It is a matter of great relief to note that the frequency of complaints has come down considerably. It may be added that no batch has ever gone out to the market until it was cleared by the Q.C. Department.

The Company has fixed house standards well above the pharmacopoeial limits prescribed by the statute. The company has a well-equipped Quality Control Laboratory manned by reputed scientists. The batch is certified only after it meets with the pharmacopoeial as well as house standards. In view of these, each and every batch that leaves the company would have gone through the rigid process of testing and conforming to the specifications before it was certified. Regular checks are also carried on continuous basis on the stability of the various products and formulations during the life period of such product. In case any of the parameters in the prescribed standard is not met with in the case of any product, the company voluntarily withdraws such product from the market. Simultaneously, immediate remedial measures are taken to ensure that the concerned products remain stable within the life period notified. These include substitution of synthetic butly rubber stoppers in place of natural rubber stoppers; in the latter case, the seepage of moisture resulting in deterioration of the product was observed. Various other measures taken have been listed under section on formulations. In view of these, when a product was found to be sub-standard, it does not mean that the product was sub-standard at the time of original release. The suggestion that Board/ Government should ensure a conclusive action and also take suitable measures to avoid recurrence of such cases, is accepted. The

Board would review the findings of Company's "Complaints Committee" and "Adverse Reaction Committee" during their meetings.

[M/C&F. No. 51012|2|75-DC 30-9-76].

Further information called for by the Committee

(a) Has the Board reviewed the findings of Company's "Complaints Committee" and "Adverse Reaction Committee"? If so, what is result thereof?

(b) Has any investigation been made into fatal cases? and what action has been taken as a result of such investigations?

[LSS Letter No. 21-PU/76 of 8-12-1977]

Further Reply of Government*

(a) Complaints Committee in its meeting held on 8-12-1977 have reviewed various complaints received by the Company, during April 1977 to November 1977. Observations of the Committee will be placed before the Board.

(b) Whenever a fatal case is reported after the use of our product, the Sales Dept. directs its Regional representative to personally collect further information on the reported incident for carrying out investigation. The Regional representative is also directed to liaison with the State Drug Control Dept. in this matter further. On the receipt of the official complaint, the Quality Control Dept. of HAL forthwith checks the reference vials of the very same batch on which the complaint has been received, and reports its findings as to whether the batch conforms to the Pharmacopoeial specifications. A copy of this test report is also endorsed to the Adverse Reaction Committee. Then as soon as the complaint vials are received from the State Drug Control authority, the Quality Control Lab. tests these products for conformation to I.P. Specifications and submits its report. Adverse Reaction evaluation proforma that has been drawn up by the Adverse Reaction Committee, is sent forthwith to the doctor or hospital from which the complaint was received. with a request to give all the information requested for in that proforma. The adverse Reaction Committee which normally meets once a month. reviews in-depth, all cases of adverse reactions with particular attention to instances of fatality involved, and analysis the probable causes and preventive actions to be taken. The Committee investigates the batch concerned by referring the matter to the

*Further reply not sent to Audit for vetting.

Production Dept., as soon as the results on the complaint and reference vials testing are available, it sends one of its Committee members to personally visit the hospital, etc. where the death has taken place for on the spot investigation. On few earlier occasions, the results of its findings and remedial action as well as other recommendations have been communicated to the State Drug Control and other health authorities for their consideration and suitable action. In most cases, the Medical Authorities concerned have expressed their appreciation of our organisation's efforts to investigate in-depth drug allergies, bring out relevant factors that may be involved in the reaction, and suggest remedial measures. An allergic reaction with or without fatality is the result of an extremely complex interactions between the drug, the vehicle used, the cleanliness of the equipment used particularly the syringe and the needle, the drug used immediately prior to the injection of the patient, other drugs, etc., that he may have been taking, and the medical history of the patient—as to whether he has become sensitised to the drug.

[M/C&F OM 51012/75/75-DC dated 9-1-1978]

Comments of the Committee

Please see paragraphs 20 to 23 of Chapter 1.

Recommendation No. 36 (Para 2.216)

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

Reply of Government*

As indicated in reply to Recommendation No. 35, the company has one of the best equipped Quality Control Laboratories in the country which could match similar laboratories anywhere in the world. The Company has also laid down rigid house standards which are invariably well above the prescribed pharmacopoeial standards. The company also works in collaboration with recognised drug testing laboratories. These include Central Drug Laboratory, Calcutta, Haffkine Institute, Bombay, Food & Drugs Administration, Maharashtra State, National Institute of Medical Research, U.K. Food & Drug Administration, USA, M/s Sarabhai Chemicals, Glaxo

*At the time of factual verification, Audit informed as follows :—
"Appropriate norms for rejection have not been fixed."

Laboratories, Pfizers, etc. in the field to evaluate the test and upgrade them wherever necessary. In fact, the high quality standards of the company are well recognised in the country and established viallers of repute, prefer to buy products from the company instead of taking from other sources including imports. The Food & Drugs Administration, Maharashtra State has advised number of small scale industries and hospitals manufacturing infusions to have their products tested at HAL. The company has also taken various measures to reduce the rejection rate as a result of which the rejections have come down. The senior scientists of the Q.C.L. have previous experience in reputed drugs concerns such as Glaxo, CIBA Research Institute, Central Drugs Research Institute and the company has arranged for their training in Food and Drugs Administration, USA, Institute of Health, Canada, National Institute for Medical Research, UK and Merck & Co., USA.

[M/C&F 51012/2/75-DC dt. 30-9-76]

Recommendation No. 37 (Paras 2.227 and 2.228)

The Committee view with concern that inspite of steep increase in the value of excess consumption of material which contribute to the increase in cost of production, no action seems to have been taken to investigate into the reasons for such excesses. The Committee fell that the absence of information/records to indicate the corrective action taken on various reports, it is neither possible to verify whether action has actually been taken or to fix responsibility for any lapse in this regard. In the opinion of the Committee this only indicates casualness of approach and laxity on the part of the management. The Committee therefore, recommend that the undertaking should not rest content with merely preparing a statement of variances between standards and actual consumption but also indicate and ensure corrective action.

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

Reply of Government

Variation between standards and actual consumption of raw materials in the case of Penicillin and Streptomycin is benig studied every month and remedial measures taken wherever the consumption has exceeded the norm. This is included in the quarterly Financial Review and will be put up to the Board of Directors for

their review with a view to take appropriate corrective and remedial action.

[M/C&F O.M. No. 51012/2/75-DC dt.30-9-76]

Further information called for by the Committee

Please indicate the appropriate corrective and remedial action.

[LSS 21-R/76 dt. 17-1-1977]

Further reply of Government

For studying variation between standards and actual consumption of the raw materials, standards are yet to be approved by the Board of Directors of HAL. While considering this aspect, in the Quarterly Financial Review for the quarter ending 20th September, 1976, the Board observed that standards fixed were quite some time back and required revision on realistic basis considering the pattern of raw material consumption in the present context. The Board also desired that this aspect required examination in depth keeping in view the availability of improved strain and technology in Penicillin and Streptomycin. Revised standards on this basis would be approved by the Board in due course. After standards are fixed by the Board, variation between standards and actual consumption of raw materials in the case of Penicillin and Streptomycin will be taken every month for remedial measures to be taken where wide variations are noticed.

[M/C&F O.M. No. 51012/2/75-DC dt. 24-2-77]

Recommendation No. 38 (Paras 2.229 and 2.230)

It has been stated that the criterion followed for revision of any standard in any particular raw material was that the standard was fixed or revised keeping in view the optimum consumption best suited to efficient production. Since improved strains have been introduced in the case of Penicillin from 1971 and in the case of Streptomycin during 1974-75, the undertaking should watch the performance of the new strains and take action to revise the standards after the consumption of raw materials with reference to such standards can be worked out.

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

Reply of Government*

In the case of Streptomycin, the standards have been revised and the consumption figures are being compared every month with the norms. In the case of Penicillin, the existing norms will be revised soon after the stabilisation of the new strain and technology.

The Committee's recommendations has been communicated to MD, HAL for compliance.

[M/C&F O.M. No. 51012/2/75-DC dt. 30-9-76]

Recommendation No. 39, Paras 2.39 and 2.40

The Committee regret to note that no yard-stick have been prescribed for exercising control over actual consumption of power steam and compressed air nor is there any arrangement for recording actual consumption at different plants and/or for different processes. The Committte are informed that the most important point of consumption of services being at the fermentation stage, the Management roughly compared consumption of important services per fermentation batch in the absence of necessary instruments. The Committee can not comprehend now a rough comparison of consumption of services only at the fermentation stage and could enable the management to exercise control over the consumption of services at the different stages/processes of production which is essential to control costs and cutout wastages at each stage/process. The Committee are informed that meters are gradually being installed and till then the control would be with reference to estimates. The Committee feel that installation of meters or other measuring instruments should have been done along with the equipment themselves and recommend that the undertaking should lose no further time in fixing the meters and exercising proper control over consumption of services, which has a bearing on overall cost of production.

The Committee recommend that Government/BPE should issue standing directions that measuring control instruments should invariably be provided along with the machines/equipment and should in fact form an integral part of the machines.

Reply of Government

For exercising proper control over the consumption of services in the process buildings, the work of installation of flow meters has

*At the time of factual verification Audit informed as follow:—

"In respect of strepto mycin the details of standard fixed and actual then against were not made available to Audit for vetting

been taken up and the following table gives the details of installation work done and remaining to be done:

Plant	Air	Steam	Process Water	Chilled Water	Power
(1)	(2)	(3)	(4)	(5)	(6)
Streptomycin .	Installed in May 1974	Installed in 1966	Installed in 1973	By April 1977	Since beginning of the plant
Penicillin . .	March 1975	By Sept. 1976	1973	April 1977	1962
Final Products including bulk Penicillin and formulation of Streptomycin and Penicillin	By March 1977 for H. P. steam Nov. 1976	For L. P. steam Dec. 1974	By Nov. 1976	By April, 1977	1962
Hemycin Bldg. .	By March 1977	Since the beginning of the plant.	By Nov., 1976	By April, 1977	Since the beginning of the plant.
Vitamin 'C' Bldg. .	1972	1972	1972	1972	1972

It is proposed to consult a few selected public sector undertakings with a view to find out the practicability of enforcement of the recommendation, prevailing under different situations in varying types of Public Sector Undertakings.

[M/C&F 51012(2)/75-DC dt. 30-9-76]

Further information called for by the Committee

What has been the result of such consultations? What action has been/is proposed to be taken regarding the issue of standing instructions?

[LSS O.M. 21-PU/76 dt. 17-1-77]

Further reply of Government

The company has been asked to take necessary action in this regard. They propose to take up the study of a few selected public sector undertakings in due course. After the study has been completed the question of issuing necessary standing instruction will be examined.

[M/C&F O.M. 51012(2)/75-DC dt. 24-2-77]

Further information called for by the Committee

Has the Company undertaken study of other Public Undertakings in this regard? If so, have the necessary instructions been issued.

(LSS OM-21-PU/76 dt. 8-12-77)

Further Reply of Government

HAL has already implemented the suggestion. The Committee's recommendation that Government/BPE should issue standing directions that measuring control instruments should invariably be provided along with the machine/equipment are under consideration.

(M/C&F O.M. No. 51012(2)/75-DC 9-1-78)

Comments of the Committee

Please see paragraphs 24 and 25 of Chapter 1.

Recommendation No. 40 (Paras 2.241 and 2.244)

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

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

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

Reply of Government

1. Recognising the imperative necessity to reduce incidence of plant break-down, a system of planned preventive maintenance was introduced for the whole plant during 1971. Nearly 25 senior supervisory personnel of maintenance and production departments were

trained in Preventive Maintenance, as a result of which implementation of the developed system became immediate. Status of implementation of these schedules is being monitored by weekiy review and as a result, implementation of Schedules has improved progressively during the last 4 years.

MECHANICAL

	No. of Equipments		
	Schedule	Attended	Implementation%
1972 . . .	52	41	79
1973 . . .	87	70	80
1974 .	88	68	77
1975 . . .	103	85	83

ELECTRICAL

	No. of Equipments		
	Schedule	Attended	Implementation%
1972 . . .	38	28	74
1973 . . .	70	61	87
1974 . . .	91	84	92
1975 . .	103	98	95

INST

	No. of Equipments		
	Schedule	Attended	Implementation%
1972 . . .	31	12	39
1973 . . .	48	25	52
1974 . . .	48	33	69
1975 . . .	72	53	74

As a result of progressive improvement in the implementation of preventive maintenance schedules incidence of Plant break-down and its adverse impact on production has been brought down significantly.

It may also be mentioned that a Sub-Committee of the Board of Directors of the company had already investigated the matter and on the basis of this the company had removed the then Chief Engineer from service during October, 1974.

2. The reasons for high consumption of steam during 1973-74 and that of compressed air during 1970-71 were gone into and a number of remedial measures have been implemented.

3. As a result thereof, the steam consumption during 1975-76 has gone down to 2080 lacs kgs. from 2200 lac kgs. during 1973-74 Long-term measures to improve generation of steam and economise on fuel consumption is under way.

The consumption of compressed air during 1975-76 was 3127 lacs of cubic metres compared to 3869 lacs of cubic metres during 1970-71. a reduction of 20 per cent although production of various items during 1975-76 was much higher as compared to those during 1970-71.

(N/C&F No. 51012/2/75-DC 30-9-76)

Further information called for by the Committee

What is the position with regard to consumption of compressed air during 1976-77?

Letter No. 21-PU/76 of 8-12-77 (LSS)

Further Reply of Government*

The consumption of compressed air during 1976-77 was 2810 lac cubic metre as against 3127 lac cubic metre during 1975-76.

(M/C&F 51012/2/75-DC dt. 9-1-78)

Recommendation No. 41 (Paras 2.247 to 2.252)

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

The Committee feel that in the interest of assessing the efficiency and productivity of labour it is necessary that records of utilisation

*Further reply not sent to Audit for vetting.

of labour and idle labour hours and the reasons therefor are maintained.

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

The Committee note that the bulk of the idle machine hours has been due to contamination, turnover time and breakdown of machinery. The Committee feel that there are areas which should be controlled by efficient management and the idle hours could be brought down. The Committee would like that the undertaking should take concerted measures to control idle hours on account of these factors in the best interest of production.

The Committee find that besides turnover time and shortage of raw materials and contamination has also contributed to idle hour. The Committee see no reason why the undertaking should not have kept sufficient buffer stock of raw materials and obviate the necessity of keeping machines idle for want of raw materials. The Committee would like that the undertaking should take suitable steps to control idle hours due to contamination in the best interest of production.

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

Reply of Government*

A production planning and control/works inspection cell has been created to monitor the clock utlization of machines and labour in major production lines and to assure optimum utlisation of the same.

Data on utilisation of vital machinery in production and services units and the incidence of down-time due to various reasons is being maintained.

This being a continuous process industry, forced idleness of hour will occur only when a section stops due to some reason. During

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*At the time of factual verification, Audit informed as follows:—
"Not vetted for want of details regarding plant breakdowns and idle hours."

such instance also, the production and maintenance staff are engaged for clearing and thorough overhauling of the particular sections. At times, these staff are engaged to carry out urgent work of other sections and also records are available for the same.

Information regarding idle machine hours in some vital sections are being given to the Board during the Board Meetings.

As indicated, in reply to Recommendation No. 40, the system of planned preventive maintenance has been intensified to reduce idle hours on account of idle machines due to break-down.

High percentage of idle machinery hours during 1974-75 in Streptommycin Plant (Fermentation) has been investigated and the reasons are given below:—

1. Non-availability of dextrose during the first quarter of the year 1974-75.

2. Introduction of improved strain and technology made it possible to obtain higher output per batch and thus it was possible to obtain the desired production in Fermentation with lesser number of Fermentor batches. This resulted in certain idle-hours for the fermentors. 2 Fermentors were, however, utilised for preparing starch Hydrolysate and the utilisation of the vessels for this purpose.

A systematic planned preventive maintenance system has been put into regular practice as a result of which break-down of equipments have been reduced almost completely and this has facilitated better utilisation of the machines. Vigorous efforts are being made to establish inventory control 1. marageriał control in consultation with professional consultant to maintain/optimum inventories to ensure uninterrupted production *i.e.* utilization of machines and labour.

(M/C&F OM No. 51012/2/75-DC 30-9-76)

Recommendation No. 42 (Para 3.9)

VIALLING

The Committee note that as against the installed capacity of 48,000 vials per shift based on continuous working for 8 hours about stoppage, the Ministry considered a capacity of only 36,000 vials per shift as practicable. As against this, the management assumed the working capacity to be 25,000 vials per shift. The Committee find that number of shifts actually worked was less than the available shifts, on account of absenteeism among workers, lack of trained

operators, shortage of rubber stoppers, breakdown of machines, etc. The Committee regret to note that HAL has not analysed the loss of shifts on account of each one of these reasons. The Committee agree with the Ministry that the undertaking should not have reduced the capacity because of the alleged loss of 2 hours in a shift but should find out ways and means of ensuring that the machines are actually worked for the full 8 hours so that vialling could go up. The Committee would like HAL should improve the utilisation of capacity and bring it to the level of 48,000 vials without further loss of time and money. The Committee would like to be informed of the concerted measures taken and the results achieved.

Reply of Government

During the year 1975-76 the vialling was 21508 vials per shift. The same has increased to 26750 vials per shift during the period April-June, 1976. The following measures have been taken to improve the output of vials:—

1. Two aluminium cap sealing machines have been imported and installed for replacing the obsolete sealing machines. One machine has been installed since 21-1-1975 and the other one installed as stand-by.
2. The rubber stopper machines (4 Nos.) have been fitted with new imported motors in 1975-76.
3. The hoppers of two filling machines have been modified and fitted since April, 1976 to improve the performance of the filling machines to accommodate different types of powders for giving flexibility in operations.
4. One of the supervisors of the engineering section has designed a rubber stopper pressing device for butyl rubber stoppers to ensure proper fixing of rubber stoppers on to the vials. The same is fixed on one filling machine and is regularly being used since February, 1976 with good results.
5. Introduction of systematic Plant preventive maintenance has reduced interruptions in vial filling.
6. Alternative sources of supply for glass vials and rubber stoppers have been located.
7. Proper relative humidity (30 per cent) and temperature (26.60 per cent) contol kept for vialling by proper maintenance of air conditioning equipments and change of old

*At the time of factual verification, Audit informed as follows: "It should be 26129 as indicated by Final Product Department."

and sealed chilled water coil for improving velocity of air as well as coaling of sterile air.

8. Butyl rubber stoppers for Sodium and fortified Sodium Penicillin are being used regularly. This is to avoid seepage of moisture through a stopper. Butyl rubber was imported and made available to rubber stopper manufacturers.

9. Rubber stopper and vials dimensions changed to suit each other, and these are being rigidly followed.

10. Pressure foot arrangement, for fixing up rubber stoppers on vial mouth was modified.

11. Alternative sources for supply of labels and cartons were located to ensure un-interrupted labelling and packing.

12. Running of filling lines is continued in the tea-breaks by giving staggering breaks.

13. Time-losses during any troubles at the time of filling are reduced by proper co-ordination with different units of maintenance and services.

14. Major vialling operations are carried out in the First and Second shifts where additional supervising personnel are provided.

(Min. of C&F O.M. 51012/2/75-DC 30-9-76)

Further information called for by the Committee

When does HAL expect to achieve the 48,000 vials capacity?

(L.S.S. letter No. 21-PU/76 of 17-1-1977)

Further Reply of Government

It was clarified earlier that a capacity of 48,000 vials per shift was not practicable. As against 21,508 vials per shift during the year 1975-76, 26,268 vials per shift during the period Jan. 1976—Dec. 1976 have been achieved.

(Min. of C&F O.M. 51012/2/75-DC 20-2-77)

Further information called for by the Committee

What is the number of vials per shift during the year 1976-77, as against 21508 vials per shift during the year 1975-76?

L.S.S. letter No. 21-PU/76 of 8-12-77.

Further Reply of Government*

The number of vials filled per shift during the year 1976-77 works out to 27961 vials. During the period April 1977 to Sept. 1977 number of vials filled per shift works out to 26065 vials. However, during December 1977, average vials filled per shift works out 28000

*Further reply not sent to Audit for Vetting.

vials, due to selective product mix, and streamlining of operational procedure.

(M/C&F O.M. 51012/2/75-DC 9-1-79)

Subsequent reply of the Government†

Average vials filled per shift

1976-77	27961
1977-78	26957
1978-79	31730

HAL is improving the working methods and conditions and also imparting in house training to the concerned workers to progressively achieve the higher targets.

[Min. of PC&F O.M. No. L 151012/2/75-DC dt. 31-3-1979.]

Comments of the Committee

Please see paragraphs 26 and 27 of Chapter 1.

Recommendation No. 43 (Paras 3.24 and 3.25)

The Committee regret to note that the actual production fell short of not only capacity based on 36000 vials per shift but even the reduced vialling capacity of 25000 assumed by the Management, the lowest production being 20,781 in 1974-75. The Committee recommend that the vialling capacity of each machine and the question of optimum number of working shifts should be gone into in depth with a view to identifying the constraints which affect the working of the plant at 48,000 vials and suitable measures taken to attain the full capacity under a time bound programme and the Committee informed. The Committee are also informed that the Undertaking has also now taken some measures to see that the humidity is maintained at proper level to control rejections. This being a management function, committee fail to understand as to why this could not have been taken care of at the appropriate time and rejections controlled. The Committee recommend that the measures now taken should be kept under continuous watch so that humidity is maintained at the proper level.

Reply of Government

The vialling capacity of each machine and the question of optimum number of working shifts has been examined in depth and efforts were made to run the machines during all the available shifts (2430) as can be seen from below:—

Year	*Actual Shifts working*
1974-75	2084.0
1975-76	2418.0
April-June, 1976	606.5

This will give a rate of 2426 shifts per year. As regards the efforts made to increase the output of vials per machine, the details are given under reply to recommendation No. 42.

†Furnished at the time of factual verification.

The humidity in the filling rooms is continuously recorded and a constant watch is kept in the humidity to assure that the same is kept within limits and accordingly the air conditioning section are taking immediate corrective steps. Further the chilled water cooling coil was changed on 11-4-76 and the performance has improved.

[M/C&F O.M. No. 51012/2/75-DC dt. 30-9-76]

Recommendation No. 44 (Para No. 3.26)

In regard to rubber stoppers, though the problem is reported to have been solved by shifting to synthetic rubber, the Committee see no reason why this could not have taken care by proper planning. The Committee find that the need for strengthening the inventory control procedure, building up adequate reserves and keeping close liaison with suppliers was emphasised by the Board as early as 1970. The Committee expect that the Management would keep their instructions in view and observe them so as to avoid recurrence of shortages of rubber stoppers and other vial accessories.

Reply of Government

Based on the guidelines of the (Parliamentary) Committee on Public Undertakings (40th Report 3rd Lok Sabha) on Material management in Public Undertakings, an integrated Materials Management Department was set up in 1972 and a separate inventory control cell was created. Subsequently pursuant to the decision of the Board of Directors in 1973 that the Company should streamline and introduce an effective material management system with the assistance of professional agencies specializing in inventory control, the National Institute for Training in Industrial Engineering, Bombay was engaged as the consultant to the company and a task force was constituted to work under the guidance of the consultant. The task force evolved systems on sound material codification, stores relocation and identification and segregation of surplus inventory. As a result of this, the inventory control system is being streamlined and strengthened.

Most of the suppliers of rubber stoppers are drawn from one of the ancillary units located in the Company's estate, and close liaison has been maintained with the supplier as a result of which, interrupted supplies have been ensured.

Although the above measures enabled the Company to carry on uninterrupted production, adequate inventories can only be maintained when the ways and means position of the company improves further.

[M/C&F O.M. No. 51012/2/75-DC dt 30-9-76]

Further information called for by the Committee

When did the task force give its Report and how soon will the inventory control system be streamlined and strengthened?

[L.S.S. O.M. No. 21-PU/76 dt. 8-12-77]

Further Reply of Government

The task force had submitted reports on certain aspects of inventory Control System *viz.* liquidation of surplus inventory, inspection of inward items, valuation of Departmental return items, perpetual stock checking control of discrepencies, stores relocation and progress made on the development of integrated Materials, Management System, during 1974. The codification of items has been almost completed. Concerted efforts at various levels are being made to tackle the situation and it is expected that in future there will be no interruption of production for want of raw materials.

[M/C&F O.M. No. 51012/2/75-DC dt. 20-5-77]

Recommendation No. 45 (Paras 3.27 and 3.29)

The Committee note that one of the reasons for the shortfall in vialling operations has been reported to be shortage of vials. The Committee find that HAL has been getting the vials of BP 58 specification produced by only one private sector firm situated as an ancillary unit on the land belonging to HAL. The Committee feel that agreement should have contained suitable provision for meeting the demand of the main undertaking in full and also the price to be paid for supplies should have been indicated in some detail keeping in view the cost of production and international price etc. The Committee are of the opinion that the private firm which was nurtured as an ancillary unit with all the attendant facilities, should have given priority of supplies to the main undertaking HAL according to the terms of the agreement and even if there has been any dispute about rates those could have been resolved by arbitration etc. at a later stage. The Committee fail to understand as to why no legal action was taken against the private firm by the undertaking to enforce the terms of the contract. The Committee are constrained to observe that HAL allowed a situation to develop in which the private sector company was able to hold it to ransom by interrupting supplies of glass vials and forcing it to agree to price increase just to avoid stoppage of production. The Committee are led to conclude that the agreement with the company either did not adequately safeguard the public interest or the provisions thereof were not effectively and promptly invoked. The committee would like that the agreement and the role of HAL in drawing and implementing it should be

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

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

Reply of Government

According to the terms and conditions of the established ancillary unit on the company's estate, the company invites open tenders for items required by it. This practice is followed by the company in order to assess the competitiveness of the offer made by the ancillary industry. In case the offer of the ancillary unit happens to be the lowest and they have adequate capacity, the entire order is placed on the said ancillary unit. If the offer of the ancillary unit is not the lowest, then the ancillary unit is required to supply at least 50 per cent of the requirements at the lowest reasonable prices obtained in such open tender invitation.

According to the latest agreement entered into with M|s. J. G. Glass Industries Limited in 1966, the firm is to supply vials to the company at the lowest reasonable rate received by the company as a result of tender invitation. If the quotation given by the firm in such tenders is the lowest, the firm shall supply the entire requirements of the company at the lowest quotation or in any quantity decided by the company. If on the other hand, the quotations given by the firm are higher, or if the firm had not given any such quotation, the firm shall supply to the company at least 50 per cent of the requirements of the company at the lowest reasonable price obtained in such tender invitation. Over the years, when tenders are invited for supply of glass vials, invariably only M|s. J. G. Glass Industries Limited, have been quoting for the same. Negotiations were held with the firm after receipt of tender from time to time, as a result of which, the price was reduced to a reasonable level mutually accepted, based on which the supplies were effected. However, during the pendency of the contract, the firm came up with a request for the price revision in 1973 and again in 74 on the plea that their cost of production has escalated steeply on account of abnormal increase in the prices of furnace oil, other materials and wages. Enquiries made by the company revealed that there was actually increase in the cost of their inputs particularly furnace oil and they

have also increased the prices of glass vials for other formulators. However, discussions were held with the firm with a view to avoid increase in the price and at the same time, ensure uninterrupted supplies. Efforts were also made to procure supplies of glass vials from alternative sources, but in vain. After examination of their cost data, a reasonable price increase was granted with a view to ensure continuous production. It was also ensured that the price paid by HAL to the firm was lower by about 3 per cent than what the firm charged to other formulators.

In the light of the above, the question of taking legal action against the firm did not arise. As already indicated, it was not considered in the best interest of the company to take legal action since there was no alternative source of supply from which risk purchases could have been made. Any attempted legal action may have resulted in complete closure of the formulations unit of HAL resulting in heavy losses to the company and non-availability of life saving drugs to the Government Hospitals and institutions all over the country.

This could have also forced the company to supply bulk drugs to other formulators who would have profited at the cost of HAL. It was not considered desirable that a risk of this nature may be taken. From the above, it is obvious that the Company, all long, has acted in the public interest.

The question of drawing up a model agreement is being pursued with DCSSI, who are concerned with Small Scale ancillary Units.

[Min. of C&F O.M. No. 51012/2/75-DC dt. 30-9-76]

Further information called for by the Committee

What precise action has been taken for drawing up a Model Agreement for ancillary industries?

[L.S.S. letter No. 21-PU/76 dt. 14-3-77]

Further reply of Government

A copy of the draft agreement drawn up by DCSSI for adoption by all Public Enterprises on a uniform basis for entering into contracts with their ancillary units is attached. [Not reproduced]

[Min. of C&F O.M. No. 51012/2/75-DC dt. 9-5-77]

Further information called for by the Committee

Has the draft agreement since been finalised in consultation with the Bureau of Public Enterprises?

[L.S.S. letter No. 21-PU/76 dt. 8-12-77]

Further Reply of Government

Draft copy of Model Agreement has been obtained from the Bureau of Public Enterprises. However, Agreements already entered into between the Ancillary Industries and HAL are long term and hence existing agreements would continue till its expiry period.

In future, new as well as renewals of agreements will be executed on the lines of model agreement.

(Min. of C&F O.M. No. 51012/2/75-DC 9-1-78)

Recommendation No. 46 (Para 3.30)

The Committee recommend that, since the public sector drug companies HAL and IDPL are reported to be facing considerable difficulties in obtaining the requisite quality and quantity of vials, Government should consider the feasibility of setting up captive vial making capacity with the public sector units after carefully examining the technical and financial implications thereof.

Reply of Government

It may be mentioned that both IDPL and HAL have a number of drug projects which they propose to take up during Fifth Plan and the question of having a plant only for making vials will require consideration taking into account the technical and managerial aspects. Normally, the manufacturers who produce glass vials are also manufacturing other glass articles like bottles etc. to make their operations more economically viable. Hence it is rather doubtful if the Government should insist on the Public Sector drug manufacturing units to enter the glass field also, where the technology is entirely of a different nature.

(Min. of C&F O.M. No. 51012/2/75-DC 30-9-76.)

Recommendation No. 47 (Para 3.43)

The Committee regret to observe that in spite of the heavy percentage of rejections no norms were fixed prior to 1973 and there was no system of controlling the rejection. The Committee strongly recommend that all the long term and short term measures recommended by the technical Committee, of the Corporation should be implemented scrupulously without avoidable delay so as to ensure that the rejections are minimised and in any case kept within the norms. The Committee would also like that a report about the rejections compared to the norms together with the remedial measures taken should be included as a standing item in the agenda for

*Further reply not sent to Audit for vetting.

the Board meeting so that the Board of Directors may have an opportunity of reviewing them.

Reply of Government

The following short-term measures have been implemented:—

(i) Relative humidity below 30 per cent and temperature below 26.6° are strictly maintained filling during operations;

(ii) House-keeping in the sterile area as well as in the adjoining non-sterile area has been improved by Stricter Supervision;

(iii) Spraying of disinfectants in the area is being done regularly in all the shifts to ensure absolutely sterile conditions;

(iv) Formol fumigation of sterile air-ducts leading to the filling cabinet is being done regularly to prevent contamination;

(v) Cleaning of ultra-violet tubes and intensive checkings of the same is being done-regularly to prevent microbial growth;

(vi) Absolute air filters are checked regularly and changed whenever necessary to ensure perfect sterile conditions in the filling area;

(vii) The dimensions of rubber stoppers, glass vials and aluminium seals have been changed to suit each other and these are being rigidly followed. This is to ensure that the sterile powders inside the vial are firmly protected against outside contamination.

(viii) Imported synthetic butyl rubber is substituted in place of natural rubber for manufacturing rubber stoppers as the former avoids seenage of moisture through the stoppers. Ingress of moisture not only decomposes the antibiotic powder, but can lead to contamination of the product.

As regards long-term measures, procurement action is on hand for obtaining specialised equipments for low humidity systems and they are in the advanced stage of finalisation. Low humidity system offer certain specific advantages like prevention of moisture absorption by hygroscopic products such as Sod. Penicillin G, reduces the chances of contamination by microbes, maintenance of free-flow characteristics. Efforts have been made by the company to procure

the low humidity system indigenously. Company's technical representatives visited and inspected the facilities in one of the indigenous firms who quoted for such an equipment. They also visited different pharmaceutical units where low humidity systems have been installed. The company came to the conclusion that the required units will not be available indigenously and invited global offers from foreign firms who quoted and these offers are under evaluation. Simultaneously, efforts were made to get clearance from the indigenous angle and obtain import licence. It is expected that the order will be placed soon and this equipment will take about one year for delivery. The systems will be utilised for the manufacture of bulk Penicillin as well as for formulations based on Penicillin and Streptomycin. Arrangements are being made to modify sterile air cooling zone on the tunnels of two machines in place of the existing system. Investigations are being carried out to find out suitable Laminar Flow system for vial filling operations. Discussions were held with the suppliers of glass vials and rubber stopper manufacturers and rigid specification have been laid down and these are followed closely. In addition to weekly preventive maintenance, systematic and improved maintenance has been introduced. Action has been taken for replacement of obsolete equipments like old type filling machines. Certain equipments such as two cap-sealing machines, and Norva Rubber Stopper washing machines have already been received and installed. Motors of the rubber stopper units have been replaced by new ones. Hoppers of the Accofil machines have been modified. Other equipments are expected to be received in due course.

GAS STERILISATION: In the pharmaceutical industry, sterilisation with Ethylene Oxide is in vogue in order to reduce contamination and bring down rejections. The company has made arrangements to introduce this process for its bulk Penicillin product. The required equipments and accessories have been ordered some of which have been received. Based on the present estimates, the system would be ready for operation by the end of November 1976.

As a result of taking the above measures, the average rejection rate at 4.6 per cent in 1974-75 came down to 3.98 per cent in 1975-76. The rejection rate further came down to 3.3 per cent in April, 1976 and 1.4 per cent in May, 1976. A statement at Appendix III shows the percentage rejection for vialled formulations product-wise, from which it may be seen that the rejection rate generally has come down.

(Min. of C&F O.M. No. 51012/2/75-DC 30-9-76.)

Further information called for by the Committee

Has the system of sterilisation with the ethylene oxide been introduced in November, 1976?

What is the latest position in regard to rejections?

(L.S.S. O.M. No. 21-PU/76 dated 14-3-77)

Further reply of Government

The work of Ethylene Oxide Sterilisation System could not be completed due to certain materials could not be procured in time on account of acute shortage of funds. The work is now in progress and it is expected within next three months, this could be completed. The work is in progress and is expected to be completed shortly.

However, the incidence of rejections from on formulations as well as bulks is very much under control now as could be seen from the comparative figures for the last 3 years furnished below:

Sr. No.	Product	percent of rejection		
		1974-75	1975-76	1976-77 April to Jan. 77
1.	Procaine Pen.	1·11	2·54	1·83
2.	Sod. Pen.	1·98	1·91	2·48
3.	Benzathine Pen.	Nil	0·085	0·027
4.	Pot. Pen.	Nil	Nil	Nil
5.	Fort. Proc.	0·025	Nil	Nil
6.	Streptopen. 1/2 gr.	0·05	Nil	Nil
7.	Pen. V.	6·77	3·02	1·78
8.	Streptopen. 1 gr.	Nil	Nil	Nil
9.	Benzathine Pen. Aq. Inj.	Nil	Nil	Nil
10.	Proc. Aq. Inj.		..	
11.	Sodium Pen.*	..	..	..

(Min. of C&F O.M. No. 51012/2/75-DC dt. the 9-5-77.)

Further information called for by the Committee

What is the latest position in regard to the rejection?

Is the report about the rejections with reference to norms been included as a standing item in the agenda for the Board Meeting so

*At the time of factual verification, Audit informed as follows:— "Item" not included in reply vetted by Audit.

that the Board of Directors may have an opportunity of reviewing them?

(L.S.S. letter No. 21-PU/76 of 8-12-1977.)

Further Reply of Government*

The position showing the rejection during the period April 77 to August 77 is shown below:

Sr. No.	Product	% of rejection		
		1976-77	April to August 1977	
1.	Procaine Pen.	3·00	1·64	
2.	*Sod. Pen.	2·40	8·55	*Sterile
3.	Benzathine Pen..	2·79	19·33	
4.	Pot. Pen.	Nil	Nil	
5.	Fort. Proc.	Nil	Nil	
6.	Streptopen 1/2 gr.	Nil	Nil	
7.	Pen. V.	1·77	3·85	
8.	Streptopen. 1 gr.	Nil	Nil	
9.	Benzathine Pen. Aq. Inj.	Nil	Nil	
10.	Proc. Aq. Inj.	Nil	Nil	
11.	**Sod. Pen.	Nil	Nil	**Non Sterile.

(Reasons and remedial measures taken to control high rejections during April-August 1977 are indicated below).

A report about the rejection of vialled antibiotics is included as a standing item in the Agenda for the Board Meeting to have an opportunity to the Directors for reviewing the same.

From the position of rejection of vialled antibiotics for the period April 1977 to August 1977, it could be seen that rejection was high, mainly due to following reasons.

1. Changes in testing procedure for sterility as it came into effect from 1st April 1977.

2. Environmental conditions such as relative humidity, air and temperature in the filling rooms.

*Further reply not sent to Audit for vetting.

3. Procedural lapses including inadequacy in the type of equipment used, rubber stopper sterilisation and subsequent handling.

4. Marginal sterility in the bulk.

Following remedial reasures are taken:—

(1) Sterile areas both for sub-division as well as bulk formulations, with the following requirements:

(a) Sterile bulk manufacturing areas:—

(i) Where bulks are not exposed—

Temp. 24° to 26° C RH % 45 to 55

(ii) Where bulk are exposed—such as milling, canister filling, weighing for formulations—

Temp. 24° to 26° C RH % 25 to 30

(b) Sterile sub-dividing area—

(i) In the rooms—

Temp. 24° to 26°C RH % 25 to 30

(ii) In the Filling Cabinets—

Temp. 24° to 26°C RH % 25—20

(2) Carboxide gas sterilisation of Penicillin before sub-division as well as for formulated bulks.

(3) Laminar flow for Filling Cabinets and Laminar flow over the sealing machines (downward).

(4) Inverted vial washing to be introduced. This is also recommended by FDA authorities earlier.

(5) Penicillin milling and centrifugation area in crystallisation to be properly enclosed for giving 16 air changes per hour.

(6) Tunnel cooling zone air distribution modified similar to original design of the manufacturer.

(7) Rubber Stoppering Unit to be brought nearer to Filling Machine or if a turn table in between is contemplated, then put U.V. tubes directly above vials.

(8) Wrapping rubber stopper trays with brown paper, to avoid exposure during sterilisation.

(9) To put more number of U.V. tubes in the area where sterilised rubber stoppers are stores before use. Partial action in this regard has already been taken.

(10) To supply dry sterile air to cooling zone.

(11) Storage of bulks required for filling under cool conditions. At present these are stored in washing area, which is very hot.

(12) Selection of personnel handling sterile production.

As a result of the remedial measures taken overall rate of rejection during Sept. and—Oct. 1977 has sharply declined from 18 per cent to 11.9 per cent and 18 per cent to less than 10 per cent respectively.

[M/C&F 51012/2/75—DC 9-1-78]

Recommendation No. 49 (Para 3.45)

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

Reply of Government

The recommendation is noted for suitable action.

The Department of Industrial Development are concerned with the above recommendation and it has been sent to them.

[M/C&F OM 51012/2/75—DC dt. 30-9-76]

Further information called for by the Committee

How many vial making plants have gone into production? If they have not, what action has been taken by Government on such licences.

[LSS OM 21—PU/76—DC of 8-12-77]

Further reply of Government*

There are at present following two units exclusively licensed for the manufacture of vials.

1. M/s. J. Glass Industries Ltd., Poona with a licensed capacity of 200 min. nos. of vials p.a.

2. M/s. Packart Pvt. Ltd., Baroda with a licensed capacity of 105 min. nos. of vials p.a.

*Further reply not sent to Audit for vetting.

In addition there are five other units licensed/registered and engaged in the manufacture of vials within their licensed/approved capacity for the manufacture of glass bottles, vials etc. A statement indicating licensed/installed capacity, production etc. is attached (*See* Appendix IV). It may be added that at present there is no industrial licence for the manufacture of vials as unimplemented.

M/s. Hindustan Antibiotics Ltd. and Indian Drugs & Pharmaceuticals Ltd. in their letters dated 18-4-1977 and 28-4-1977 respectively addressed to the Ministry of Chemicals and Fertilizers, have confirmed that there is no shortage of vials. Actually, capacity utilisation for the manufacture of vials is only 70 per cent on account of lack of demand.

J.G. Glass Industries Ltd., Poona have requested for approval to the diversification of their production as they are not able to utilise their full capacity for the manufacture of vials for want of demand. M/s. Mahalakshmi Glass Works Ltd., Bombay have also informed that they are not getting orders against their quotations, while their prices are comparable to the prices of imported vials.

[M/C&F 51012/2/75—DC dt. 9-1-78]

Recommendation No. 50. (Para 3.51)

The Committee are concerned to note that the spillage and overages have always been in excess of standard and cumulative loss on this account during the last 8 years was of the order of Rs. 50.33 lakhs. The Committee stress that the reasons for such spillages and overages should have been critically analysed and timely action taken to arrest such excess spillages and overages. The Committee recommend that the standards which were fixed in the initial stages should be reviewed by the R&D Wing of the company in the context of the present stage of equipments and processes and stricter standards evolved for the purpose of assessment of the efficiency of the vialling operations.

Reply of Government

The Company has fixed an average of 5 per cent *i.e.* 5 per cent extra by weight of the antibiotic powder than what is declared on the label as dosage, to ensure that no vial would contain less powder than what is declared on the label. These norms are rigidly followed. Dosages of powders filled are often as low as abaut 330 mgs. per vial and there is a limitation of the machines filling such small dosages with a narrow tolerance. The accuracy with which the machine can fill

the powder also depends upon the flow characteristic, bulk density of the material, relative humidity etc. The actual overage obtained also depends on the quantum of the dose, *i.e.* the bigger the does the closer to the limit fixed. However, constant efforts are made to restrict it to 5 per cent as already indicated. As a result of this, the actual overages are close to 5 per cent as can be seen below:—

	1974-75		1975-76	
	Pen.	Stpt.	Pen.	Stpt.
(*i*) Percentage of actual overage to standard consumption .	4·86	5·48	4·93	5·8

The Drugs (Prices Control) Order, 1970 allows an process loss 10 per cent in the case of injectable preparations and 5 per cent for tablets and capsules.

Spillages: Spillage is due to the following reasons:—

(i) Some powder falls from the filling machines outside the vial mouth, due to inexact functioning of any one of the machines, involved in the operations of, such as filling machines, sealing machines, glass vial conveyer belt, rubber stoppering machine etc.

(ii) At the beginning of each vialling operation, the machine has to be adjusted for vial filling, number of vials to be filled and the contents weighed to fix the accurate dosage. Sometimes at the end of the filling operation, some powder actually remains in the hopper of the filling machine which is collected and accounted as "Spillage".

(iii) In case of any defect in the vial filling, stoppering and sealing operations, such vials are inspected and opened out and the powder from them is collected and is also classified as "spillage".

(iv) In case of any unforeseen power failure resulting in dislocating the sterile conditions humidity, temperature, etc. all the powder in the hopper, filling, machine is taken out and is classified under "spillage".

Measures taken to control spillage

Systematic preventive maintenance of each and every machine in vial filling is carried out to ensure that all the machines function accurately. Precautionary measures are taken to ensure that there

is no failure of any parameters within the premises rendering the exposed powder non-sterile and classified as spillage. Strict care is exercised by the operative and supervisory staff to ensure correct operations and functioning equipments.

The Company has fixed 5 per cent allowance for what is termed as spillage. As a result of the concerted measures taken, the actual spillage has come down as can be seen from the statement given below:—

	1974-75		1975-76	
	Pen.	Stpt.	Pen.	Stpt.
(*i*) Percentage of actual spillage to standard consumption .	7·92	7·40	6·67	5·63

All the antibiotic powders collected due to spillage and other reasons indicated above are re-processed into finished bulk form for use in a formulation.

All the precise figures for similar norms adopted by other vialling units are not available. It is understood that their norms are similar to those adopted by the company.

As recommended by the Committee the R & D unit of the company will be called upon to review the standards fixed by the company in the context of the present stage of equipments and processes and stricter standards evolved for the purpose of assessment of the efficiency of the vialling operations.

(M/C&F O.M. No. 51012/2/75-DC dt. 30-9-76)

Further information called for by the Committee

Has any such review been conducted? If so, whether any other stricter standards were evolved. Please also furnish details thereof.

(L.S.S. O.M. 21-PU/76 dated 14th March, 1977)

Further reply of Government

This is under the active consideration of the Company and it is expected that suitable norms would be evolved with Board's approval in the near future.

(Ministry of Chemicals and Fertilizers O.M. No. 51012/2/75-DC dated the 9-5-77).

Further information called for by the Committee

Has the proposed review of the standards fixed by the Company been made?

What is the position in 1976-77?

(L.S.S. Letter No. 21-PU/76 dt. 8-12-1977)

Further Reply of Government*

(a) *Overages*: The maximum percentage allowable by the Statutory Regulations have been strictly kept in view in our Formulations Department for both the injectable and non-injectable preparations. The norms for overages constitute the product guarantee to the consumer for having a minimum of the effective drug in the given dose form. These are fixed keeping in view the normal variations that are encountered while using equipment and machinery currently in use at HAL and with other formulators. With the introduction of better technology that is being envisaged in the Formulations Plant expansion at HAL, it would be possible to control the overages and reduce the level further, while at the same time assuring dose-level uniformity to the consumer. The R&D and the Production units have had discussions with equipment manufacturers and suppliers on this very question, and hope to achieve improvements in this in their plants.

Actual overage for Penicillin and Streptomycin products for the year 1976-77 and April 1977 to October 1977 are furnished below:

	1976-77		1977-78 (April to Oct.)	
	Pen.	STPT	Pen.	STPT
Percentage of actual overage to standard consumption.	7·01	6·99	8·27	6·83

It would be observed from above that actual percentage of overage as compared to standard consumption has shown increased trend both in Penicillin and Streptomycin. This is due to the fact that existing machines in the Formulation Plant have become old and many cases of underages were noticed. Therefore, the machines have been adjusted to higher overage percentage within the pharmacopoeial standards prescribed for potency for Penicillin and Streptomycin products. HAL has also taken procurement action for modernising existing Formulation Plant.

*Further reply not sent to Audit for vetting.

(b) *Spillages*: The wastage due to spillages can be attributed to, (1) handling losses, and (2) old and warn-out equipment used in the vialling, tabletting and capsuling operations. The vialling machines at HAL are the earlier proto-types and are being replaced with more efficient and faster machines under both the renewals and replacement scheme, as well as in the setting up of the new Formulations II Plants at Pimpri. The present norm for spillage which has been fixed at 5 per cent overall, could not be maintained primarily due to the factor mentioned above. We are confident that with the installation of the newer equipment, it would be possible to drastically bring down the wastage due to spillage. The Production Department has taken several measures to cut down handling losses and constant vigilance will be maintained on this to reduce it still further. The percentage loss due to spillage during 1976-77 and for the period April 1977—October, 1977 are furnished below:

	1976-77		1977-78 (April 77—Oct. 77)	
	Pen.	STPT	Pen.	STPT
Percentage of actual spillage to standard consumption.	5·56	5.19	5·71	5·48

Min. of C&F O.M. No. 51012/2/76-PC dt. 9-1-78)

Subsequent reply of the Government£

	Overages		*Spillage*	
	Penicillin	Streptomycin	Penicillin	Streptomycin
1976-77	7.01	6.99	5.56	5.19
1977-78	8.08	7.14	5.38	5.44

[Ministry of Petroleum & Chemical's & Fertilisers O.M. No. 51012|2|75|-DC dt. 31-3-79].

Furnished at the time of factual verification.

Comments of the Committee

Please see paragraphs 28 to 32 of Chapter I.

Recommendation No. 51 (Para 3.52)

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

Reply of Government

The above recommendation has been noted for a necessary action by the undertaking.

Min. of C & F O.M. No. 51012|2|75-DC 30-9-76.)

Recommendation No. 52 (Paras 3.65 and 3.67)

The Committee were informed that the operable installed capacities of tabletting and capsulation machines these were fixed on the basis of actual trials and were lower than mechanical capacity of machines on account of lack of ancillary equipments. The Committee see no reason as to why such ancillary facilities could not have been provided along with machines so as to utilise the full capacity and why only 58 per cent of the capacity was put to effective use. The Committee are informed that these facilities have since been provided in tabletting section and new machines have been added and the installed capacity has been increased to 1800 lakh tablets and machines have been added and the installed capacity is now rated as 1248 lakhs and 137 lakhs per annum respectively. The Committee do not see the rationale behind fixing the operable capacity at a reduced figure even after addition of new machines and facilities and stress that concentrated measures should be taken to ensure full utilisation of the installed capacity for tabletting and capsulation.

Reply of Government

As against the installed capacity of 1800 lakh tablets per year, the operable capacity was earlier rated as 1248 lakh tablets per year. The company has been further measures to increase the operable capacity to installed capacity and these are as follows:—

TABLETS: In case of Penicillin 125 mg. tablets, the company has realigned the drying facility and improved the operation of vacuum oven as a result of which the capacity of 240 lakhs tablets per annum has been raised to 720 lakhs tablets per annum: In case of Vitamin C 100 mg. tablets, certain formulation details are changed and granulation and drying facilities are relocated in November, 1975. As a result of this, operable capacity of this product is now 1080 lakhs tablets per annum. Thus the total tableting capacity at present is 1080 lakh tablets per annum.

CAPSULES: The limitation in capsulation capacity was in getting proper quality capsules from indigenous suppliers. A constant dialogue was maintained between the manufacturers of the capsules and company's technical staff as a result of which a source of supply of capsules has been developed which can work on the automatic machines. Secondly, as a result of certain modifications in the formulations, the capacity has now come to 144 lakh capsules per annum.

As regards the actual utilisation of capacity in the case of Vitamin C, the biggest constraint is availability of the bulk material from the company's own Vitamin C plant in which production is yet to be stabilised. While efforts are being made to augment production in this plant, arrangements have been made to obtain Vitamin C bulk from canalisation sources, and higher capacity of tabletting is expected to be utilised during the year 1976-77. As regards utilisation of capsulation capacity, here again, the biggest constraint is the availability of bulk Tetracycline Hydrochloride from the canalisation sources because of paucity of funds to purchase the released bulk Tetracycline Hydrochloride, since the company has to pay in advance for such purchases on the other hand, the process of capsulation, distribution to Government hospitals/institutions and realisation take about 4 months. This situation will improve as the company's working results become viable. Hence, during the course of the year, the company expects to utilise bigger capacity for both tabletting and capsulation. There has been definite improvement in the utilisation of tablets in the year 1975-76 as compared to 1974-75; while the utilisation of capacity of capsules remain more or less the same due to the constraints already indicated. The actual production figures of tabletting and capsules are given below:—

(All figures in lakh Nos.)

Year	Product	Actual production	Percentage utilisation of capacity
(1)	(2)	(3)	(4)
1974-75 . .	Tablets	149·62	8·31
	Capsules	75·73	52·59
1975-76 . . .	Tablets	416·61	23·16
	Capsules	71·48	49·62

Air conditioning facilities have been installed.

(Min. of C&F O.M. No. 51012/2/75-DC dt. 30-9-76)

Further information called for by the Committee

What are the actual production figures of tabletting and capsules and percentage utilization of capacity during 1976-77?

(L.S.S. letter No. 21-PU/76 dt. 8-12-1977.)

Further Reply of Government

Actual production figures of Tableting and Capsules and percentage of utilization of capacity during 1976-77 is given below:

Year	Product	Actual Production (in lakhs Nos.	Percentage utilisation of capacity
1976-77	Tablets	353·66	19·65%
1976-77	Capsules	258·24	67·19%

[Min. of C&F O.M. No. 51012/2/75-DC dt. 9-1-78.]

Comments of the Committee

Please see paragraphs 33 to 37 of Chapter 1.

Recommendation No. 53 (Para 3.68)

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

Reply of Government

The Company have been considering proposals to increase the market force and the Board has approved in 1976 to increase the strength of the marketing organisation in a phased manner. With

*Further reply not sent to Audit for vetting.

the increase in sales force and with better productivity of the company, it is expected that HAL would be able to enter the market with a better impact.

The Board of Directors have been examining the constraints and would go deeper into them as regards the marketing of tablets and capsules and the further reasons for the under utilisation of their capacities.

[Min. of C & F O.M. 51012/2/75-DC dt. 30-9-76.]

Further information called for by the Committee

What precise action has been taken on this recommendation?

[L.S.S. C & F O.M. 21-PU/76 dt. 14-3-1977.]

Further Reply of Government

The Board approved 30 posts to be filled in, a phased manner in their meeting held in November, 1976, the details of which are as under:—

Posts	Sanctioned	Filled
Sales Representatives	20*	10
Depot Supervisor	4	
Asstt. Store Keeper	1	1
Agricultural Assistant	1	1
Junior Stenographer	1	1
LDC—Typists	3	

(*These should be responsible for sales and sale collections).

Considering higher output and with a net sales target of Rs. 14 crores for the year 1976-77 and Rs. 16 crores for the year 1977-78, it was felt that it would be necessary for the company to enter the trade to achieve these targets. With this view in mind, the Board approved the above referred posts as a part of HAL's marketing organisation.

Percentage of sale of capsules and tablets during the year 1976-77 were 6.701 per cent and 6.89 per cent respectively to net turnover of Rs. 1380.45 lakhs subject to adjustment and percentage sale of capsules and tablets, it is estimated, would be 8.83 percent and 9.95 per cent respectively to net turnover of Rs. 1644.40 lakhs during the year 1977-78.

In the last quarter of 1976-77, with improved availability of bulk for tableting and capsuling, the utilisation of capacity was very much improved as per figures shown below:—

	Tablets		Capsules	
	Capacity	Actual prodn.	Capacity	Actual prodn.
	lacs per month	lacs	lacs per month	lacs
January 1977	150	28·84	32	32·45
February 1977	150	32·55	32	42·38
March 1977	150	40·79	32	77·89

It is expected that in the current year i.e., 1977-78, the utilisation of capacity would be better.

[Min. of C & F O.M. No. 51012/2/75-DC dt. 20-5-77.]

Comments of the Committee

Please See paragraphs 33 to 37 of Chapter 1.

Recommendation No. 54 (Para 3.69 to 3.71)

The Committee regret to note that in spite of the fact that vialling, tableting and capsuling capacities had been underutilised, the quantities issued for vialling and tableting have been less than the quantities produced. The Committee regret to note that while on the one hand the undertaking was not utilising its vialling and capsulation/tableting capacity in full, on the other hand it had been cancelling orders in various years due to inability of the Company to meet the demand for formulations. The Committee regret to observe that in spite of formulations being a profitable proposition, the undertaking did not make any attempt to increase the capacity for formulations. The Committee are doubtful whether this underutilisation of capacity was deliberate and they would like that this matter should be critically gone into. In this connection, the Hathi Committee on Drugs and Pharmaceutical Industry have recommended in April, 1976 that at least 60 per cent of bulk drugs produced by the Public sector industry should be formulated by itself and in the disposal of the remaining 40 per cent first preference should be given to meet the needs of the Indian Sector particularly the small scale/units.

The Committee are informed that the Government have accepted these recommendations of Hathi Committee. At the present moment the Company has the capacity to formulate 45 per cent but it

is operating this capacity either for Penicillin or for Streptomycin, depending on which more advantageous to formulate. They would like HAL to investigate the constraints on the optimum utilisation of the existing formulation capacity, take conclusive measures to remove these constraints and ensure that not less than 60 per cent of production is utilised for formulations.

Reply of Government

Prior to the establishment of Hindustan Antibiotics Limited, in 1954, bulk Penicillin and Streptomycin were being imported and utilised by viallers for formulations. After HAL started basic manufacture of Penicillin and Streptomycin sulphate, the import of these antibiotics was progressively reduced and HAL supplied these antibiotics in bulk to different viallers in accordance with the allocations made by the Government. While allocation of Penicillin was discontinued in 1966, the subsequent distribution of Penicillin to formulators continued. The allocation of Streptomycin Sulphate by Government still continues. Even prior to undertaking the manufacture of bulk Penicillin and Streptomycin, HAL commenced formulations of these antibiotics. HAL progressively increased these capacities as can be seen from Appendix V. The quantities of different bulk antibiotics used for captive consumption by HAL and that made available to different viallers during the four-year period 1972-73 to 1975-76 is given at Appendix VI. It can be seen from this annexure that by and large, cent per cent of the bulk drugs produced in the case of Benzathine Penicillin, Ampicillin and Vitamin C have been utilised for captive consumption and the percentage of bulk drugs used for captive consumption in the case of Penicillin and Streptomycin is around 40 per cent and the balance of around 60 per cent sold to viallers. This percentage has been attained by progressively increasing the formulation capacity of HAL in consonance with the increase in the capacity of bulk drug products. For example, the vialling capacity which stood at 150 lakhs vials per annum in 1955 was progressively increased to 600 lakh vials per annum, i.e. 400 per cent increase by 1964. Similarly increase took place in the capacities in the case of tablets and capsules. Constant efforts are being made by the Company to increase the quantum of formulations as can be seen from the fact that in the year 1975-76 the output of filled vials has gone up by 20 per cent over that in the previous year. The output of vials during April—June, 1975. Similarly, the output of capsules and tablets has gone up 117 per cent in 1975-76 as compared to the previous year. The company has approached the Government for further expansion in the formulations capacity and the revised feasibility report entailing an investment of

Rs. 4.46 crores is under consideration of the Government. With the establishment of these additional capacities in formulations. HAL expects to formulate about 60 per cent of the bulk drugs manufactured by it taking into account the enhanced bulk production capacities contemplated under the Fifth Five-Year Plan. This is also in line with the recommendations of the Hathi Committee that the public sector should formulate atleast 60 per cent of its bulk products.

[Min of C & F O.M. No. 51012/2/75-DC dt. 30-9-76.]

Further information called for by the Committee

What has been the captive consumption of different products in 1976-77?

[L.S.S. letter No. 21-PU/76 dt 8-12-1977.]

Further Reply of Government*

Quantities of captive consumption for different products in the year 1976-77 is indicated as below:—

Sr. No.	Product	Unit	1976-77			
			Qty. used for captive consumption	Percentage	Qty. sold to formulators	Percentage
1.	Penicillin G	mmu	24·38	43·57	31·57	56·43
2.	Penicillin V Pot.	,,	6·17	43·39	8·05	56·61
3.	Benzathine Pen.G.	,,	4·29	100	Nil	Nil
4.	Streptomycin Bulk	kg.	39765	43·30	52068	56.79
5.	Vitamin C Bulk	kg.	1532	100		
6.	Ampicillin	kg.	839	100	..	..

[M/C&F-DC 51012/2/75-dt. 9-1-78]

Additional reply of Government

Government have approved the expansion of Formulation capacity of HAL as follows:—

(i) Formulation plant II involving outlay of Rs. 309.03 lakhs.

(ii) Joint Venture formulation units in association with State Governments/State Government Corporations in

(a) Karnataka.

*Further reply not sent to Audit for vetting.

(b) Maharashtra near Nagpur—each involving outlay of Rs. 283.86 lakhs.

With the establishment of these formulation units, HAL will be utilising 60 per cent of their production of bulk drugs.

[Min. of C&F O.M. No. 51012/2/75-DC dt. 1-12-1978]

Comments of the Committee

Please see paragraphs 38 to 45 of Chapter I.

Recommendation No. 55 (para 3.84 to 3.91)

The Committee note that major portion of the total production of different products of Hindustan Antibiotics Limited (HAL) is sold in bulk form to private viallers, although sale in vialled formulations was more profitable than sale in bulk. They are unable to appreciate why the company has not been fully utilising its vialling capacity and why it cancelled orders for formulations and why the Government thought that they "had also an obligation to supply the bulk drug to private viallers" even though the bulk sales has been substantial factor contributing toward losses which the Company has been sustaining currently.

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

The Committee recommend that the company should identify such of the formulations which are a losing proposition and critically go into all the factors which have been affecting the profitability on formulations so as to take suitable remedial action without further delay. Since the cost of formulation also depends on the cost of bulk drugs, the Committee recommend that the undertaking should

take concerted measures to bring down the cost of bulk production, the cost of vialling and elimination of all wastages and heavy rejections by stricter management controls. They would like this matter to be included as a regular item of the agenda at the meetings of the Board of Directors so that it receives contemporaneous attention and effective measures are taken to bring down the cost of production of bulk and formulations.

The Committee note that the cost of production of bulk in most cases exceeds the selling price which is fixed for them with the result that the private viallers find it an attractive proposition to purchase bulk from HAL and to make formulations therefrom and this gives them a better margin of profits.

In this connection, the Hathi Committee have recommended that if the multinationals are to continue in the field of drug production, they should continue under certain disciplines and should be required to go into bulk production and to give at least 50 per cent of their bulk production to associated formulators. These recommendations are stated to be under the consideration of the Government. The Committee would like the Government to take an early decision in the matter so as to ensure that the public sector does not have to continue to supply bulk products to formulators, more particularly foreign drug companies at a loss to itself and the Committee informed of the decision taken in the matter within three months of the presentation of the Report.

Reply of Government

The manufacture of bulk drugs is both capital intensive and technology oriented. Before the public sector projects were set up, the country was mostly dependent on import of bulk drugs and formulating them in India. The Public Sector projects were set up with the main object to produce some of the essential bulk drugs so as to achieve a measure of self-reliance and to reduce undue dependence on imports. After HAL started basic production of penicillin and streptomycin, the import of these antibiotics was progressively reduced and HAL supplied these bulk antibiotics to different viallers (formulators) in accordance with the allocations made by Government. While allocation of penicillin by the Government was discontinued in 1966, the subsequent distribution to formulators by HAL continued. In 1970, along with the system of canalisation to chemicals including drugs through STC, the system of distribution of bulk drugs which are on the production programme of IDPL also commenced through IDPL. Streptomycin was one of the drugs imported by STC and distributed through IDPL. It may

be mentioned that after a drug is canalised for imports, it becomes essential for the Government to ensure supply to non-associated formulators who are licensed for its manufacture and imports are arranged only for such quantity as it necessary to meet the demand. This explains the responsibility of Government or the Public Sector Unit to supply bulk drugs which are not formulated by them to viallers (formulators). The Government through its mechanism of licensing has over a period of time created formulation capacity for various items. The formulators of such items having installed capacities for those items involving financial investment are entitled to secure the bulk drug in accordance with Import Trade Control Policy in force from time to time. Whenever the production of bulk drug is commenced either by Public Sector or Private Sector, in the country, the responsibility of supply of such bulk drug to formulators shifts from imports to indigenous producers. This has happened in the case of HAL also. Since this is the policy of Government, we feel that the question of either not adhering to "obligation" or fixing the responsibility does not arise.

HAL could not utilise its vialling capacity mainly because of their inability to meet the orders for formulations due to the difficulties encountered in the production of formulation which are indicated below:

(a) Obsolesence of equipment;

(b) Limited availability of Rubber Stoppers; and

(c) Problems connected with humidity in vialling operations.

There was no desire on the part of the Company to make available their bulk drug to other formulators.

The question of under-utilisation of capacity of HAL was looked. According to the manufacturers, the vial-filling mechines had a capacity of 48000 vials per shift of 8 hours actual working. This question was looked into earlier by Government and it was felt that the capacity of filling machine could be 36000 vials per shift on the basis that the machine works for 6 hours continuous'y without any interruption. Again the capacity utilisation is strictly governed by the availability of glass vials, rubber stoppers and aluminium seals strictly within the rigid tolerances prescribed, the conditions of relative humidity, temperature and sterility remaining within certain rigid parameters throughout the year despite wide variations in the climate and the bulk antibiotics of certain flow characteristics being available. Unlike in the case of non-parenteral drugs, it has to be ensured that in the case of each and every injectible vial, all the

above conditions are available within the rigid limits stipulated. However, in actual practice this was not feasible within the rigid limitations stipulated and hence there was shortfall in the actual output and resultant under utilisation of capacity. On the basis of the experience gained by the company over a number of years it has been found that average capacity of 25000 vials per shift including multidose vials in attainable and on this basis the actual capacity utilised is given in Appendix VII.

A committee of Directors is being asked to look into utilisation of vialling capactiy/formulation capacity and to submit a report to the Government as soon as a new Board is constituted for 1976-77. As regards indifference to the need to augment formulation capacity the expansion of the company in various areas has been undertaken in accordance with plan provisions, which in turn are based upon market needs and capability of the company to produce and sell its products. However, the Committee of Directors will be asked to go into this aspect also and to state whether there has been any failure on the part of the Company in this regard.

The Company had also taken various measures to meet the output of vials and these are indicated in Appendix VIII.

As recommended by the Committee, the Company had also identified such of the formulations which are losing propositions. In this process penicillin G sodium 5 lakhs, procaine fortified with sodium 4 lakhs units, streptomycin one gr., strepto-penicillin 1 gm. and strepto-penicillin 1/2 gram were found to be not profitable and were dropped from its production range. The company is making all efforts to bring down the cost of production of bulk drugs as well as formulations by stricter management control. The company has already introduced since April 1976, improved strains and technology obtained from m/s. Toyo Jozo of Japan. Through these strains and technology productivity up to 26000 u/ml. of penicillin has been obtained in the main plant in trial batches as against the average of 7000 u/ml. obtained by the company over the past 3 years for penicillin. With the increase in productivity of penicillin, the cost of production will go down substantially. In the case of streptomycin through the introduction of improved technology, the company has achieved full capacity utilisation of 7.5 tonnes per month or 90 tonnes p.a. and this will bring down the cost of production appreciably.

The company has been asked to keep the Board of Directors informed from time to time, the measures taken towards increase in production, reduction in the cost of production, profitability, etc.

The Hathi Committee's recommendation that multi-national firms should make available 30 per cent of their bulk drug production to non-associated formulators is already being implemented by Government. As a rule manufacture of formulations is not permitted to the foreign Companies unless the concerned bulk drug is also manufactured by them. In the case of Public Sector, the Hathi Committee has recommended that 60 per cent of the bulk drug production should be formulated by themselves. On the basis of this recommendation Government propose to establish formulation plants through IDPL and HAL as well as Joint Sector Units in various states to implement this recommendation. It is expected that by the measures taken by HAL for the fuller utilisation and increasing formulation capacity for the manufacture of vials, capsules, tablets etc. it should be possible for the company to formulate 60 per cent of their bulk drug production in the very near future.

[Min. of C & F O.M. No. 51012/2/75-DC dt. 15-9-1976.]

Further information called for by the Committee

1. (a) When was the Committee of Directors appointed?

   (b) What are the terms of reference of the Committee?

   (c) When is it expected to give the Report?

   (d) If the Report has already been submitted, what are the main recommendations of the Committee and what action has been taken thereon?

2. It has been stated that the Company is making all efforts to bring down the cost of production of bulk drugs as well as formulations by stricter management control. Please state the specific steps taken in this regard.

3. Please state the steps taken for improving production/productivity—also state the results achieved so far as a result of these steps.

4. When were matters regarding measures taken towards increase in production, reduction in the cost of production, profitability, etc. placed before the Board of Directors of HAL and what were the reactions of the Board.

[L.S.S. O.M. No. 21-PU/76 dt. 22-9-1976.]

Further Reply of Government

The Board of Directors consisting only of officials has been so far constituted for the year 1976-77 and the point raised by the Committee is being sent to the Managing Director for placing it before the

next meeting of the Board of Directors for constituting a sub-committee, to enquire and report to Government through the Board of Directors on the following terms of reference:

(i) Reasons for under-utilisation of formulation capacity, *viz.*, vials, tablets and capsules in the HAL Plant;

(ii) Fixation of installed capacities that could be attained in regard to the formulations for various categories;

(iii) Whether there was any deliberate under-utilisation of capacity by the company and if so, who is responsible for such under utilisation.

(iv) Any other matters pertaining to the above.

The Board of Directors will be requested to submit the report within three months.

2 and 3. The specific steps taken to bring down the cost of production of bulk drugs as well as formulations and also for improving the production/productivity are as follows:—

(a) The induction of high-yielding strains and technology obtained from M/s Glaxo. of U.K. has ensured full utilisation of the capacity and the output of streptomycin sulphate. The production during January-August 1976 was 56 tonnes representing 100 per cent utilisation of the capacity.

(b) As a result of introduction of high-yielding strain and technology obtained from M/s. Toyo Jozo of Japan, it has been possible by the company to obtain with minor modifications over vigorous efforts are being made to complete the project for attaining about 300 per cent increase in the productivity in the plant.

With this, the company will possess some of the best technology in the field of penicillin and streptomycin available in the world. As penicillin and streptomycin in the form of bulk and formulation constitute over 95 per cent of the sales turnover of the company, the induction of new technology coupled with other measures to ensure full utilisation of installed capacities of these antibiotics, will improve the working results of the company during the year 1976-77. It is expected that the company will break-even during this year.

(c) Towards improved capacity utilisation of the company has implemented an action oriented production plan and adopted the systems approach in plant preventive maintenance. The latter has brought about a significant reduction in plant breakdown. Steps have also been taken to remove the bottlenecks and constraints in production. This also has resulted in better utilisation of capacity in the manufacture of bulk penicillin and streptomycin.

(d) HAL has also taken concerted action to increase the output of vials and other non-parenteral formulations where by the output of injectable vials filled during 1975-76 went up to 522 lakhs which was 20 per cent higher than that obtained during the previous year. The improved performance in vialling has been pursued on a much more vigorous scale during the current year which enabled the company to fill 292 lakhs of vials during April-August 1976 representing 116 per cent utilisation of vialling capacity.

To improve its profitability, the company commissioned a new formulation unit to enhance the output of tablet and capsules which are more profitable then bulk sales and implemented a time-bound programme for effective utilisation of formulation capacity. During 1975-76 a cumulative output of 488 lakhs of tablets and capsules was obtained which represents 108 per cent higher production than what was achieved during the previous year. The total output of tablets and capsules during the period April-August 1976 was 164 lakhs which is 39 per cent more than the production attained during the corresponding period of the previous year. In view of the higher output of vials and other formulation, HAL utilised higher quantum of the bulks for its own captive requirements and made available higher volume of formulations to its institutional customers.

(e) Apart from the area of preventive maintenance the company is adopting systems approach in inventory management and manpower deployment. Manpower assessment has been done for the whole organisation which has shown surplus strength. Accordingly, further recruitment in categories where there is surplus strength has been frozen. The average sale per employee has also registered a rise to Rs. 0.37 lakhs during 1975-76 from Rs. 0.26 lakhs during preceding year.

(f) A new orientation has been given by the R & D Wing and distinct project groups have been formed on the basis

of time bound projects. A close liaison is being maintained between production and R&D to resolve outstanding production problems.

(g) The company has taken several measures to tone up discipline and improve security. More than 70 persons have been removed from services on charges of indiscipline, chronic absenteeism, etc. Central Civil Service Rules have been made applicable to the officers of the comany.. Financial and Administrative powers have also sub-delegated to the officers for smooth conduct of business. These measures have shown impressive results particularly after emergency. In pursuance of the Prime Minister's 20 Point Economic Programme shop floor committees have been constituted to facilitate worker participation in management and bring improvement in production and productivity with the active involvement of shop floor workers. This has motivated the employees to offer some valuable suggestions and these have been implemented.

The Company has also launched an extensive drive to effect economy in major materials like Furnace oil, solvents, etc., and obtained encouraging result.

4. Review of (a) Production and sales performance of the company.

(b) Implementation of the preventive maintenance schedules,

(c) Inventory control position, and

(d) Overall working results and profitability forms regular item during each meeting of the Board of Directors of HAL. Thus, any improvement in production and productivity or in the cost of production is brought to the notice of the Board regularly. The Board of Directors review these aspects and lay down further measures in certain cases towards further improvements. The Board has expressed their satisfaction on the recent improvements effected as a result of improvement in strain and technology, adopting system approach and enforcement of discipline

[Min. of C&F O.M. No. 51012/2/75-DC dt. 11-10-76.]

Further information called for by the Committee

Has the Sub-Committee of the Board of Directors enquiring into reasons for under-utilization of formulation capacity completed its investigation? If so, what are its findings?

[L.S.S. letter No. 21-PU/76 dt. 8-12-1977.]

Further Reply of Government'

A Sub-Committee of the Board of Directors will be constituted in the next meeting of the Board to enquire and to report to Government through the Board of Directors in respect of the terms of reference indicated in Government's letter No. O.M. No. L—51012 (2)/75-DC dt. 11-10-1976.

[Min. of C&F O.M. No. 51012/2/75-DC dt. 9-1-78.]

Additional Reply of Government

The Sub-Committee of the Board of Directors to enquire into the reasons for under utilisation of formulation capacity has submitted its report, a copy of which is attached. (*See* Appendix IX) The company is making all efforts for improved utilisation of formulation capacity.

[Min. of C&F O.M. No. L-51012/2/75-DC dt. 1-12-78.]

Comments of the Committee

Please see paragraphs 46 to 49 of Chapter I.

Recommendation No. 57 (Para 5.7)

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

Reply of Government

It may be observed here that bulk Penicillin or Streptomycin are not offered to the trade but only to the viallers and other formulators

for formulation purposes. The position in respect of bulk penicillin and Streptomycin is indicated below:—

2. *Penicillin*: The capacity utilisation of Penicillin plant of HAL between 1963-64 to 1975-76 ranged 71 per cent to 106.33 per cent despite constraints on account of non-availability of raw materials, power shortage and fluctuations and paucity of working capital. The company has entered into a collaboration with M/s. Tayo Jozo company of Japan for the supply of highyielding strain and technology for Penicillin. This new technology is in the process of establishment, in the plant, and is expected to enable the company to produce Penicillin beyond the approved capacity by adding certain balancing equipments and to bring down the cost of production considerably. The company has also submitted proposals to the Government for expansion of Penicillin production from the existing 84 mmu to 160 mmu and these are under the active consideration of the Government. With the completion of the expansion project, the share of bulk drug production will go up considerably.

3. *Streptomycin*: The capacity utilisation of Streptomycin plant by the company during the period 1963-64 to 1975-76 ranged between 76 per cent to 104 per cent despite non-availability of certain raw materials, power shortage and fluctuations and paucity of working capital. The company has acquired a high-yielding strain from M/s. Glaxo Limited, U.K. and established the technology in the plant, as a result of which the production of streptomycin during the period of January-August, 1976 was 56 tonnes, which is a much higher utilisation of the capacity at a lower cost. The company has submitted proposals to the Government for expansion of capacity from 85 tonnes to 160 tonnes which are under the active consideration of Government. After the completion of this expansion, the company share of production will go up considerably.

[Min. of C&F O.M. No. 51012/2/75-DC dt. 30-9-76.]

Further information called for by the Committee

When were the proposals for expansion of Penicillin and Streptomycin plants submitted to Government? What is the latest position in this regard?

[L.S.S. O.M. No. 21-PU/76 of 14-3-77.]

Further Reply of Government

This refers to Penicillin expansion and Streptomycin expansion projects submitted as a part of Fifth Five Year Plan projects. These projects were submitted as a profile in 1973. These were revised from time to time as desired by Government and a fresh feasibility report was submitted in September—October, 1975. These projects were considered along with the proposals of IDPL for expansion in similar items and were approved by the PIB in their meeting held on 17th December 1976. Government's sanction to these projects has also been issued *vide* Ministry of Chemicals and Fertilizers on 26th February, 1977 after taking the approval of the Cabinet.

[Min. of C&F O.M. No. 51012/2/75-DC dt. 9-5-77.]

Recommendation No. 58 (Para 5.18)

The Committee also note that even the total sales has only increased marginally from Rs. 712.97 lakhs in 1967-68 to 748.90 lakhs in 1974-75. But the sale expenses have nearly doubled from Rs. 19 lakhs in 1967-68 to Rs. 33 lakhs in 1974-75. The Committee cannot appreciate the phenomenon of rising sales expenses *vis-a-vis* declining sales and why strict watch was not kept on this aspect. They would like HAL Government to analyse the various factors comprising the sales expenses and the reasons for the increase under any or all the items so that suitable action may be taken to effect economics in sales expenses.

Reply of Government

A detailed analysis of the various factors comprising HAL's expenses has been carried out, and is given below:—

	1967-68	1974-75	1975-76
	(Rs. in lakhs)		
Wages (including C.P.F. etc.)	3·08	11·66	11·82
Rent . .	0·73	1·01	1·38
Freight . .	5·11	4·17	6·88
Packing	4·76	5·53	6·60
Others—Travelling expenses, postage, telegrams, advertisement, samples etc. . . .	6·40	10·83	12·08
Total Expenses . .	19·08	33·20	38·76
No. of employees	67	89	87

It can be seen from above that major increase was due to escalation in the wages on account of increase in the Cost of Living Index and increase in wages and allowance on account of revision of the wages and allowances to the employees in general in 1973. For example, increase in sales expenses in 1975-76 as compared to 1967-68 was 19.68 lakhs, out of which the increase due to wages close amount to about Rs. 8 lakhs. Making allowance for the addition of 20 per-cent to the sales organisation, the increase in wages and allowances for the same number of persons during the above period works out to Rs. 6.54 lakhs. There was some increase in the rental or account of adding one more Depot at Bangalore as well as upward revision in the rate of rent. Some increases were also due to increase in frieght rates, packing charges, etc., during the period.

However, as a result of increase in the volume of sales, the percentage of selling expenses to total turnover in 1975-76 has come down to 3.74 per cent as against 4.46 per cent in 1974-75.

[Min. of C&F O.M. No. 51012/2/75-DC dt. 30-9-76.]

Further information called for by the Committee

What is the percentage of selling expenses to total turnover in 1976-77?

[L.S.S. O.M. No. 21-PU/76 of 8-12-77]

Further Reply of Government*

Percentage of selling expenses (Rs. 47.21 lakhs) to total gross turnover (Rs. 1523.22 lakhs) in the year 1976-77 works out to 3.09.

[Min. of C&F O.M. No. 51012/2/75-DC dt. 9-1-76.]

Recommendation No. 60 (Para 5.25 to 5.27)

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

The Committee are informed that the company is now not offering higher discount against tenders and even when higher discounts were offered in certain cases, parties who used to place direct orders were in a more advantageous position as they were entitled to a uniform discount on all products. The Committee would like that the new arrangements are kept under continuous and constant review and modified if necessary in the best interest of Undertaking and Government institutions.

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*Further reply not sent to audit for vetting.

Reply of Government

Most of the formulations manufactured by the Company are sold directly to various Government Institutions/Hospitals all over the country. As far as purchases by Central Government Institutions are concerned, these are normally governed by the DGS&D contract, which is operated either on rate contract basis or on quantity contract basis. As regards sale of formulations to the State Government Institutions/Hospitals, there is no uniform pattern, and each State has got its own system of procurement, and the company tenders for the same. However, the company has been endeavouring to supply formulations at uniform prices all over the country on the basis of an understanding with other public sector undertakings, *viz.*, Indian Drugs and Pharmaceuticals Limited, in this regard. The company has also been making efforts to prevail upon the various State Governments to place their orders directly on HAL without calling for tenders, quotations, etc. and some states like Tamil Nadu, Madhya Pradesh and Andhra Pradesh have already started placing orders without calling for tenders, quotations etc.

The company sells, in many cases, its formulations to various Government Institutions and Hospitals against open tenders. The company has to offer varying rates of discounts from time to time and from product to product to be able to secure the orders on a competitive basis. Some State Government Institutions/Hospitals also place orders for various formulations on the company directly. It is ensured by the company that prices offered to such Government Institutions/Hospitals are comparable to those offered by the company to other State Government Institutions/Hospitals purchasing against open tenders. In fact, the prices offered by the company to other Government Institutions/Hospitals who place orders directly on the company, or to those who purchase their requirement through open tenders, are uniform.

[Min. of C&F O.M. No. 51012/2/75-DC dt. 30-9-76.]

Recommendation No. 62 (Paras 5.54 and 5.55)

The Committee note that the Company entered the export market from 1965-66 under a commitment made to Government in 1962 in consideration of release of fee foreign exchange amounting to Rs. 34 lakhs for streptomycin expansion project. Though it was obliged to export products worth Rs. 34 lakhs the Committee regret to observe that the Undetaking had not been able to fulfil the commitment and till 1974-75 it had exported products worth only Rs. 11.14 lakhs and that too resulted in a loss of Rs. 3.66 lakhs. The Committee need hardly stress that profit or loss should be reckoned on the

total price and not separately on fixed or variable cost. The Committee also do not appreciate the justification sought to be given viz. that domestic market was also not favourable and the company was to lose either in exports or in domestic sales. If so, the committee fail to understand as to why the offer of the Ministry to get a waiver of the legal obligation to export was not availed of. The Committee are surprised to note that while, on the one hand, Penicillin G and Streptomycin are being imported in bulk for being converted into vials to meet the internal demand, on the other hand, HAL has been exporting its vialled products at a loss.

The Committee recommend that Government should review its orders of 162 and consider revising them suitably so as not to put the undertaking into losses in the fulfilment of its export obligations. The Committee also stress that so long as the country is dependent on imports for the essential drugs, the company would do well to concentrate all its marketing efforts on sales in the domestic market and after establishing a name in domestic market for formulations consider extending its sales activities in foreogn markets.

Reply of Government

As recommended by the Committee, Governnient will review the conditions imposed on the company in 1962, keeping the request of the company when received. Government will also need to consider the possiblility of exports by this company, after the production of the bulk antibiotics has been established following the induction of the improved strains and technology recently acquired by them. It is accepted that in general, exports should be only after meeting the internal requirements of the medicines.

[Min. of C&F O.M. No. 51012/2/75-DC 30-9-76.]

Further information called for by the Committee

Has this review been conducted?

[LS.S. O.M. No. 21-PU/76 dt. 14-3-77.]

Further Reply of Government*

Government has written to HAL that HAL may not export its product at a loss, HAL has since approached Government for waiver of the Export Committee of Rs. 18.72 lakhs remaining unfulfilled amount of the total commitment imposed on it in 1963. This is under consideration of Government.

[Min. of C&F 51012/2/75-DC 9-5-77.]

Further information called for by the Committee

Has the request of HAL to waive the export commitment been considered by the Government? If so, what is the present position?

[L.S.S. letter No. 21-PU/76 dt. 8-12-77]

Further Reply of Government*

The request of HAL to waive the balance of export commitment was considered by Government and the Government sanctioned waiver export commitment under its letter No. L-35011(1)/77-DC dated 27-9-1977, from Ministry of Chemicals and Fertilizers, New Delhi a copy of which is reproduced below. (*See* Appendix X)

[Min. of C&F O.M. No. 51012/2/75-DC dt. 9-1-78.]

Recommendation No. 63 (Para 5.56)

The Committee are not aware as to how M/s. Unichem were selected for exporting the products of the company and whether any offers of other companies in this regard and their terms and conditions were examined. The Committee would like that this matter should be investigated by Government to see how far the terms and conditions and arrangements with M/s. Unichem have subserved the interest of the undertaking and whether HAL products are not being sold under the Unichem's brand names.

Reply of Government

The recommendation has been accepted and will be enquired into through the Board of Directors.

Further information called for by the committee

Has the enquiry been completed? If so, what are the findings and what action has been taken thereon?

[L.S.S. OM No. 21-PU/76 dated 14-3-77]

Further reply of Government

The Board of Directors has gone into the question of arranging export of HAL's product through UNICHEM in their meeting held in March, 1977, and its findings are reproduced below:

The Committee have raised three points: (i) how M/s. Unichem were selected for exporting the products of the company; (ii) how far the terms and conditions of the arrangements with M/s. Unichem have subserved the interests of the Undertaking; and (iii) whether

*Further reply not sent to audit for vetting.

HAL's products were not being sold under M/s. Unichem's brand name. In so far as the first question is concerned, M/s. Unichem were not selected by HAL, it was M/s. Unichem who approached HAL with an export offer. M/s. Unichem has negotiated export orders with certain countries, and they wished to include vialled antibiotics which they were not producing themselves. They, therefore, approached HAL with an offer to include antibiotics produced by HAL in their export plan. HAL for its part had an export commitment of Rs. 34 lakhs arising out of certain capital goods licences for the Streptomycin plant, and had not made much headway in fulfilling that commitment. The management of the company felt that it would be difficult for the company to make a break through in the field of experts on its own, and they felt therefore that the offer of M/s. Unichem should be availed of. This was also approved by the Board.

As regards the term and conditions of the arrangement, the Board finds that there was no formal agreement but letters had been exchanged by HAL and Unichem. Boardly speaking, the arrangement was that HAL would supply its antibiotics to Unichem for export purposes at international prices and would receive in addition to that price 60 per cent of the R.E.P. import entitlement obtained by Unichem on the exports. The balance 40 per cent of the import entitlement as well as the cash subsidy on the exports would be retained by Unichem. This arrangement was no doubt some what weighted in favour of Unichem. However, considering that HAL had no experience in the export market, that at the time when Unichem approached them, they had been able to effect exports only to the extent of Rs. 85,000 out of the total obligation of Rs. 34 lakhs; and that S.T.C. had not yet entered the field of export of drugs and pharmaceuticals, the arrangement was on the whole not an un-reasonable one. Further if HAL refused to supply its products to Unichem, Unichem would have been able to obtain the supplies from other viallers.

As regards the third point made by the Committee, it was found that the labelling of the antibiotics for export purposes was done by HAL itself in its own plant though the labels were got printed by Unichem, and that the products were sold under HAL's own name, and not under Unichem's name.

(M/C&F O.M. No. 51012/2/75-DC of 20-5-77.)

Comments of the Committee

Please *see* paragraphs 62 to 64 Chapter I

Recommendation No. 64 (Paras 6.18 and 6.19)

Although it has been claimed by the HAL that research laboratories has been continuously rendering technical advice and assistance for improving the quality of products and in suggesting improvements to have higher productivity by selecting improved strains etc. and also rendering service in the adoption of better fermentation and extraction techniques, as pointed out in the relevant sections of the performance chapter in this Report, these are not borne out by facts/details. In the opinion of the Committee not much seems to have been done in regard to up-scaling of technology.

The Committee feel that R&D wing should direct its efforts to the task of not only absorbing the technology on which the projects of HAL have been set up but upscaling it, suggesting ways and means for improving the utilisation, reducing rejections and cutting down the cost of production.

Recommendation No. 65 (Paras 6.20 and 6.21)

The committee are informed that the company is spending about Rs. 26 lakhs per year on research and development; *i.e.* about 3 per cent of the sales turnover which the general level of R&D in big drug companies is stated to be of the order of 6 to 15 per cent. The management is of the opinion that the percentage should be round about 10 per cent. The Committee agree that it is not the percentage which counts but what really the Undertaking wants to do and achieve. In this connection, the Hathi Committee has recommended that the public sector unit should, to begin with, set aside at least 5 per cent of their turnover for this purpose. The Committee are informed that the Board of Directors had also some time back decided to spend about 5 per cent of the sales turnover on R&D. But according to the Managing Director, even this level of expenditure would be meagre. In this connection, the Committee would like to draw attention to suggestions made by the Hathi Committee, in paragraph 99 of chapter 3 and paragraph 37 of Chapter 7 of their report and recommend that the company should take immediate steps to strengthen its R&D efforts to bring it to a level of meaningful productivity and to equip it with such R&D pilot plant equipment as may be necessary for this work as a sound R&D base is the best insurance for growth of drugs in pharmaceutical industry. The Committee also recommend that the personnel selected for R&D should be dedicated and accountable.

Recommendation No. 66 (Paras 6.22 and 6.23)

The Committee recommend that the projects which have a bearing on the existing working of the plants and maximisation of the existing capacity and future development of the drug industry should be identified for research work by the R&D wing and on analysis of the projects which had been carried forward to the stage of commercial exploitation or are making progress or are stuck up should be made so that it is possible not only for the R&D wing to take stock of its achievements and failures but also for the Government and the Undertaking to evaluate its performance with reference to investment made in it during the year. The Committee also recommend that a list of the achievements made by R&D should also be included in the annual report of the undertaking. The Committee on Drugs & Pharmaceutical Industry (Hathi Committee) in para 101 of their report that the public sector units should establish closest liaison with the other R&D laboratories such as the CSIR, ICMA, ICAR, etc. and state institutions like the Haffkine Institute, the IIT's Universities, etc. as such coordination is vital for development and that appropriate facilities should be created in the identified institutions, wherever necessary, to permit time-bound completion of individual projects.

The Committee recommend that there should be a High powered Committee in the Ministry which should demarcate areas of R&D and allot them to the various institutions and contemporareously monitor the programme and review them from time to time with reference to the allocation of money and time schedule.

Recommendation No. 67 (Paras 6.24 and 6.25)

The Committee are surprised to note that HAL has no authentic information in regard to the activities pursued by the R&D wing of the IDPL. When these two public sector units have been manufacturing some drugs (*viz.* Penicillin and Streptomycin) though based on different processes and technologies, the least that the Committee expect is that there should be a system of coordination between the two public sector units, so that one could benefit from the achievements of the other in larger national interest.

In this connection, the Committee would like to invite attention to the recommendation made by the Hathi Committee in para 100 of Chapter III, of their Report to the effect that as between these three units (at Pimpri, Rishikesh and Hyderabad), avoidable duplication of efforts must be discouraged and the results available at each unit must be made available to the other related unit. There

should be no secrets between the public sector units and any improvements, in a strain, process or a plant developed in the R&D laboratory of one unit, should be freely available for use of the other unit. The Committee hope that HAL would lose no further time in establishing a close liaison and coordination with R&D laboratories of the other public sector drug units on these lines.

Reply of Government

The R&D wing of HAL has been re-organised with a project and task orientation consisting of multi-disciplinary projects groups with definite time and goal targeted objectives. The Projects are taken up on the basis of the on-going production activities in the main plant, projects identified in the Fifth Five Year Plan, expansion programmes of HAL and, the long-term R&D project that would necessarily have to be developed for the future requirements of both HAL and the country. The projects are in-charge of project leaders who are senior scientists and would include other scientists and several members belonging to different scientific and technological disciplines. In the frequent project group meetings, but within the R&D and the Managing Director, a thorough review of the progress and the difficulties of the past period of one month or so is reviewed and corrective measures and other support facilities given. The project groups also discuss their project work with the technical and scientific sub-committee of the Board of Directors at least twice a year, at which time a critical review of the progress made is done and further laying of work batches, time targets and additional support needed identified and given. Under this new system, the project leaders and group leaders are held accountable for fully implementing the project programmes and achieving targets.

During the past year, two detailed R&D project reports have been submitted to the HAL Board identifying the major project arrears and other facilities in support required to achieve the objectives and targets. A summary of the progress made in the last year in some of these projects is given in Appendix XI to illustrate the working of the new system in the R&D. Since the pilot plant is the key for the proper development and upsealing of the projects and processes, a lot of emphasis is being laid on the modernisation and updating of the pilot plant facilities the HAL Board is also giving full support to this. Already, steps have been taken to strengthen both the equipment and staff in pilot plant and further strengthening is also planned for the immediate future. As a result of such reorientation and strengthening in the pilot plant. It has been possible to full absorb the Toyo Jozo Penicillin technology and achieve

within the short period of three months removal batches that have yielded 30,000 units of Penicillin per ml. or more in 180 to 200 hour c/s. based on the pilot work, the implementation of the Toyo Jozo technology in a main plant is progressing satisfactorily.

While a lot of emphasis is being placed on the up-gradation of the strain and technology for the current products of manufacture of HAL, the R&D group is also spending a small part of its efforts towards discovering new antibiotics and developing new and improved technology and fermentation Enzyme Engineering. It is hoped that within the next year a strong centre of Fermentation technology Enzyme Engineering and bio-engineering would be built up at the R&D centre which would, doubtless, go a long way in building up the required modern technological base to progress and keep HAL with better technology.

As regards recommendation made by the Hathi Committee, and referred to in the above recommendation, it may be mentioned that there is already close cooperation between Public Sector Projects and National Laboratories. All the recommendations now under consideration of Government and a decision is expected to be taken shortly.

The demarcation of areas for R&D development, and allotting them to various institutions etc. has already been done through NCST. The scrutiny and the assessment of work done as well as Finance therefor are also done by the Department of S&T annually. The Government accepts the recommendation that there should be close coordination between R&D Departments of HAL and IDPL.

[M/C&F O.M. No. 51012/2/75-DC dt. 30-9-76.]

Recommendation No. 68 (Para 7.8)

While the inventory of imported raw materials in subsequent years was within the norms, in the case of indigenous materials it was in excess of the norms. Inspite of this heavy investment in raw materials, the Committee regret to observe that due to shortage/ non-availability of essential raw materials like soyabeen, etc., the undertaking could not keep up the production of streptomycin.

Reply of Government

The recommendation has been noted.

HAL are making vigorous efforts to establish inventory control/ management control in consultation with professional consultants to maintain/optimise inventories to ensure uninterrupted production.

[M/C&F O.M. No. 51012/2/75-DC dt. 30-9-76.]

Recommendation No. 69 (Paras 7.9 and 7.10)

The Committee are constrained to observe that while on the one hand production of formulations is stated to have suffered due to shortage of vials and rubber stoppers, on the other hand there has been an increase in the inventory of general items and spares from Rs. 99 lakhs at the end of March, 1971 to Rs. 127 lakhs at the end of March, 1975 thus indicating accumulation of non-essential stores.

The Committee see no reason for delays in the finalisation of order by DGS&D. In fact DGS&D should give preference and every facility to public sector undertaking to meet the demands/requirements of Government to the maximum extent. The Committee would also like Government to go in depth into the causes for the delays in finalisation of orders by DGS&D and remove any procedural lacuna which may be responsible for such delays.

Reply of Government

Government have not received any report from HAL about undue delay caused in the finalisation of orders by DGS&D. It is proposed to examine this in detail and to go into the causes, if any, for delays in finalisation of the orders by DGS&D and remove the procedural lacuna.

[M/C&F O.M. No. 51012/2/75-DC dt. 30-9-76.]

Further information called for by the Committee

What concrete measures have since been adopted?

[L.S.S. OM No. 21-PU/76 dated 14-3-77]

Further reply of Government

At present there is no delay or difficulties in finalising the rate contracts of A/Ts with DGS&D, New Delhi due to the vigorous efforts made by the Sales Organisation of HAL. The DGS&D also continues to extend 10 per cent price preference over the lowest quotation to Public Sector enterprises while finalising Rate Contracts as well as *ad-hoc* Tender enquiries.

[M/C&F O.M. No. 51012/2/75-DC dt. 20-5-77.]

Recommendation No. 70 (Para 7.11)

The Committee also note that the finished stock included Aureofungin (Rs. 3.33 lakhs) and Streptocycline (Rs. 2.63 lakhs) accumulated since 1967-68. The Committee have already given their recommendations regarding these products in another chapter of the report. The Committee are not sure whether these still retain their efficiency and are fit for disposal.

Reply of Government*

The Board of Directors in their meeting held in 1973 examined the question of utility of Streptocycline, the life of which expired and decided to write-off Rs. 1,17,731 being the book value. Similarly in 1975 the Board examined the utility of Aureofungin in stock (455 packets) which was old and could not be sold. For the balance Quantity of Aureofungin the company will examine the possibility of reprocessing the same to salvage any portion thereof.

[M/C&F O.M. No. 51012/2/75-DC dt. 30-9-76.]

Further information called for by the Committee

Why was this item manufactured in excess? Was there any market or demand or orders? If so, what was the difficulty in disposing these in time before they lost efficacy?

[L.S.S. O.M. No. 21-PU/76 dt. 14-3-77.]

Further reply of Government

A Potent antifungal antibiotic was discovered by the Research Laboratories of HAL. It has been shown to be active at extremely low concentrations against a wide variety of fungi including several major plant pathogens. This antifungal antibiotic was tested widely in different agricultural research stations round the country against several plant diseases including paddy blight, sugarcane redrat, diseases of grapes, coconut, arecanut, rubber and others. Its efficacy against plant diseases under field conditions was not only established but was confirmed by several independent workers in India and this is evidenced by the number of original research papers that have been published so far. As is well known, the establishment and introduction of new antibiotics either for human or agricultural uses into the market is an extremely long, difficult and expensive process. While conceding the fact that HAL has not so far sold very large quantities of this antibiotic in the market, it has to be appreciated that with the limited R&D facilities for conducting field trials and demonstration plots etc. as also the limited marketing force the company possesses, it has been difficult for them to successfully introduce this compound in the market.

Considered against the above background, the company had to retain this item in its line of production even though the material produced in earlier years had not been sold out because continuity of supply of non-time-expired stocks had to be maintained till the product was established firmly in the market and regular production

* At the time of factual verifica tion, Audit informed as follows: "The reply as changed not sent to Audit for vetting".

could commence on the basis of actual forecast demand. Thus between 1966 and 1976, a total quantity of 1.303 tonnes were produced to support the marketing wing in the introduction of this new item. However, when the market did not respond quickly and the financial position of the company also did not permit further expenditure on this new item, it was decided to discontinue the production of this item.

The company has pointed out that when a new product is to be introduced, it is not possible to plan production against advance indents, and that the normal practice is to make a survey of the demand prospects in the country and plan production on that basis. Further, in this particular case, it was explained that the demand was contingent on the incidence of a particular fungal disease and that production had to be planned in advance of such a contingency and not after it had occurred. It has also been explained that the production was always planned in consultation with the Ministry of Agriculture, State Government etc. and with reference to the indications given by them of the probable demand. The Board of Directors of the Company has found this explanation quite reasonable.

The Board has also found that the quantity which was on hand at the close of 1971-72 was time-expired and that efforts to re-process the time-expired products were not successful. At the same time, the demand for the product arose and the quantities produced in subsequent years have also been sold. There are no stocks of the product at present.

[M/C&F O.M. No. 51012/2/75-DC dt. 20-5-77.]

Recommendation No. 71 (Paras 7.12 and 7.13)

The Committee also find that the stock of materials under reprocessing has shown a steep increase from nearly Rs. 4 lakhs at the end of 31st March, 1974 to over Rs. 11 lakhs at the end of 1974-75. The Committee feel that such expenditure on reprocessing is avoidable. The Committee would like that Government/Undertaking should critically go into the causes for this steep increase and take suitable remedial measures to control the rejections and eliminate reprocessing.

Considering the inventory of general stores and raw materials during the last many years and the steep increase in stock of finished goods at the end of 1974-75, the Committee feel that the steps stated to have been taken for toning up materials management have not

produced the desired results. They would, therefor, like that the measures should be reviewed and tightened up to ensure that there is no unnecessary accumulation of inventory resulting in blocking of funds and accentuating the financial difficulties experienced by the Undertaking.

Reply of Government

The value of materials under reprocessing during 1975-76 has come down to Rs. 10.58 lakhs when the total value of production was Rs. 928.08 lakhs. This was Rs. 11.16 lakhs in 1974-75 when their value of production was Rs. 790.21 lakhs. This will show that the percentage has come down from 2.45 per cent to 1.13 per cent of value of production and it is expected that with further control measures undertaken by the Company this will come down further.

Based on the guidelines of the Parliamentary Committee on Public Undertakings (40th Report—3rd Lok Sabha on material management in public undertakings), an integrated materials management department was established in 1972 and a separate inventory cell was created. Subsequently, pursuent to the decision of the Board of Directors in 1973 that the company should streamline and introduce an effective materials management system with the assistance of professional agencies specialised in inventory control, the National Institute for Training in Industrial Engineering, Bombay was engaged as the consultant to the company and a task force was constituted to work under the guidance of the consultant. The task force evolved systems on material codification, stores relocation and identification and segregation of surplus inventory. As a result of this, the inventory control system has been streamlined and strengthened.

The position of inventory of spares and general stores and raw materials *vis-a-vis* the total value of production as on 31-3-1975 and 31-3-1976 was as under:—

	31-3-1975	31-3-1976
	(Rs. in lakhs)	
Spares and General Stores	126·68	127·11
Raw materials	117·82	100·90
Total inventory of raw-materials. stores and spares	224·50	228·01
Total value of production	790·21	928·08

From these figures, it will be evident that the increase in inventory stores/spares has been controlled. This has been possible by creating an inventory control cell and review of non-moving, slow moving items and close scrutiny of spare and stores requirements before procurement.

(M/C&F 51012/2/75-DC dt. 30-9-76.)

Recommendation No. 72 (Para 7.14 and 7.15)

The Committee also note that the value of surplus and obsolete stores has increased from Rs. 2.68 at the end of 1970-71 to Rs. 4.45 lakhs at the end of 1972-73 and declined to Rs. 3.41 lakhs at the end of 1973-74 and again increased to Rs. 7.27 lakhs at the end of 1974-75. The Committee feel that had suitable maxima minima and ordering levels been laid down and adhered to, the undertaking would not have been faced with such surplus and obsolete inventories. The Committee would like that the Government should go into the reasons for a steep rise in the inventory and non-moving items at the end of 1974-75.

The Committee would like that the undertaking should conduct a review of non-moving and obsolete stores periodically at least once in a year and report the position to the Board of Directors who should carefully go into the causes and take effective remedial measures. The Committee are also informed that a Task Force consisting of officers from various departments has been constituted to work under the overall guidance of the consultants. The National Institute for Training and Industrial Engineering and certain actions have been taken to streamline the materials management. The Task Force has so far worked on identification of non-moving stock, material codification and physical lay out of stores. The Committee recommend that the Task Force should complete its work soon so that inventory control is put on sound footing without delay and the management should report the progress made in this regard to the Board.

The Committee stress the need for timely remedial measures so that inventories are put on most rational and economic basis in the interest of production.

Reply of Government

The review of non-moving items is made periodically to segregate the insurance spares from obsolete ones, so that action may be taken to dispose of the obsolete spares/stores. After review of non-moving items during 1975-76, a further inventory of 94 items valued at

Rs. 2.89 lakhs has been declared surplus during period ending March 31, 1976 and the value of surplus items declared for disposal as on 31-3-1976 was Rs. 9.11 lakhs. However, as on date further liquidation of Rs. 2.69 lakhs has been made and the value of available obsolete items now stands at Rs. 6.42 lakhs.

The fixing up of maxima and minima and ordering levels in respect of spares will be taken up after completion of the catalogue and implemented by the end of the year (1976). However, as regards raw materials and general stores, maximum and minimum levels are being fixed up and are being operated upon.

The review of non-moving and obsolete items is being made annually and reported to the Board of Directors.

Further to the creation of a Task Force and appointment of consultant, codification of all items according to the new codification system is under compilation and will be completed by the year end. After the compilation of a catalogue of all items, it will be easier to weed out duplicate cards and have better control on requisitioning of stores and spares. During 1975-76, 88 items valued at Rs. 1.04 lakhs have been disposed of. The progress in disposal of obsolute spares and stores has not been encouraging because of unfavourable market conditions and difficulty in selling spares of specialized machinery which are obsolete.

Similarly, the closing stock of finished goods stood at Rs. 113.66 lakhs as on 31-3-1976 as against the corresponding figure of Rs. 164.25 lakhs as on 31-3-1975 as a result of various measures taken to increase the quantum of formulations and boost sales.

In view of the fact that the company and the Board are keeping a constant vigil over the inventories the levels thereof are under control. Therefore, there does not appear to be any need to investigate the reasons for the steep rise in inventories and non-moving items, earlier. However, Government propose to keep a watch on the situation.

As regards 1974-75, the company is being asked to submit a report giving detailed/codification for the steep rise in inventory.

(M/C&F 51012/2/35 dt. 20-9-76.)

Further information called for by the Committee

(a) What steps have been taken to dispose of the obsolete items to the best advantage of HAL to other Public Undertakings through BPE?

(b) Has the codification of all the items and fixing of maxima and minima and ordering levels of spares been completed?

(c) Has HAL submitted the report on the steep rise of inventory. If so, what action has been taken by Government thereon.

(L.S.S. O.M. No. 21-PU/76 dated 14th March 1977)

Further Reply of Government

(a) The task force had studied the possibilities in reduction of obsolete/surplus inventory specially of Engineering stores and spares and recommended during January 1974, liquidation of 2895 items comprising a book value of Rs. 14.14 lacs. Subsequently, after transfering some of these items for expansion projects and consuming some for maintenance/modification, items worth Rs. 7.27 lacs were identified for disposal. Present stock of surplus inventory is worth Rs. 6.24 lacs.

(b) Work on Material codification was taken up during October 1973 and the designing of a 8-digit material coding manual was completed during September 1974. All the items have now been codified upto 6th digit and items thus codified have been sorted out in Data Processing Unit for the purpose of merger of identical items currently stored under different names at different places. Currently, the last two digits are being allotted to complete the 8 digit code, and the new coding system will be implemented thereafter.

(c) The value of the surplus stores worth Rs. 7.26 lakhs as on 31-8-75 increase to Rs. 8.92 lakhs as on 31-3-76. However, this increase is due to one lot of soyabean meal valued at Rs. 2.57 lakhs being declared surplus during 1975-76, which has since been disposed off during the year 1976-77.

The Inventory Control Cell had made a critical review of all the items in stock as on 31-3-75 and had arrived at a list of items which would not be required by the company in the near future valued at Rs. 7.27 lakhs. However, much headway could not be made in the final disposal of these items by auction or by a sale tender as the Material Management Deptt. has been working under tremendous strain in the last two years or so. The company had sustained a loss of Rs. 2.91 crores in 1975-76, and had sustained a loss of Rs. 1.3 crores in 1976-77 upto end of October 1976. These cash losses coupled with company's inability to augment the resources by increased bank accommodation obliged the company to delay the payments of bills for raw materials and stores received from its suppliers for a considerable length of time. These delays actually resulted in a

situation where extra-ordinary and special efforts were required to be made by the Material Management Deptt. even for procurement of essential raw materials from limited sources which were unwilling to make further supplies pending settlement of their previous claims. The trend became accentuated when the new strain and technology obtained from Japan for the Penicillin Fermentation was to be introduced with a more or less completely new set of fresh raw materials to be obtained. Simultaneously, Engg. stores were also required in appreciable quantities for quickly carrying out modifications to the existing design and plant so that the new high yielding strain could be established in the shortest possible time in the main plant resulting in considerable improvement in the operational results of the company. Actually these efforts have resulted in the new strain and technology obtained in April 76 being put on the main plant on a continuous basis from December 1976 onwards, i.e., within a short period of 9 months. In fact, we have been using the new strain and technology in an increasing proportion from an earlier period, and this had helped the company to arrest the losing trend which had been noticed un-interrupted for the last 3 years, and to show a marginal profit in its operations from November 1976 onwards. Today, the expectation is that the company would be incurring a loss of only around Rs. 60 lakhs during the whole of 1976-77, compared to Rs. 2.91 crores in the previous year and even compared to Rs. 1.3 crores loss upto October 1976. Today, the company's fund flow position is also much better and we do not anticipate any major problem in providing raw materials for maintaining un-interrupted production. As soon as this position stabilises, the Materials Management Deptt. would be in a position to pay adequate attention to the question of reorganising inventories and liquidating the surplus materials. One of the reasons for not going ahead with final disposal of this surplus material is also the fact that in December 1976 the P.I.B. had approved five new/expansion schehme for this company and the Govt.'s approval to these schemes being implemented was conveyed in February 1977. With the prospect of substantial expansions taking place in the near future, it was felt desirable to review the list of surplus items to see whether the items which were declared surplus earlier would require any modification in the light of the requirements for the new expansion schemes. It is, therefore, submitted that the company would be taking the problem of disposal of surplus materials on hand immediately and appreciable results are expected to be achieved in the current year.

Regarding introduction of modern systems and procedures, the work had been entrusted to a consultant who was with N.I.T.I.E.

Before he could complete the work, he had quit the organisation, and therefore, the work had remained in-complete. It has now been decided to request the same individual to complete the work even though he is no longer with N.I.T.I.E. He has been requested to complete the work. However he had not so far conveyed his consent and this is being persued with him.

Position of inventories as at 31st March during the years 1976, 1977 and 1978 was as under:

	Rs. in lakhs 31.3.1976	31.3.1977*	31.3.1978*
General Stores and Spare parts	127·11	136·30	142·59
Raw materials . .	100·9	133·54	167·85
Work under process . .	114·68	138·38	184·84
Finished goods . .	111·93	37·53	105·64
Materials under-processing . . .	10·58	22·81	27·36

During the year 1976-77, the company had achieved higher level of production and all round improvement in sales. Better availability of bulk Tetracycline is one of the factors that has resulted in increased turnover. Figures of inventories as at 31st March 1977 are under compilation, and it is expected that the inventories will then be at a lower level compared to previous year's.

[Min. of C & F O.M. No. 51012/2/75-DC dt. 20-5-77]

Further information called for by the Committee

What is the latest position in regard to inventory control?

(L.S.S. letter No. 21-PU/76 of 8-12-1977)

Further Reply of Government*

Considering the inability of the NITIE Consultant to continue and complete the assignment and considering the urgency and importance of developing sound inventory control system and recognising the importance of this function, HAL has constituted following Committees for going into the aspects of disposing surplus material, completing balance of codification work and fixing the maxima and minima norms in respect of stores items.

(1) *Committee for disposing surplus items*:

Non-moving items and slow-moving items have been identified and the Committee will attend to disposal of surplus items.

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*Information furnished by the Ministry at the time of factual verification.

**Further reply not sent to Audit for velting.

(2) *Cell for Codification etc.*

HAL has appointed a cell to complete remaining 40 per cent of work of codification of stores items as well as fixing maxima and minima norms for the stores items.

(3) *A Committee for reviewing 'A' items of important raw materials:*

A Committee for reviewing 'A' items of important raw materials on a continuous basis has been constituted who are examining these items for ensuring a level of inventories to be held which constitute 50 per cent of the total raw materials consumed in a year.

[M/C&F O.M. 51012/2/75-dt. 9-1-78.]

Comments of the Committee

Please see paragraph 65 to 71 of Chapter I.

Recommendation No. 73 (Para 8.13)

The Committee regret to note that though the number of employees had gradually increased from 2,026 in 1967-68 to 2,568 in 1973-74 and the average earnings per employee have also correspondingly increased from Rs. 6,135 to Rs. 10,167 the average sales per employee has come down from Rs. 31,916 to Rs. 30,580. The Committee cannot but conclude from this that the productivity of employees has been going down from year to year and the under taking does not appear to have taken any tangible action to arrest the decline. The Committee recommend that the Corporation should make a critical study of the reasons for the decline in productivity and take concerted measures to bring it up to the optimum level.

Reply of Government

As a result of implementation of several time bound measures including adopting systems approach, revamping technology, toning up of discipline and increasing the utilisation of capacity, particularly that of formations, the Company attained a record sales turnover of Rs. 1,030.76 lakhs during 1975-76, which exceeded the sales of 1974-75 by more than 38 per cent.

As a result of various measures taken to improve utilisation of the vialling capacity, the output of injectable vials filled during the year went up to 522 lakhs which was 20 per cent higher than that obtained during the previous year. A significant break through was also achieved in the case of non-parenteral formulations and the cumulative output of 488 lakhs tablets and capsules attained during the year represents on all-time record and it is 108 per cent

higher than what was achieved during the previous year and this enable the company to make available a higher quantum of formulations to its institutional customers. Production of bulk Penicillin and Strepetomycin was also maintained at a high level utilising above 75 per cent of the installed capacities, inspite of high incidence of power cut in the entire year ranging upto 40 per cent during some months and shortage of certain essential raw materials like Procaine hydochloride, soluable vegetable protein (imported) and phenylacetic acid. Production of basic Penicillin at 97.09 mmu and that of bulk Penicillin at 64.78 mmu (including 6.58 mmu of potassium Penicillin in non-parenteral) achieved during the year exceeded previous year's figure by nealy 5 per cent and 4 per cent respectively. The output of Streptomycin was also maintained at 61.79 tonnes in spite of power cut and non-availability of an essential imported raw materials.

In the light of above, the average sales per employee has registered a 50 per cent increase as can be seen from below:—

		1974-75	1975-76
1. No. of Employees .		2.572	2,572
2. Average sale per employee	. Rs.	25.791	37.389
3. Average earning per employee	. Rs.	12,192	12.873

The company would continue to investigate into the possibilities of improving productivity.

[M/C&F O.M. No. 51012/2/75-DC dt. 30-9-1976]

Recommendation No. 74 (Para 8.14 to 8.16)

The Committee are led to conclude that the undertaking had been complacent about the general overall profitability inspite of the reduction in profits year after year from 1966-67 and had not taken any effective action to improve the position. The Committee have already pointed out that there had been a lag in the technical development of the strain for penicillin and streptomycin and their consequent effect on production and production costs.

The Committee are constrained to observe the lack of foresight and the serious managerial lapses in properly organising the undertaking to maintain and improve the productivity and profitability. The Committee need hardly stress that it is the primary responsibility of the Management to keep a meaningful watch on the working of the undertaking and take appropriate remedial measures in

time to set right any deficiencies. The Committee recommend that the entire matter should be thoroughly investigated with a view to fixing responsibility for these grave and avoidable lapses which have turned a profit-making undertaking into a losing enterprise and a report furnished to the Committee within six months.

The Committee are informed that besides seeking in an increase in the selling price of its products, the undertaking has taken certain measures to check the decline in profitability as a result of introduction of new high yield strain for streptomycin which has been able to increase its production by 16 per cent during first quarter of 1975-76 and reduce the cost of production and improve utilisation of capacity.

In the case of Penicillin it is stated to be finalising proposals for acquiring improved strain and technology. It has been stated that a new formulation unit has been constructed to increase the output of drugs. A systems approach is being adopted for systematic plant maintenance, proper material management, man power assessment, etc. As a result of these measures the company expects to turn the corner in 1975-76 and become profitable. The Committee hope that with the steps now taken and with the implementation of the recommendations of the Committee in this report it should be possible for the undertaking to improve the productivity and thereby profitability.

Reply of Government*

As a result of implementing a series of time bound measures like revamping the technology, to enhance production and productivity, adopting systems approach and toning up discipline particularly after the Emergency, the Company turned the corner during the year 1975-76 and the working results during January—March 1976 resulted in a surplus of Rs. 3.52 lakhs for the first time during the past 3 years. This is also reflected in the overall improvement in the working results for 1975-76 compared to the previous year.

Some of the important measures taken are indicated below:—

(a) *Improving production and productivity:*

STREPTOMYCIN.—HAL entered into technical collaboration with M/s. Glaxo Laboratories of U.K. in 1973 as a result of which a high yielding strain and technology were successfully introduced in the plant. This ensured full utilisation of the capacity and the output of Streptomycin Sulphate from January to August 1976 was 56 tonnes representing 100 per cent utilisation of the past fermentation capacity.

PENICILLIN.—The Company has entered into technical collaboration with M/s. Toyo Jozo Company of Japan in January, 1976 as a result of which a high yielding strain and technology have been successfully introduced in the plant with minor modifications, it was possible to obtain over 100 per cent increase in the productivity in the plant and vigorous efforts are being made to complete the project for attaining about 300 per cent increase in the productivity in the plant.

The Company will thus be possessing some of the technologies in the field of penicillin and streptomycin available in the world. As Penicillin and Streptomycin in the form of bulk and formulations presently constitute over 95 per cent of the sales turnover of the Company, the induction of new technology coupled with other measures to ensure fuller utilisation of installed capacities of these antibiotics, will improve the working results as evidenced from the financial results of 1975-76 and April—July, 1976.

(b) *Improved Capacity utilisation*:

The company has implemented an action oriented production plant and adopted a systems approach in planned preventive maintenance. The latter has brought about a significant reduction in plant breakdowns. Speedy action has also been taken to remove bottlenecks and constraints in production. As a result, it has been possible to attain impressive utilisation of capacity in respect of bulk Penicillin and Streptomycin. Thus in spite of high incidence of power cut ranging upto 40 per cent during some months, non-availability of certain essential raw materials like Procaine Hydrochloride, Phenylacetic acid and soluble vegetable protein (imported) and difficult financial position of the company on account of un-economic selling prices and steep escalation in the cost of inputs making it difficult to maintain optimum inventories, the above measures made it possible to maintain capacity utilisation of Penicillin and Streptomycin plants beyond 75 per cent during 1975-76. This has significantly improved during the period April-August, 1976 when 36.2 tonnes of Streptomycin have been produced, representing 103 per cent utilisation of installed capacity.

(c) *Higher output of formulations*:

HAL took concerted action to enhance the output of vials and other non-parenteral formulations whereby the output of injectable vials filled during 1975-76 went upto 522 lacs which was 20 per cent higher than that obtained during the previous year. The improved performance in vialling has been pursued on a much more vigorous

scale during the current year, which enabled the company to fill 292 lacs of vials during April—August, 1976 representing a much higher utilisation of vialling capacity.

To improve its profitability, the company commissioned a new formulations unit to enhance the output of tablets and capsules which are more profitable than bulk sale, and implemented a time bound programme for effective utilisation of formulations capacity. Thereby, a significant break through was achieved during 1975-76 when a cumulative output of 488 lacs of tablets and capsules was obtained which represents an all time record and 108 per cent higher production than what was achieved during the previous year. Due to higher output of vials and other formulations, HAL utilised higher quantum of the bulks for its own captive requirements and made available higher volume of formulations to its institutional customers.

(d) *Revitalisation of Vitamin C and Ampicillin plants*:

Due to strenuous efforts made by the company, a stream of Vitamin C production has been established and during 1975-76. 3.94 tonnes of pharmaceutical grade Vitamin C were produced. Efforts are being continued to step up production by upgrading the efficiencies at two stages in consultation with outside experts. The Government have also constituted a task force under the Chairmanship of Director General of Technical Development to examine the problems of Vitamin C plant. (The company is now working in technical collaboration with M/s. Roche Products Limited for bringing up the production to rated capacity at an economical cost).

The Company has commenced commercial production of Ampicillin from 6 APA for the first time in the country and steps have been taken to enhance its output during 1976-77. The erection of the third stage of the project for the conversion of Penicillin first crystals into 6 APA by a process worked out by the company's R&D wing will be completed in October, 1976. The above steps to augment the output of Vitamin C and Ampicillin will have favourable impact on the working results of the company.

(e) *Intensified System/Approach*:

Apart from the area of preventive maintenance, the company is adopting systems approach in Inventory Management and Manpower deployment. Manpower assessment has been done for the whole organisation which has shown surplus strength, Accordingly, further recruitment in categories where there is excess strength has been frozen. As a result, average number of employees on roll has come down to 2527 during 1975-76 from 2578 during the previous year.

Average sale per employee has also registered a rise to 0.37 lacs during 1975-76 from 0.26 lacs during the preceding year.

(*f*) *Effective involvement of R and D in production:*

A new orientation has been given to its R & D Wing, and distinct project groups have been formed on the basis of time bound projects. A close liaison is being maintained between Production and R & D to resolve outstanding production problems. A phased programme has been drawn for introduction of new products in the market as a measure of diversification and four new formulations thus developed are being introduced in the market during first half of 1976-77.

(*g*) *Expansion and Diversification*:

The Company has submitted proposals for nine projects towards expansion and diversification during the fifth plan period entailing an expenditure of Rs. 30 crores. Based on the suggestion made by the Governmental authorities, the revised feasibility reports relating to the expansion of Penicillin, Streptomycin, Semi-synthetic Penicillin, Erythromycin, Gentamycin, Industrial Enzymes and establishment of formulations plant II have been submitted by the HAL. The proposals are under active consideration of the Government. The expansion plans when fully implemented will result in annual turnover of about Rs. 70 crores.

(*h*) *Improved Discipline and Employee Participation:*

The Company has taken several measures to tone up discipline and improve security. More than 70 persons have been removed from services on charges of indiscipline, chronic absenteeism, etc. Central Civil Service Rules have been made applicable to the officers of the Company. Financial and Administrative powers have also been sub-delegated to the officers for smooth conduct of business. These measures have shown impressive results particularly after emergency. In pursuance of the Prime Minister's 20-Point Economic Programme, shop floor committees have been constituted to facilitate-worker participation in management and bring improvement in production and productivity with the active involvement of shop floor workers. This has motivated the employees to offer some valuable suggestions and these have been implemented.

(*i*) *Economy in the use of Materials*:

The Company has also launched an extensive drive to effect economy in major materials like Furnace oil, Solvents etc. and obtained encouraging results.

(j) Revision in the Selling Price by the Government:

The Company had approached the Government to revise the prices of Penicillin and Streptomycin to meet several fold increase in the cost of raw materials and other inputs. The Government has since notified the revised prices of bulk Penicillin and Streptomycin during the last quarter of 1975-76.

Various measures taken by the company as enumerated above together with the fixation of revised selling prices of the products, have made the operations of Streptomycin plant viable. Similarly, the operations of Penicillin Plant will be viable after successful establishment of Japanese Technology. Thus, as a result of revamping its technology, measures taken to enhance capacity utilisation, adopting a systems approach and toning up discipline, the working result of HAL during the quarter Jan.-March, 1976 resulted in a surplus of Rs. 3.52 lacs for the first time during the past three years, as compared to a loss of Rs. 68.88 lakhs in Jan.-March, 1975. This is also reflected in the improvement in the overall working results of 1975-76 compared to those in the previous year. Similar improvement could be noticed in the working results of April-July, 1976. Thus there is a progressive improvement in the working result. The Company has set a sales target of Rs. 15 crores for 1976-77, representing 50 per cent increase over 1975-76 and HAL is poised for a further improvements during 1976-77.

Various aspects concerning the company are already being looked into, by the Government. These are indicated below:—

(i) Government have appointed a Task Force under the Chairmanship of Secretary, T.D. to investigate into Vitamin 'C' project.

(ii) The Board of Directors have appointed a technical sub-committee to investigate into Hamycin Project.

(iii) The Board had earlier appointed a sub-committee to investigate into the production failures and maintenance failures in respect of Penicillin and Streptomycin projects. On the basis of their findings Former Chief Engineer and Production Superintendent were removed.

Government propose to look into the entire matter after the report on Vitamin C project and Hamycin project has been received. Based upon the findings of the Task Force and the sub-committee of the Board for Hamycin projects it would be possible to decide as to

whether there is a need for further investigation with a view to fixing responsibility for the lapses referred to in the report.

[Min. of C&F O.M. 51012/2/75-DC dt. 9-5-76.]

Further information called for by the Committee

(a) When is the Report of the task force under the Chairmanship of Director General of Technical Development to examine the problems of Vitamin C Plant is expected to be available?

(b) When are the findings of the task force and the sub-Committee of the Board for Hamycin Project likely to be received? If already received, what are the findings and action taken by the Government thereon.

[L.S.S. O.M. No. 21-PU/76 dated 14-3-1977.]

Further Reply of Government

(a) The Report of the Task Force under the Chairmanship of the DGTD in respect of examine the problems of Vit C Plant as since been received by Government.

The Task Force has come to the conclusion that HAL should go ahead with the rehabilitation of the existing Vitamin C Plant with the assistance of M/s. Roche Products Limited. This recommendation has been accepted by Government and preparation of feasibility study and project report for rehabilitation of the Vitamin C Plant has been taken on hand.

(b) The Sub-Committee of the Board of Directors of HAL for going into the question of utilisation of HAL's Hamycin Plant had preliminary discussions in this regard with concerned Heads of Departments of HAL. Certain data and details in respect of production and sale of this product as well as quality, stability and toxicity studies of the product were called for. These have been furnished to the Sub-Committee, and the recommendations of this Sub-Committee are awaited.

[Min. of C&F O.M. 51012/2/75-DC dt. 30-9-76.]

Further information called for by the Committee

What is the latest position with regard to the utilisation of Hamycin Plant?

[L.S.S. letter No. 21-PU/76 of 8-12-1977.]

As the meters are installed and regulated, the consumption of services based on the meter readings would be taken for working out the cost of different products.

The cost figures for 1975-76 have been reconciled with the financial figures for the same year. Similarly, the cost figures for April—June 1976 have been reconciled with the financial results for the corresponding period of 1976 and this is made a regular feature.

The cost figures for April—June, 1976 have been reconciled with the corresponding financial figures. This review along with the analysis of the variances will be put up to the Board along with the quarterly financial review. The cost accounting has been put on a scientific basis and as already indicated this report will form part of the quarterly financial reviews to be submitted to the Board of Directors for consideration along with the financial accounts.

(M/C&F L-51012(2)/75-DC dt. 30-9-1976.)

Recommendation No. 76 (Para 8.32 and 8.33)

The Committee would like that the undertaking should critically go into each one of the operations and the factors which are contributing to the cost and take suitable action to improve efficiency and reduce consumption of material, bring down the percentage of rejections and wastages and achieve reduction in cost at the different stages and ultimately of the finished products.

The Committee would also like that R & D should also be closely associated so that they may suggest ways and means of improving the techniques and reducing costs without sacrificing quality of the products.

Reply of Government

As a result of implementation of various time-bound measures such as introduction of new strain and technology to increase productivity, utilisation of higher capacities, reduction of wastages and improvement in efficiencies resulting in lower consumption of raw materials per unit of production, the unit cost of production has come down in the case of Penicillin products as can be seen from the following:—

Base : 1973-74=100

to be given for	1974-75	1975-76
Penicillin G. First crystals	141	128
Penicillin V first crystals	139	132
Potassium Penicillin G. bulk	137	135
Sodium Penicillin bulk	134	130
Procaine Penicillin bulk	145	141

With the establishment of the improved Japanese strain and technology, the cost of production of different Penicillins will come down.

In the case of Streptomycin, although production was marginally lower in 1975-76, due to 40 per cent power cut, during some months and although the cost of inputs such as wages, furnace oil, power and raw materials has gone upto a considerable extent, the cost of production remained the same at the index 117 (1973-74 base 100) in 1975-76 as compared to 1974-75 as a result of implementation of various measures as indicated above.

Task forces were constituted by the company comprising scientists from R & D for penicillin and streptomycin to stabilise and upgrade technologies, to improve efficiencies with a view to reducing the cost of production. The R & D has been re-organised based on distinct project groups working within fixed time frame. These measures involve the R & D personnel closely with the production activities. The R & D unit developed an efficient process of enzymatic conversion of Streptomycin B to A, which has been successfully introduced in the plant. The R & D unit continued to assist the plant in utilising starch in place of dextrose in the manufacture of Streptomycin. The R & D unit was also actively engaged in the development of new products as a measure of diversification with a view to improve the profitability.

[Min. of C&F O.M. No. 51012/2/75-DC dt. 30-9-76]

Further information called for by the Committee

What is the latest position in this regard?

[L.S.S. letter No. 21-PU/76 of 8-12-77.]

Further Reply of Government*

In the last 18 months the R & D has continued its close working with the Production Department and has in several instances contributed to increased production and improved quality. Examples are:—

(1) The introduction of New Penicillin Strain and Technology from Japan which has resulted in the improving Penicillin productivity twofold thus reducing the cost of production. They are at present working on improving the extraction and purification of the Penicillin for improving process efficiencies and product quality.

(2) In Streptomysin the R & D Project Group has significantly contributed in standardising raw materials quality and fermentation process parameter which has resulted in maintaining the present high fermentor productivity and exceeded the plant capacity.

*Further reply not sent to Audit for vetting

(3) The process of manufacture of 6 APA which was developed by R & D has been introduced for the large scale manufacture for this key intermediate in production of Ampicillin. Working in close collaboration with Production Department the rated process efficiencies in different steps in manufacure of 6 APA have now been established.

(4) R & D and production Department along with M/s. Roche Products India Limited are at present working intensively on the technological rehabilitation of Vitamin C Plant in order to achieve the rated plant capacity of 125 tonnes/A of Pharmacoepical grade Vitamin C. This is expected to be completed by the middle of 1978.

[Min. C&F O.M. 51012/2/75-DC 9-1-78]

Recommendation No. 77 (Para 8.38)

The Committte do not see any justification for huge outstanding from private viallers to the extent of Rs. 43 lakhs, when the credit system permits only supplies to them against advance payments. The Committee find that instead of realising the dues of about Rs. 2 crores from the Government Departments and private viallers in time the undertaking has obtained Rs. 2 crores as short-term loan for working capital requirement on which it has to pay interest charges. The Committee stress that the Government/HAL should undertake a review of the credit arrangement obtaining so far with a view to ensuring that such arrangements are in the best interests of the undertaking. The Committee would also like that the billing and recovery system should be streamlined so as to ensure realisation of outstandings within the credit periods allowed to the parties. The Committee also recommend that in respect of outstandings in the Government Departments the matter should be taken up with the appropriate Governments/Ministries and amounts realised without further delay.

Reply of Government

The system of billing has been streamlined by the Company. Based on Challan-cum invoice, the final bill is prepared with which the railway receipts are sent to the consignees. The medical stores of the individual consignee receives the consignment, certifies one of the copies of the bills, the receipt of the materials and then forward the same to their accounts departments for passing the bill. As a result of this the delay in payments was considerably reduced. The final bill now reaches the party alongwith the concerned document within a week before the receipt of the consignment.

The company supplies to over 7000 Government institutions and hospitals all over the country. Some of the supplies are made to the Government institutions through Central Government agencies such as Government Medical stores, against D. G. S. & D. contracts. The transit time for the consignments extends upto 30 days depending upon the destination and mode of transport. The State Government institutions have to follow certain procedures which differ from State to State as well as for supplies under DGS & D. Inspite of all efforts, it is found that the collection period stands a round 90 days which include about 30 days of transit time. Further measures are being taken such as approaching the various institutions and hospitals through the Company's medical representatives, de-centralising despatches by opening depots in various states in order to reduce the transit time and approaching government authorities directly. Collection drives are also launched from time to time particularly after the budget sanctions are available to the Government institutions. DGS & D has been requested to allow 98 per cent payment against proof of despatch and this has been agreed to by the DGS & D for some of the supplies. Based on this analysis, the State Governments are being approached to agree for similar payment system. Some of the Government Institutions and hospitals have also defaulted for periods ranging over 1 year and all persuasions have proved of no avail. The Company may be constrained to discontinue supplies in extensive case to such defaulting institutions.

As regard collection of outstandings of bulk sales, supplies are made to formulators against payment and this usually takes 7 days from the date of despatch. Of late, the Company has been availing of the Bills Discounting Scheme for sale of bulk as a result of which cash is realised immediately.

It may be mentioned that such delays in payment by the government institutions and hospitals takes place invariably in the case of other formulators who supply drugs to the Government Institutions.

As a result of various measures taken as outlined above the outstanding as on 20th September, 1976 stood at 187 lakhs which represent approximately 80 days' sale.

[Min. C&F O.M. 51012/2/75-DC 30-9-76.]

Further information called for by the Committee

What is the position of outstanding as on 31-3-1977.

(L.S.S. letter No. 21-PU/76 dt. 8-12-1977.]

Further reply of Government*

Latest position in respect of outstandings is as follows:—

as on 31-3-1977	.. Rs. 307.29 lakhs
as on 31-3-1977	.. Rs. 307.29 lakhs
as on 31-3-1978	.. Rs. 331.46 lakhs**
as on 31-3-1979	.. Rs. 375.00 lakhs**

[Min. of C&F O.M. 51012/2/75-DC dt. 9-1-1978.]

Comments of the Committee

Please *See* paragraphs 72 to 75 of Chapter I

Recommendation No. 78 (Para 8.40)

The Committee are glad to note that the company has been able to effect a net saving in foreign exchange to the extent of over Rs. 10 crores from 1968-69 to 1973-74 by producing drugs which were previously being imported. The Committee expect that the HAL should strive to contribute more imports substitution, develop new technologies towards indigenisation and upscale technology already absorbed with a view to save more in foreign exchange.

Reply of Government

The R&D unit continued to make contribution towards import substitution. For example, it developed an enzymatic process for conversion of Penicillin to 6 APA and standardized in the pilot plant. Based on this, a plant is being set up for the manufacture of 5 tonnes of 6 APA annually from basic penicillin produced by the company and this plant is expected to be completed by October, 1976. The R&D also developed a process for enzymatic conversion of Streptomycin B to A which has been successfully introduced in the plant. The R&D unit was actively associated with the introduction of high-yielding strain and technology in the case of streptomycin as well as penicillin.

It may be seen from the above that the recommendation is being implemented.

[Min. of C&F O.M. 51012/2/75-DC 30-9-76.]

Recommendation No. 79 (Paras 8.51 and 8.52)

The Committee regret to note that though the undertaking started production as far back as 1961-62, there was neither an ac-

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*Further reply not sent to Audit for vetting

**Information furnished by the Ministry at the time of factual verification.

counting manual laying down the detailed procedure for compilation of accounts nor was there a system of reporting the points raised by internal audit and action taken thereon to the Board of Directors. It is stated that these have been introduced and implemented from 1974-75. The Committee need hardly stress that observations and comments made by a audit should receive prompt attention of management at all levels and necessary follow-up action taken expeditiously. The system of cost accounting should be on scientific lines and appraisal thereof should be included in the programme of internal audit.

The Committee also regret to note that only partial appraisal of the Company's working was in the year 1974-75 in terms of the recommendations of the Committee on Public Undertakings contained in their Fifteenth Report (4th Lok Sabha) on Financial Management in Public Undertakings which required that the functions of internal audit should include a critical review of systems, procedures and operations as a whole. The Committee emphasise that such a critical appraisal is all the more necessary in a public undertaking which has started losing after making profits for years. The Committee recommend that HAL should implement this recommendation which has been accepted by Government in letter and spirit. The critical review should also receive the special attention of the management/Board/Government who should take appropriate follow up action.

Reply of Government.

The observations and comments made by Internal Audit receive prompt attention of management at all levels, and necessary follow up action is being taken expeditiously. The system of cost accounting has been put on scientific lines and action is being taken for its appraisal in the programme of Internal Audit.

The function of Internal Audit includes a Review of system, procedure and operations as a whole. The critical review will be submitted to the Board for taking appropriate follow up action.

[Min. of C&F O.M. No. 51012/2/75-DC dt. 30-9-76.]

III

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

Recommendation No. 14 (Para 2.62)

The Committee also recommend that a case study should be made to draw suitable lessons in order to obviate recurrance of such a situation in this or any other public sector undertaking. The Committee would like that this matter should be gone into in depth so as to take corrective action and to streamline procedure in order to ensure that such a situation does not recur.

Reply of Government*

The system of billing has been streamlined by the company. Based on challan-*cum*-invoice, the final bill is prepared with which the railway receipts are sent to the consignees. The medical stores of the individual consignee receives the consignment, certifies one of the copies of the bill the receipt of the materials and then forward the same to their accounts department for passing the bill. As a result of this, the delay in payments was considerably reduced. The final bill now reaches the party alongwith the concerned document within a week before the receipt of the consignment.

The Company supplies to over 7000 Government institutions and hospitals all over the country. Some of the supplies are made to the Government institutions through Central Government agencies such as Government Medical Stores, against D.G.S.D. contracts. The transit time for the consignment extends upto 30 days depending upon the destination and mode of the transport. The State Government institutions have to follow certain procedures which differ from State as well as for supplies under DGS & D. In spite of all efforts, it is found that the collection period stands around 90 days which includes about 30 days of transit time. Further measures are being taken such as approaching the various institutions and hospitals through the Company's medical representatives, de-centralisation despatches by opening depots in various States in order

*At the time of factual verification, Audit informed as follows:—

"Not susceptible of verification in the absence of documentary proof."

to reduce the transit time and approaching government authorities directly. Collection drives are also launched from time to time to the particularly after the budget sanctions are available to the Government institutions. DGS&D has been requested to allow 98 per cent payment against proof of despatch and this has been agreed to by the DGS&D for some of the supplies. Based on this analysis, the State Governments are being approached to agree for similar payment system. Some of the Government institutions and hospitals have also defaulted for periods ranging over 1 year and all persuations have proved of no avail. The company may be constrained in extreme cases to discontinue supplies of such defaulting Government institutions.

As regards collection of outstanding of bulk sales, supplies are made to formulators against payment and this usually takes 7 days from the date of despatch. Of late, the company has been availing of the Bills Discounting Scheme for sale of bulk drugs as a result of which cash is realized immediately.

It may be mentioned that such delays in payment by the Government institutions and hospitals take place invariably, also in the case of other formulators, who supply drugs to the Government Institutions.

As a result of various measures taken as outlined above, the outstandings have come down considerably. At the end of 1975-76, the outstandings were Rs. 252.17 lakhs and these have been brought down to Rs. 187 lakhs as on 31-7-1976.

In 1974, when the company was in difficult financial position due to credit squeeze, Government also had taken up the matter with the concerned Government institutions/Departments to settle the outstanding quickly.

[Min. of C&F O.M. No. 51012/2/75-DC 30-9-76.]

Further information called for by the Committee

Please state whether the case study has since been made. If so, what are the results thereof?

[LSS OM No. 21-PU/76 of 17-1-77]

Further Reply of Government

The company has reviewed the position of sundry debtors outstanding. HAL have decided to take series of measures with a view to bringing down the outstandings within a reasonable limits. These are: (1) it is proposed to ask for advance payment on proof of despatch so that at least 90—95 per cent would be realised in 2-3 week's time. To begin with, the Railways have agreed in principle to

consider payment of advance against future orders; (ii) it is proposed to make out a list of major customers who account for about 80 per cent of HAL's sales and ensure that the outstandings from these parties are effectively chased at least once in a month by personal contact by company's field staff. Recent addition of six Sales Representatives is expected to facilitate this; (iii) Customers have been approached individually wherever amounts have been outstanding for considerably long periods requesting them to expedite payment by target date failing which interest will be charged on the outstandings. They have been intimated that further supplies would be stopped in case they would not pay by a stipulated date.

Each Public Sector Undertaking is supposed to lay down norms and procedures for realising outstanding of sundry debtors including dues from Government institutions.

Position in respect of HAL nas been analysed and no case study as such is now contemplated.

[M/C&F OM No. 51012/2/75-DC of 24-2-77]

Recommendation No. 48 (Para 3.44)

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

Reply of Government

Over the years, M/s. J. G. Glass Industries was the only firm to supply glass vials according to the specifications of the company. As they were also sole supplier of glass vials to other major formulators, they adopted standard specifications of dimension which

deviated to a very minor extent from the specifications of HAL. The Company prevailed upon them to adhere to the dimensions specified by HAL. However, the firm expressed its inability particularly in view of the fact that the Government have forced them to transfer two automatic glass vials making machines to Uttar Pradesh where due to non-availability of power supply, these machines remained idle for a considerable period. Enquiries made by HAL revealed that this was a fact and it was also a fact that Messrs J. G. Glass Industries were supplying glass vials of uniform specifications to all the other viallers. In view of this, and in view of the fact that M/s. J. G. Glass Industries constituted the only source of glass vials, the company standardized the dimensions of rubber stoppers to suit the glass vials. Such rubber stoppers were readily available from another ancillary unit located in the Company's estate. It should be mentioned that the standardisation of specifications involved a very minor change in the dimension of the glass vials, but the quality of glass vials in no way was changed and the glass vials continued all along to conform to pharmacopoeial specifications.

From the technical stand point, a change in specification of a minor nature did not alter the quality or suitability of the vials in any way whatsoever. In view of this it was a prudent management decision.

[Min. of C&F O.M. No. 51012/2/75-DC 30-9-76.]

Recommendation No. 61 (Paras 5.36 to 5.41)

The Committee find that the company has in addition to the distributors appointed thirteen sales representatives.

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

The Committee also feel that such stray attempts at sales promotion as have been made by the company so far are not likely to make any worthwhile dent in the highly competitive market which is at present dominated by multinational and big private companies. Unless the products of the company are detailed to the medical profession, unless the medical profession is convinced of the high quality, easy availability and competitive prices of the company's products, and unless the net work of distributors, stockists and also

of the sales representatives are made result oriented, no sales promotion campaign can hope to achieve the desired success. The Committee would like HAL to undertake a study in depth as to how leading pharmaceutical firms in the country have built up their sales organisation for efficient sale service and distribution of drugs to customers, so that the company can take advantage of such studies in planning its sales and distribution mechanism.

The Committee also recommend that pending the setting up of the Central Marketing Organisation the industry should review the working of the existing marketing agencies and functionaries spell out their roles and targets, introduce schemes of incentives and take positive measures to ensure that all of them put in all possible efforts to promote the sales of the company's products. The Committee regret to find that even though none of the six distributors appointed all over the country, lifted even half of the stipulated minimum during 1968-69 and 1969-70 the company did not enforce the refund clause in the agreement.

The Committee are not satisfied with the justification for not enforcing the recovery clause for non-lifting of minimum quantity especially when according to Management the minimum quantity was decided on ideal share that HAL should have in market.

The Committee are not convinced as to why inspite of the earlier poor performance of distributors in Maharashtra and Bihar the distribution arrangement in these two States were continued. The Committee find that even during the years 1970-71 to 1973-74, sales effected by the distributors in Maharashtra and Bihar have been much below the stipulated minimum. In the opinion of the Committee panel clauses which are incorporated in agreements but are not enforced encourage the trade not to take the company seriously and instead of providing incentive to affecting greater sales of the company's products embolden them to ignore HAL's interests and pay greater heed to the products of other companies which seriously enforce such clauses. The Committee would like Government to take immediate steps to enforce the panel provision and effect the recovery of due. The Committee would also like Government to go into the causes of the poor off-take of distributors. The Committee recommend that HAL should impress upon the distributors the need to take serious interest in promoting the sales of its products and to make it known to them that if they do not discharge their obligations under the agreements, not only the panel clauses will be enforced but the award of distributorships to them may also have to be reviewed. This is all the more necessary now when HAL is poise-

for entry in the open market at a much bigger scale. The Committee are not sure whether proper distributors were selected by the Undertaking to promote the sales of its products. They would like the undertaking to select established distributors who have standing and experience in the field for marketing its products.

Reply of Government

Up to 1975-76, the company, in all had only 13 sales Representatives. The main function of the Sales Representatives was to procure orders from Govt. Institution/Hospitals, to follow up deliveries, pursue the settlement of bills, attend to complaints and expedite the collection of outstandings. This sales force was the bare minimum that was necessary to service an annual sale turnover of around 6 crores of formulations to about 7000 Govt. Institutions/Hospitals spread all over India, particularly in view of the keen competition in sales to institutional consumers. Their participation in sales to trade was incidental, but not their main pre-occupation. In view of this, any conclusions drawn on the performance of sales, representatives in trade sales alone may not give a proper assessment of their performance.

The marketing organisation of HAL was studied by an inter Ministerial Committee constituted by BPE, which made comprehensive recommendation in 1971 to build up a marketing organisation for the company. The company has also examined the possibility of utilising the marketing organisations of the other public sector undertakings. The company has also held discussions with some established private marketing organisations. The Board of Directors have examined the various possibilities and decided in 1976 to strengthen the marketing organisation of the company in a phased manner. The company is also in constant touch with the marketing trends in the country both in the private and public sector, with a view to formulate its own marketing stretegy. Puruent to the decision of the Board in 1976, the company is strengthening the sales organisation in a phased manner. The immediate object is to handle 50 per cent increase in sales turnover targeted for 1976-77 compared to that of 1975-76. The company has also formulated incentive shcemes to enter trade with the assistance of outside agencies. The role of the sale representatives and the functionaries in the sales organisation has been clearly spelt out, and their performance is being monitored. Sales conferences are held from time to time to co-ordinate their activities and to further the marketing strategy of the company. Incentives are also offered to the sales personnel showing outstanding performance.

As the Committee has observed, the trade sales of formulations constitutes a highly competitive field dominated by multi-national and big private companies. These concerns, in most of the cases, have their own marketing organisations whereby the storage, distribution and detailing are carried out throughout the country by the concerns themselves. In some of the cases, the Firms appoint various distributors to store and distribute their formulations. Even in these cases, the manufacturing company maintains a sales force for detailing its products to medical profession and creating the demand. As HAL did not have any sales force for deployment in trade sales, it tried a regional distributorship arrangements, on an experimental basis, for selling in trade. In all the cases, certain minimum sales targets were fixed with a view to motivate the distributor to exert his utmost to attain the maximum sales turnover. However, this experiment was successful only partially, as it could not be backed by the requisite sales force for detailing the products to the medical profession and for procuring orders. The Board of Directors of HAL have reviewed the question in depth during June, 1974, and decided to waive the enforcement of recovery clause for non-lifting of the minimum quantity stipulated, since it was beyond the control of the latter to penetrate into the highly competitive trade field.

In other words, detailing of the formulations to the medical profession and creating demand is invariably done by the drug manufacturing unit itself. As HAL had only 13 sales representatives and they were the bare minimum required to service the sales of formulations to Govt. Institutions and hospitals spread all over the country, the company launched, as an experimental measure, the appointment of regional distributors. The regional distributors are elected by inviting offers through advertisements in the press. In all, six regional distributors were selected and a minimum sales target of Rs. 5 lakhs was fixed in each case, with the anticipation that it would be possible for the distributors to attain this target with a reasonable period. However, in actual practice it was found that it was indeed difficult to make a significant dent in the trade without the necessary sales force for detailing the company's products and to establish their superiority over the similar drugs with brand names marketed through high pressure salesmanship by the multi-national companies. In view of this, four distributors out of the six found it absolutely uneconomical to pursue this and relinquished the distributorship on their own accord.

The distributors of Bihar and Maharashtra showed some promise and continued the distributionship. Even in these cases, they failed to reach the minimum target since it was beyond their control to

penetrate the highly competitive field without high pressure detailing strategy. The enquiries made by the company revealed that the distributors in each and every case had no other products similar to those manufactured by HAL and they made serious attempts to market the same, but due to reasons mentioned above could not make much headway. Pending the creation of a marketing organisation of HAL, alternate sources were explored with a view to find agencies for marketing HAL's products on the distributorship/stockistship basis. The main aim of the company was to attract some competent parties to create demand for company's products, so as to attain a reasonable share in the market. Five parties were appointed for marketing formulations after making on-the-spot assessment of their standing and capabilities. It may be noted that as a result of these efforts, one of the distributors has crossed the Rs. 5 lakhs target fixed even within the first half of 1976-77. The remaining four are expected to cross the target during the year.

The company has also contacted established distributors with a view to undertake storage and distribution work for the company. They include M/s. Voltas, Parry & Co., Rallis India and M/s. Chika Limited. Some of the parties were not willing to undertake distributorship for the company's products since they were already handling similar products manufactured by other competitors. The other parties wanted the entire sales volume of the company including the sales to the Government to be handed over to them, and this was considered not in the interest of the company since the company all along sold to the Government Institutions and hospitals directly, and appointing an intermediary at this stage could only mean paying commission to the latter without getting corresponding advantage. Further, these Firms also insisted on HAL having its own sales force for detailing its products.

[Min. of C&F O.M. No. 51012/2/75-DC 30-9-76.]

IV

RECOMMENDATIONS/OBSERVATIONS IN RESPECT OF WHICH REPLIES OF GOVERNMENT HAVE NOT BEEN ACCEPTED BY THE COMMITTEE

Recommendation No. 6 (Para 2.28 to 2.29)

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

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

Reply of Government

The Company is keeping itself abreast of the developments taking place in the technology. When such an improved strain along with the associated fermentation technology was available, the company with the approval of Government concluded the agreement. Works is now in progress for achieving the desired results and stabilisation thereof.

The potency of the strains now obtained by HAL from Toyo Jozo of Japan is far superior to the ones presently available with the other Indian firms.

The status of technology of various products of the company is constantly kept under review. While doing so, the comparative statistics of output and technology to the extent available, are made use of so as to arrive at a correct assessment.

Further information called for by the Committee

Has the case study been conducted?

(L.S.S. OM No. 21-PU/76, dt. 17-1-77)

Further Reply of Government

As stated earlier the company is keeping itself abreast of the developments taking place in the technology and making all effort to secure improved technology and strains as and when available. For instance the company has already obtained and introduced improved strain and technology for the manufacture of Streptomycin and Penicillin from M/s. Glaxo (UK) and M/s. Toyo Jozo (Japan) respectively and are in the process of introducing improved technology for the manufacture of Vitamin 'C' obtained from M/s. Roche Products.

A study in respect of company's output and technology used in the undertaking with the units in the country appears to be not feasible as the results of operation/data in each of other units in the country and outside are not available for comparison. The status of technology of various products of the company is, however, constantly under review. Comparative statistic of output and technology to the extent available are made use of for correct assessment.

In the above back-ground case study as recommended by the Committee may not be feasible.

[Min. of C&F O.M. No. 51012/2/75-DC 24-2-77.]

Comments of the Committee

Please *See* paragraph 4 to 9 of Chapter 1.

Recommendation No. 17 (Para 2.105)

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

Reply of Government

The Government propose to examine critically in consultation with other concerned, the reasons for the delay on the Part of HAI in not deputing its officers to Mercks. Before doing so, it is proposed to get an investigation done by the Board.

[Min. of C&F O.M. No. 51012/2/75-DC of 30-9-76.]

Further information called for by the Committee

What is the delay?

[L.S.S. O.M. No. 21-PU/76 of 17-1-77.]

Further Reply of Government

The investigation contemplated by the Board has also been taken up by the Board of Directors of HAL. Their report is, however, awaited.

(M/C&F OM No. 51012/2/75-DC of 25-2-77.)

Further information called for by the Committee

Has the investigations into the reasons for delay on the part of HAL in deputing its officers to Mercks and not keeping itself concurrently informed of the improvements in the strain of Streptomycin been completed? If so, has the responsibility been fixed.

[L.S.S. O.M. No. 21-PU/76 of 8-12-77.]

Further Reply of Government*

The Board had examined the matter and the minutes of the meeting held on the 3rd March, 1977 containing their views are reproduced below:

According to the contract, Merck & Co. were only required to keep HAL informed of any new improvements made by them in the process of sub-cultures for the production of Streptomycin. In this particular case, according to them, no such improvement had been achieved in their own laboratories, but they had purchased an improved strain from Glaxo who made a break-through in this regard. In view of this, Merck's failure to inform HAL about the improved strain cannot be held to be incorrect in terms of the contract.

Upto the year 1969, Merck's performance in terms of titres achieved showed a slight improvement with fluctuations up and down, but there was no dramatic increase warranting special enquiry, during the same period, there was some decline in the production performance of HAL, but this was stated to be the result of import substitution measures in raw materials. It was only in 1970 that the results obtained by Mercks showed a significant increase in titres obtained in comparison with previous years, and when this was noticed HAL deputed two officers in 1971, in order to find out

*Further reply not sent to Audit for vetting.

what improvements had been carried out by Mercks for getting better yields.

(M/C&F O.M. 51012/2/75-DC dt. 9-1-78.)

Comments of the Committee

Please see paragraph 10 to 14 of Chapter I.

Recommendation No. 18 (Para 2.106)

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

Reply of Government

Please see reply of recommendation Nos. 64—67 in regard to restructuring the R & D division to made it project oriented.

As regards investigation please see reply to Recommendation No. 17.

(Min. of C&F OM No. 51012/2/75-DC dt. 30-9-76)

Further Reply of Government

The Board of HAL had examined this also and their views are reproduced below:

The Board noted that the management of HAL had been endevouring to keep itself abrest of developments in India and abroad by organising symposia, deputing personnel to seminars and symposia in India and abroad, subscribing to over 40 foreign journals in the field of antibiotics and allied subjects. However, the information relating to productivity particularly in the field of antibiotics is highly secretive and is not readily divulged by the firms concerned. It is only as a result of the efforts made by the Company that it was able to locate and obtain improved technology in the case of Penicillin recently. As regards the question of keeping itself informed of the developments and improvements of Mercks in the

manufacture of Streptomycin, this is covered in reply to recommendation No. 17.

(Min. of C&F O.M. No. 51012/2/75-DC of 9-1-78.)

Comments of the Committee

Please see paragraphs 10 to 14 of Chapter I.

Recommendation No. 24 (Para 2.164)

The Committee note that on the basis of a process developed by NCL for production of Vitamin C in 1960 a preliminary project report for a capacity of 50 tonnes per annum was prepared in June, 1960 for establishing the capacity in HAL after the management of HAL was satisfied about the successful trials of production in the NCL laboratory as well as in NCL pilot plant. Since Vitamin C was already under production in the country, the Committee feel that Government should have made a thorough evaluation of the technology and cost of production before the go-ahead order was given. The Committee find that in February, 1963 in an interministerial meeting it was decided that since HAL had no experience in the manufacture of Vitamin C, HAL should first establish pilot plant. This was again confirmed an interministerial meeting in July, 1963 where it was decided that the pilot plant should be established in about 4 months and a joint report with NCL about pilot plant runs should be submitted to Government by January, 1964. It was also decided that a decision regarding large scale production should be taken after a technical committee appointed by Government had examined the joint report by HAL and NCL. The Committee fail to understand as to why the techno-economic evaluation of the project based on the joint report of HAL and NCL was not undertaken as envisaged earlier and a decision was taken by Government without making sure of upscaling the technology or examining the cost. The Committee would like that this aspect should be investigated and responsibility fixed for the lapse.

Reply of Government

The recommendation of the Committee has been examined in this Ministry. In an Inter-ministerial meeting held in the former Ministry of Commerce and Industry on the 14th February, 1963 to consider the proposals of HAL for setting up Vitamin 'C' and Hamycin Projects in their existing undertaking at Pimpri, the following decision was taken in regard to the Vitamin 'C'.

"Since HAL have no experience in the manufacture of Vitamin 'C' they should first establish a pilot plant which will cost

Rs. 2.3 lakhs of foreign exchange in the shape of machinery. Exact requirements of foreign exchange and the rupee expenditure will be worked out by HAL and indicated to the Ministry of C & I."

No representative of CSIR attended the meeting but immediately represented to the Ministry of C & I and the NCL had completed their work on the pilot Plant production of Vitamin 'C' as early as 1961 and that it was only after the completion of the pilot plant work that the laboratory approached the interested parties for putting up a commercial plant. Thus it was mentioned, the technical and economic aspects of the process have been evalued, tested and the project was ripe for industrial utilisation.

The Planning Commission also simultaneously took up this matte with the Ministry of C & I. The then advisor (I&M) Planning Commission wrote to the Secretary (C&I) *vide* his letter of 12-3-63 pointed out that the Planning Commission had approved this project for implementation and felt that doubts and hesitations of the kind that have been manifested in this case were not at all healthy and there should be some finality. Also once a carefully considered decision was taken it ought to be implemented and that from this point of view and because formalities including Government's sanction have been completed, the Planning Commission felt that Vitamin 'C' project should not be lightly abandoned in favour of other items like hemycin etc. also stated that the implementation of Vitamin 'C' scheme was necessary to reach the third Plan target and also pointed out that several months have been lost.

In view of these representations a further inter-ministerial meeting was held on 5-7-63 and the following decisions were taken in the above meeting:

(a) HAL undertakes to arrange for pilot plant runs of Vitamin 'C' from Sorbitol (or Glucose, if equipment and process become available) on the scale of 15 to 20 kg. per day.

(b) HAL undertakes to set up the plant required for this purpose in about four months.

(c) HAL will complete pilot plant runs and submit a joint report with NCL to the Government by January, 1964.

(d) Before the pilot plant runs are undertaken, NCL will supply to HAL full particulars regarding the process conditions for all the individual stages.

(e) The pilot plant runs will be undertaken at HAL under the joint supervision of HAL and NCL.

(f) The data collected during the pilot plant runs will be continuously exchanged with NGL and mutual consultations will be held to enable the plant to be run smoothly and uninterruptedly.

(g) The pilot plant work will be regarded as satisfactory when the conversions mentioned in the HAL project report of 1960 are achieved over an uninterrupted and continuous runs of at least 10 days.

(h) The decision regarding undertaking large scale production of Vitamin 'C' by HAL, will be taken after the above work is completed and if necessary after the joint report has been examined by a Technical Committee appointed by the Government.

(i) HAL will have the first refusal for the process and for collaboration with N.R.D.C. for its exploitation.

The Joint Report which was completed in the later half of 1965 *inter alia* made the following observations in their report:

> "On the whole, it could be stated that the efficiencies indicated in the original report have, by and large, been achieved, and there is every justification to expect that in properly designed and installed production plant, this could be bettered".

It will be seen from the above that the Joint Report had been made a favourable report on the trials of Vitamin 'C' Pilot Plant and hence it was then not considered to have a further technical or economic evaluation of the project based on the Joint Report of HAL and NCL. It may also be mentioned that a number of years was lost in making the Pilot Plant trials and seeking Government's approval and in the meantime the private sector Company which was the only monopoly producer was making progress in the manufacture of Vitamin 'C'. It may be mentioned that it was in their eagerness to produce Vitamin 'C' as early as possible that the Company and Government went ahead with the implementation of the Vitamin 'C' project for 125 tonnes capacity.

Unfortunately however, the operation of the plant did not yield the desired results on a commercial scale. Government thereafter considered the whole matter afresh and appointed a Task Force to study the problems involved in the matter and report/recommend after thorough examination a suitable course of action to retrieve the plant already installed for achieving rated capacity production.

In view of the above background, we are sure that the Committee nay like to re-evaluate the position as investigations under the circumstances does not appear to be necessary.

[Min. of C&F O.M. No. 51012/2/75-DC dt. 30-9-76.]

Comments of the Committee

Please See paragraphs 15 to 19 of Chapter 1.

Recommendation No. 25 (Para 2.165)

The technology for Vitamin C which was developed in 1960 is stated to be obsolete in today's context. While the Committee are all for affording every encouragement to indigenous know-how, the Committee now hardly stress that every prudent care should have been taken to have selected the appropriate technology and no efforts should have been spared to critically evaluate the same before taking the investment decision.

Reply of Government

The chances and scopes for adoption and function of locally developed technology would fade if only the tried and established technologies were to be taken up. There is always a risk involved in adopting a newly worked out technology especially in the field of chemicals manufacture involving several steps of operation. Since in the present case, the technology was developed in a National Laboratory, it was considered that the risk was worth taking.

[Min. of C&F O.M. No. 51012/2/75-DC dt. 30-9-76.]

Comments of the Committee

Please see paragraphs 15 to 19 of Chapter 1.

V

RECOMMENDATIONS/OBSERVATIONS IN RESPECT OF WHICH FINAL REPLIES OF GOVERNMENT ARE AWAITED

Recommendation No. 56 (Paras 4.27 to 4.35)

Pricing Policy:

The Committee note that the cost of production of various bulk drugs and formulation by HAL has more than doubled since 1966-67 in most cases and the cost of production of many items has been higher than the selling prices fixed by the Government. The Committee recommend that the undertaking should take concerted measures to reduce its cost of production by better utilisation of the capacity, improving its efficiency and controlling rejections and eliminating all wastages.

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

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

Reply of Government

As a result of implementation of various time-bound measures such as introduction of new strain and technology to increase productivity, utilisation of higher capacities, reduction of wastages, and

improvement in efficiencies resulting in lower consumption of raw materials per unit of production, the unit of production has come down in the case of penicillin products as can be seen from the following:—

Base 1973-74=200

	1974-75	1975-76	1976-77	1977-78
Penicillin G. first crystals	141	128	137	131
Penicillin V first crystals	139	132	89	64
Potassium Penicillin G Bulk	137	135	131	140
Sodium Penicillin Bulk	134	130	132	1504
Procaine Penicillin Bulk	145	141	156	14

In the case of Streptomycin, although production was marginally lower in 1975-76, due to 40 per cent power cut, during some months and although the cost of inputs such as wages, furnace oil, power and raw materials has gone upto a considerable extent, the cost of production remained the same at the index 177 (1973-74 base 100) in 1975-76 as compared to 1974-75 as a result of implementation of various measures as indicated above.

Based on the recommendation of the Bureau of Industrial Costs and Prices the Manufacturers of Penicillin and Streptomycin, which are two major products in the production range of HAL were given price increases in the last quarter of 1975-76 compensate the manufacturers for escalation in material costs and other input costs. With a view to make the essential drugs available to the consumer at cheap prices, the question of reduction of excise duty on certain intermediates which are used for the manufacture of essential bulk drugs is also under examination of the Government.

The report of the Hathi Committee is still under the consideration of Government and decision is likely to be taken soon.

[Min. of C&F O.M. No. 51012/2/75-DC dt. 30-9-76.]

Further Information Called for by the Committee

(a) What is the latest position regarding reduction of excise duty on intermediates?

(b) What is the decision of Government on the recommendation of the Hathi Committee Report in this regard?

[L.S.S. O.M. No. 21-PU/76 dt. 14-3-77.]

Further reply of Government

(a) The matter is still under the consideration of Government.

(b) The pricing policy of drugs proposed for adoption on the basis of the recommendations of the Hathi Committee is also under the consideration.

[M/C&F O.M. No. 51012/2/75-DC dt. 9-5-77.]

Further information called for by the Committee

Has a decision been taken on the issue of reduction of excise duty on certain intermediates used for the manufacture of drugs with a view to making the essential drugs available at cheap prices? What decision has been taken on the Hathi Committee Report in this regard?

[L.S.S. O.M. No. 21-PU/76 dt. 8-12-77.]

Further reply of Government*

All these issues are still under consideration of Government, in the context of the Hathi Committee's recommendations. A decision on the Hathi Committee's recommendations is likely to be taken very early.

[Min. of C&F O.M. No. 51012/2/75-DC dt. 9-1-78]

Additional reply of Government

The pricing policy of Government on the basis of the recommendations of the Hathi Committee has been decided and this is contained in paras 44 to 68 of the Statement laid on the Table of the Lok Sabha on the 29th March, 1978. (See Appendix XII).

As regards rationalisation of Taxes, the matter would be pursued with the Ministry of Finance.

[Min. of PC&F O.M. No. 51012/2/75-DC dt. 1-12-78]

Comments of the Committee

Please see paragraphs 50 to 57 of Chapter 1.

Recommendation No. 59 (Paras 5.19 & 5.20)

The Committee had in paragraph 5.79 of their 40th report on "Role and Achievements of Public Undertakings" presented to Parliament in September 1973, recommended that Government should evolve, if possible, a centralised sales and marketing set-up

*Further reply not sent to Audit for vetting.

for each type of industries and, if that is not possible, at least for specified products which are manufactured by more than one Public Undertakings. The Ministry has stated that the aspects concerning creation of one more marketing organisation in big way will have to be gone into in greater depths. The Committee feel that the Government have already taken over 2½ years to take a final decision about the shape and size of the centralised marketing set up for HAL and IDPL even though the need to strengthen the marketing organisation has been accepted in principle. They would like the Government not to lose any more time to decide about the set up of a central marketing organisation which would not only be economical but would also lead to greater co-ordination evolution of effective sales strategies and development of expertise in the field of sales and management. The Committee also stress that there should also be a regular feed back of market intelligence so that the Undertaking may plan regulate its production/sales operation accordingly.

Reply of Government

In pursuance of the recommendation of COPU on IDPL, a Committee was appointed to investigate into the problem of S.I.P. of IDPL. The Committee has submitted the report and in one of the recommendations, it has been suggested that the S.I.P. may be delinked from IDPL. The recommendation if accepted, would involve a reorganisation of IDPL and possibly HAL also. Pending a decision on the overall changes, the matter concerning marketing reorganisation cannot be decided upon in isolation. However, the Board of Directors of HAL have already improvised upon the management that a link up with the marketing organisation of Smith Stanistreet and Co. on the one hand and of IDPL on the other should be pursued. This is being attended to. The allocation of streptomycin which is on the production range of both IDPL and HAL is being issued presently by IDPL. Therefore, an introduction of marketing in a very limited way has been under way for some time.

[M/C&F O.M. No. 51012/7/75 dt. 30-9-76.]

Further information called for by the Committee

What action has been taken in regard to introduction system of regular feed back of market intelligence?

What have been the effect of link up with the marketing organisation of Smith Stanistreet & Co. and IDPL?

[L.S.S. O.M. No. 21-PU/76 dt. 14th March, 1977.]

Further reply of Government

HAL have at present 20 representatives on their Marketing Organisation, of which 6 representatives are exclusively for trade for getting market information. These 6 representatives are working in Bombay, Ahmedabad, Jodhpur, Delhi, Kanpur and Patna areas. The remaining representatives are working for Government business in Delhi, Haryana, Punjab, U.P., West Bengal, Madhya Pradesh, Maharashtra excluding Bombay City, Hyderabad, Secunderabad, Andhra Pradesh and Tamil Nadu.

From the representatives who are working for Trade, information regarding new products competitors' product/activities, etc., are collected and compiled.

Doctor's Cards are also maintained for representatives working for Trade and from these cards list of Doctor as per classification like Gynaecologists, Children Specialist, ENT Specialist, etc., are being prepared for collection of market information as well as for mailing.

For the representatives working in Government Business, Master Cards for important Hospitals are maintained and information of past consumption. Orders received, payment outstanding etc., are recorded and used for feed in/feed back information for representatives. Similarly information regarding new products, consumption, pack price, manufactures is collected from these important Hospitals.

At the meeting of the Board of Directors of HAL held on 29-11-73 a suggestion was made that HAL may enrol itself as a member of the Operations Research Group of Sarabhai on payment of necessary fees. There were certain advantages in the information that would be made available by O.R.G. Due to actute shortage of funds it was not possible for HAL to take membership of O.R.G. against payment. The question of obtaining membership of O.R.G. will be examined further.

Discussions with Smith Stanistreet & Company Ltd., regarding the marketing operation are in progress, but no final tie-up has yet been worked out.

[Min. of C&F O.M. No. 51012/2/75-PL dt. 9-5-77.]

Further information called for by the Committee

Has a decision been taken on a centralised sales and marketing set up of IDPL and HAL?

[L.S.S. O.M. No. 21-PU/76 dt. 8-12-77.]

Further Reply of Government

The Ministry of Chemicals and Fertilizers, Government of India, New Delhi, has constituted a working group comprising of the following *vide* their communication No. L-38023 (35)/77-DC dated 17-9-77, to consider the matter for marketing of drugs produced by IDPL, HAL and Smith Stanistreet.

1. Joint Secretary (Drugs) Ministry of Chemicals & Fertilizers
2. Chairman & Managing Director, IDPL (Convenor)
3. Chairman & Managing Director, HAL
4. Chief Executive of M/s. Smith Stanistreet & Co.

The Committee have had initial sittings and an interim note has been prepared. The Committee will meet again in January 1978 and make their final recommendations to the Ministry.

(Min. of C&F O.M. No. 51012/2/75-DC dt. 9-1-78)

Comments of the Committee

Please see paragraphs 58 to 61 of Chapter 1.

NEW DELHI;
April 2, 1979.
Chaitra 12, 1901 (*S*).

JYOTIRMOY BOSU

Chairman,
Committee on Public Undertakings.

APPENDIX I

(*Vide* reply to recommendation at S. No. 8)

COPY OF LETTER NO. L-55013(3)/76-DC DATED 24-3-1976 FROM SHRI V. RAJAGOPALAN, US, TO SHRI C. N. CHARI, MD-HAL REGARDING FIXING OF TARGET OF PRODUCTION

We find from the material furnished by you *vide* your letter No. IE/MD/121-A/5043 dated 8-3-1976 for inclusion in the monthly summary for the Cabinet for the month of February, 1976 that whereas the Annual Budgeted Production remains unaltered, the Budgeted Production for the each month is altered by the company. We do not know the reasons for this variation. I would also like to point out that in one of the review meetings, it was decided the Budgeted Production once fixed should not be revised by the Company unilaterally. I would request you to kindly note this in future The production of the company should be analysed only on the basis of the budgeted production fixed before the commencement of the year.

APPENDIX II

(*Vide* reply to recommendation at S. 9)

COPY OF MINISTRY OF CHEMICALS & FERTILIZERS LETTER NO. L-51012(2)/76-DC, DATED THE 12TH OCTOBER, 1976, TO THE MANAGING DIRECTOR, HAL, REGARDING ACTION TAKEN ON THE RECOMMENDATIONS OF THE 80TH REPORT ON PUBLIC UNDERTAKINGS ON H.A.L.

I am directed to forward herewith two copies of the replies to the recommendations made by the Committee on Public Undertakings in their 80th Report on HAL required on the basis of the materials furnished by you after discussions with the officers of HAL.

You are requested to place the replies before the Board of Directors in their next meeting. It will be seen therefrom that the following matters referred to in the recommendations of the Committee have to be investigated by the Board.

Recommendation No. 1.—Delay in the installation of extractors and fixation of responsibility for the delay.

Recommendation No. 17.—Delay on the part of the HAL in deputing its officers to M/s. Merck & Co. in regard to the supply of know-how and strains by M/s. Merck to HAL for the manufacture of Streptomycin.

Recommendation No. 18.—The R&D not keeping a watch on the trends of requirements of the Undertaking with reference to production and HAL not keeping itself informed of the developments and the improvements in the strains of Streptomycin by Mercks.

Recommendation No. 28.—Manufacture of Aureofungin without examining the efficiency and without obtaining any commitments of indents from State Governments.

Recommendation No. 63.—Export of the products of the company through M/s. Unichem and investigation into the terms and conditions and arrangements entered into by HAL with M/s. Unichem and whether the interest of the undertakings was taken into accounts.

Apart from the investigation to be made by the Board of Directors, there are many recommendations on which company has to take further necessary action. These are also indicated below:—

Recommendation No. 7.—Review of the standards for extraction of efficiency and yield and fixation of realistic standards for assessing the performance.

Recommendation No. 9.—Exercising proper and effective system of control over different stages of production with reference to the protocol laid down therefor.

Recommendation No. 11.—Comparative economics of replacement of equipment in piece meal *vis-a-vis* wholesale substitution of equipment with reference to new strain and technology to be examined.

Recommendation Nos. 15 *and* 21.—Strict adherence to the preventive maintenance protocols and adhering to the recommendations of the Committee of Board of Directors.

Recommendation No. 16.—Revision of the norms for harvesting in order to evaluate the efficiency of harvesting operations.

Recommendation No. 20.—Review of the production performance of Streptomycin with reference to new strains and revision of the standard efficiency and capacity so that evaluation of production could be done in a meaningful way.

Recommendation No. 32—Efforts to be made by the company to bring down the rejections in the case of bulk drugs.

Recommendation No. 35.—Measures to be taken to avoid despatch of sub-standard drug to the market and consequent withdrawal resulting in loss of the company.

Recommendation No. 37.—Increase in the value of excess consumption of raw material and inclusion of a statement of variance along with the action taken in the monthly/quarterly financial review to be placed before the Board of Directors.

Recommendation No. 38.—Revision of the standards of raw materials consumption in the case of penicillin after the introduction of new technology.

Recommendation No. 39.—Supply of measuring control instruments along with the machines/equipment that may be supplied by the manufacturers as an integral part of the machines in consultation with public sector undertakings.

Recommendation No. 50.—Review of norms for spillage and overages by the R&D for the purpose of assessment of the efficiency of the vialling operations.

Recommendation No. 51.—Watch on the percentage of spillage and overages so that suitable remedial steps may be taken in time to keep them within the norms fixed for the purpose.

Recommendation No. 53.—Review of the constraints in the marketing of tablets and capsules and examining the reasons for the under-utilisation of their capacity through the Board of Directors.

Recommendation No. 70.—Examining the possibility of reprocessing the quantity of Aureofungin remaining in the stocks with the company.

Recommendation No. 72.—Submission of a report giving details justifications for the steep rise in inventory during 1974-75.

Recommendation No. 73.—Investigation into the possibility of improving productivity and taking measures to bring it to the optimum level.

Recommendation No. 79.—Submission of critical review by the Internal Audit into the systems/procedures and operations of the Company to the Board of Directors for taking appropriate follow-up action.

These are some of the recommendations on which further action has to be taken by the company. You are, however, requested to examine the entire recommendations and replies and take necessary action as recommended by the Committee and by Government. The progress in this regard may be intimated to this Ministry from time to time. The Board may please be requested to investigate into some of the recommendations of the Committee detailed above within a period of three months and submit their report to Government.

Yours faithfully,

Sd/-

(B. K. Keayla).

APPENDIX III

[*Vide* reply to recommendation at S. No. 47]

The percentage rejections of vialled formulations.

Product	1974-75	1975-76	1976	
			April	May
1. Penicillin G Sodium 5 lacs .	11·97	3·20	7·0	1·6
2. Penicillin G Sodium 10 lacs .	7·45	4·80	Nil	Nil
3. Procaine Fortified with Sodium 4 lacs .	5·12	2·60	2·4	5·5
4. Procaine fortified with Sodium 20 lacs .	3·72	Nil	5·4	Nil
5. Streptopenicillin half gram . . .	4·81	0·90	Nil	Nil
6. Streptopenicillin one gram . . .	2·53	2·40	Nil	Nil
7. Streptomycin 1 gram	Nil	2·10	2·6	Nil

APPENDIX IV

[*Vide* reply to recommendation at S. No. 49]

Statement showing the installed/licensed Capacity and Export of Pharmaceutical Vials

Sr. No.	Name of the Unit	Capacity/ Licensed/ Installed	Types of vials	Production (in mln. nos.)			Export			Remarks
				1974	1975	1976	1974	1975 (in mln. Nos.)	1976	
1	2	3	4	5	6	7	8	9	10	11
1.	M/s. Jg. Glass Industries Ltd. Poona.	200 mln. nos.	(a) Pharmaceutical Bottles & Vials Type 'III'	180	202	137	1974-75 335 mln. Nos. valued at Rs. 35·52 lacs	1975-76 24 mln. Nos. valued at Rs. 16·47 lacs.		Jg. Glass Unit is one of the source of supplies of pharmaceutical vials to Hindustan Antibiotics Ltd. Unit. Jg. Glass Unit Viz., BEADRA(UP) has been fully meeting the requirements of Indian Drugs & Pharmaceuticals Limited.
2.	M/s. Vazir Glass Works Ltd. Bombay	1440 tonnes	Morosilicate and Soda Lime Flint and Amber vials mostly for pharmaceuticals.	Not given	130	156	1·4 mln. Nos. valued at Rs. 2·5 lacs	19 mln. nos. valued at Rs. 27·6 lacs	16 mln. nos. valued at Rs. 56·71 lacs.	—

1	2	3	4	5	6	7	8	9	10	11
3.	M/s. Mahalakshmi Glass Works Ltd., Bombay	600 M.T.	Pharmaceutical vials of various types— 7·5 cc, 10 cc, 15cc, and 30cc.	14	0·3	14·00	1·0 mln. nis. valued at Rs. 11,000/-	..	..	The Company has been regularly quoting against enquiries received of vial and supplied whenever an order has been placed on them. They are not receiving orders against all their quotations while the price is comparable to the price of imported vials.
4.	M/s. Borosil Glass Works Limited.	16 mln. pieces	Both clear and Amber vials conforming to U.S.P. types	2	1·6	5·4	..	Nil	..	..
5.	M/s. Packart Pvt. Ltd., Baroda.	105 mln. pieces.	Types of Vials 7·5 cc, 5cc, 10cc, 12cc, 20cc, 20cc serum	133	173	170	16.5 mln. nos. valued at Rs. 7·6 lacs	14·4 mln. nos. valued at Rs. 6·9 lacs	6·2 mln. nos. valued at Rs. 2·90 lacs (Upto Oct. 76)	
6.	M/s. Alembic Glass Industries Ltd., Baroda.	3840 tonnes	5 ml, 7·5 ml, 10ml, 12 ml, 15 ml, & 20 ml, vials.	87·6	112·6	78·5	7·77 mln. nos. valued at Rs. 5·8 lacs	16·5 mln. nos.valued at Rs. 14 lacs	8·6 mln. nos. valued at Rs. 10·6 lacs	These units along with Jg. Glass Industry are supplying glass vials to M/s. Hindustan Antibiotics Ltd., Poona
7.	M/s. Alembic Glass Industries Ltd. Bangalore.	N.A.	5 ml. vials	NA	16·6	41·4	..	Nil	..	

APPENDIX V

(*Vide* reply to recommendation at S. No. 54)

Statement showing the progressive increase in the Formulation capacities at Hindustan Antibiotics Ltd.

	Year of Installation	Capacity per annum
FORMULATIONS		
1. VIALLING		
I. Initial Filling line	1955	150 lakh vials
II. Additional line	1959	300 lakh vials
III. Third line	1964	450 lakh vials
IV. Fourth line	1964	600 lakh vials
2. CAPSULING	1962	60 lakh capsules
3. TABLETTING	1959	12 lakh tablets
4. TABLETTING	1968	120 lakh tablets
5. TABLETTING	1972	1557 lakh tablets
6. CAPSULING	1972	144 lakh capsules
7. TABLETTING	1976	1800 lakh tablets.

APPENDIX VI

[*Vide* reply to recommendation at S. No. 54]

ANNEXURE

(1) *Statement showing Bulk Antibiotics used by HAL for Captive Consumption and sold to Formulators*

Products	Units	1972-73				1973-74			
		Qty. used for captive consumption	Percentage	Qty, sold to Formulators	Percentage	Qty. used for captive consumption	Percentage	Qty. sold to Formulators	Percentage
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
1. Penicillin G	mmu	23.335	36·59	40·447	63·41	24·431	37·80	40·195	62·20
2. Penicillin V, Potassium	mmu	2.163	15.22	12.048	84.78	2.696	38.10	6.006	61.90
3. Benzathine Penicillin	mmu	1·418	100	..	..	1·482	95·37	0.072	4·63
4. Streptomycin Bulk	kg.	27375	39·154	41865	60.46	28200	41·91	39084	58·09
5. Vitamin C Bulk	kg.	..		..	..	28·750	100	..	..
6. Ampicillin	kg.	..	..	..	..	..	..	..	..

Products	Units	1974-75				1975-76			
		Qty. used for captive consumption	Percentage	Qty. sold to Formulators	Percentage	Qty. used for captive consumption	Percentage	Qty. sold to Formulators	Percentage
(CONTD)		(11)	(12)	(13)	(14)	(15)	(16),	(17)	(18)
1 Penicillin G	mmu	12·086	26·34	33.801	73·66	17·660	31·24	38·876	68·76
2. Penicillin V, Potassium	mmu	3·011	67·47	1·452	32·53	4·965	43·83	6.364	56·17
3. Benzathine, Penicillin G	mmu	0·722	63·56	0·414	36·44	1·615	64·56	0·551	25·44
4. Streptomycin Bulk	kg.	33222	59.03	23061	40.97	32122	51.65	30073	48.35
5. Vitamin C Bulk	kg.	569.750	100		..	3593·050	100	..	
6. Ampicillin Bulk	kg.	195·583	100	..	..	198·450	100	..	..

(ii) *Statement showing production and captive consumption and percentage thereof during the quarter April—June, 76*

Product	Unit	Production April-June 76'	Captive Consumption	Percentage of captive Consumption to Production	quantity sold to Formulators
1. Penicillin G. Bulk (Sodium & Procaine)	MMU	12·89	7·13	55.31	..
2. Pot. Penicillin V	MMU	2.20	0·99	46·00	..
3. Benzathine Pen. Bulk	MMU	0·07	0·20	..	Nil
4. Streptomycin Bulk	Kg.	21,487	8,864	41.25	..
5. Vitamin C Bulk	Kg.	407	648	..	Nil
6. Ampicillin Bulk	Kg.	328	254	77·44	Nil

APPENDIX VII

[*Vide* reply to recommendation at S. No. 55]

The percentage rejections of vialled formulations

Product	1974-75	1975-76	1976	
			April	May
1. Penicillin G Sodium 5 lacs . .	11·07	3·20	7·0	1·6
2. Penicillin G Sodium 10 lacs . .	7·45	4·80	Nil	Nil
3. Procaine Fortified with Sod. 4 lacs .	5·12	2·60	2·4	5·5
4. Procaine Fortified with Sod. 20 lacs .	3·72	Nil	5·4	Nil
5. Streptopenicillin half gram . .	4·81	0·90	Nil	Nil
6. Streptopenicillin one gram . . .	2·53	2·40	Nil	Nil
7. Streptomycin 1 gram . . .	Nil	2·10	2·6	Nil

APPENDIX VIII

[*Vide* reply to recommendation at S. No. 55]

Measures taken to improve out put of vials

1. Two aluminium cap sealing machines have been imported and installed for replacing the obsolete sealing machines. One machine has been installed since 21-1-1975 and the other one will be installed by the end of July 1976.

2. The rubber stopper machines (4 Nos.) have been fitted with new imported motors in 1975-76.

3. The hoppers of two filling machines have been modified and fitted since April 1976 to improve the performance of the filling machines to accommodate different types of powders for giving flexibility in operations.

4. One of the supervisors of the engineering section has designed a rubber stopper pressing device for butyl rubber stoppers to ensure proper fixing of rubber stoppers on the vials. The same is fixed on one filling machine and is regularly being used since Feb. 1976 with good results.

5. Introduction of systematic Plant preventive maintenance has reduced interruptions in vial filling.

6. Alternative sources of supply for glass vials and rubber stoppers have been located.

7. Proper relative humidity (30 per cent) and temperature 26.6°C) control kept for vialling by proper maintenance of air conditioning equipments and change of old and scaled chilled water coil for improving velocity of air as well as cooling of sterile air.

8. Butyl rubber stoppers for sodium and fortified sodium Penicillin are being used regularly. This is to avoid see page of moisture through a stopper. Butyl rubber was imported and made available to rubber stopper manufacturers.

9. Rubber stopper and vials dimensions changed to suit each other, and these are being rigidly followed.

10. Pressure foot arrangement for ciding up rubber stoppers on vial mouth was modified.

11. Alternative sources for supply for labels and cartons were located to ensure uninterrupted labelling and packing.

12. Running of filling lines is continued in the tea-breaks by giving staggering breaks.

13. Time-losses during any troubles at the time of filling are reduced by proper co-ordination with different units of maintenance and services.

14. The aluminium seals were primarily manufactured in the company with better tolerances rather than procuring the seals from outside.

15. Major vialling operations are carried out in the First and Second shifts where additional supervising personnel were provided.

APPENDIX IX

(*Vide* reply to recommendation at S. No. 55)

Agenda item for the meeting of the sub-committee to enquire into the capacity utilisation of formulations vis-a-vis the installed capacities etc. to be held on 25th April 1978.

AGENDA ITEM (Sub-Committee of the Board)

SUB: BULK VIS-A-VIS FORMATIONS

The Committee on Public Undertakings in their 80th Report on H.A. Ltd. submitted to Fifth Lok Sabha have observed on the utilization of vialling capacity of HAL that the major portion of the total production of different products of HAL is sold in Bulk Form to private viallers although sale in vialled formulations was more profitable than sale in Bulk. Committee further observed that the vialling capacity is not being used in full. Committee also gave directives to investigate this matter.

While replying to the points raised by the Committee Government has asked the Board of Directors to constitute a sub-committee to enquire into the matter and report to Government through the Board of Directors.

The Board of Directors, in their meeting held on 17-1-78 appointed a Committee consisting of Chairman & Managing Director, Dr. P. R. Gupta and Dr. B. B. Gaitonde with the following terms of reference and was authorised to finalise its report and forward the same to the Government:

(i) Reasons for under-utilization of formulation capacity viz. Vials, tablets and capsules in the HAL Plant;

(ii) Fixation of installed capacities that could be attained in regard to the formulations for various categories;

(iii) Whether there was any deliberate under-utilization of capacity by the Company and if so, who is responsible for such under utilization;

(iv) Any other matter pertaining to the above.

In order to facilitate the sub-committee to consider this issue and prepare the necessary report, the original observation of the Committee on Public Undertakings (Recommendation No. 55) on the subject; Reply by Government and further information/replies submitted by HAL from time to time are attached as Annexure *. A statement indicating actual production and captive consumption figures for the years 1973-74 to 1977-78 (from April 1977 to February 1978) is enclosed. Sub-Committee may consider.

Minutes of the meeting of the Sub-Committee of the Board of Directors of Hindustan Antibiotics Limited to enquire into the capacity utilisation of formulations *vis-a-vis* the installed capacities etc. held on Tuesday, the 25th April, 1978 at Pimpri.

PRESENT

1. Dr. P. R. Gupta—Director
2. Shri A. Swaminathan—Chairman & Managing Director

In attendance

1. Shri Y. H. Gharpure—General Manager (Mfg.)
2. Shri D. B. Telang—General Manager (Fin. & Admn.)
3. Dr. S. Ramachandran—General Manager (R. & D.)
4. Dr. C. S. Narayana—Manufacturing Manager
5. Shri M. V. Nadkarni—Production Manager (formulations)
6. Shri M. G. Banerjee—Manager (MGT Services)
7. Shri R. G. Gadgil—Dy. Finance Manager (F)
8. Shri S. S. Seth—Secy. & Admn. Manager

Shri A. Swaminathan occupied the Chair.

Leave of absence was granted to Dr. B. B. Gaitonde.

The Sub-Committee was apprised of the recommendations of the Committee on Public Undertakings, replies given by the Government and the decision of the Government for having the matter examined by a Committee of the Board of Directors. The Sub-Committee noted the terms of reference.

(1) Reasons for under-utilisation of formulation capacity *viz.* vials, tables and capsules in the HAL plant.

It was pointed out that the Committee on Public Undertakings which had examined the working of HAL was of the view that perhaps there had been a deliberate under-utilisation of the formula-

*Not reproduced, as recommendation No. 55 and reply appear in this Report.

tion capacity. This, it appeared, was based on an assumption that the output of formulations could be achieved strictly in accordance with the capacity of a "machine on" per shift basis as indicated by the manufacturers of the machines. In the case of the filling machines, the manufacturers had indicated the capacity at 120 vials/minute *i.e.* an absolute capacity of 57,600 vials in an 8 hour shift, on continuous working. The Sub-Committee noted that in practice, various factors affect the working. Even according to the manufacturers' recommendations, an allowance was required to be provided for scheduled maintenance to the extent of $1\frac{1}{3}$ hours per shift reducing the capacity to 48,000 vials per machine/shift. Furthermore, in a normal shift of 8 hours, the actual working time of the personnel was $6\frac{1}{2}$ hours only on account of dress changing tea and lunch intervals, which reduced the utilisation by another $1\frac{1}{2}$ hours *i.e.* by 10,800 vials thus reducing the capacity to 37,200 vials. Further allowance was required to be made for breakdowns, product-changes multi-dose operations, powder characteristics etc. There were other unforeseen technical factors such as power failures, stoppage due to high humidity, hot vials etc. besides reasons attributable to personnel such as high rate of absenteeism, with notice as well as without notice. In the event of high absenteeism in a particular shift, the whole schedule of operation was disrupted. Another reason was the wear and tear of the machinery over the years. Two of the four machines were more than ten years old, requiring more maintenance. Taking all these factors together, the effect of which is an additional average loss of $1\frac{1}{2}$ hours per shiftfi, the average achievable vialling capacity worked out to 26,400 per machine per shift.

The Sub-Committee observed that while in the case of vials there was a ready market, the position was different in case of other formulations in the form of tablets and capsules. The Company had a very limited range of formulations in the form of tablets and capsules. The utilisation of the installed capacity not only depended on the raw material (product to be formulated) but on the established market for the products. It was pointed out that the company could, besides formulating its own bulk products, formulate other products by purchasing from other bulk manufacturers and/or through imports. It was explained that the period covered for review by the Committee on Public Undertaking was one of the worst periods financially when it was extremely difficult to meet the working capital requirements for even the normal operations. Due to this, purchasing and formulating additional quantities of bulk was not feasible in the absence of established market.

The Sub-Committee noted that the capsulation machines were quite old and with the limited marketing organisation, it was diffi-

cult for the company to make a significant dent in the formulations field. The Sub-Committee, therefore, concluded that there were genuine reasons for under-utilisation of the capacity in respect of tablets and capsules.

In view of the above, the reasons for under-utilisation of the formulation capacity can be summarised as under:

(i) *For Vialling operations*:

(1) Regulated working hours for the personnel,

(2) High rate of absenteeism with or without notice,

(3) Time taken for breaks for maintenance, product-changes, multi-dose operations, powder characteristics etc.

(4) Unforeseen technical reasons such as power failure, stoppage due to high humidity, hot vials etc.

(5) High rate of breakdowns due to the aging of the machinery.

(ii) *For tablets and capsules*:

(1) Limited range of products,

(2) Absence of established market for company's products—limited marketing force,

(3) Paucity of funds,

(4) Aging of machinery.

(2) *Fixation of installed capacities that could be attained in regard to the formulations for various categories*:

In view of the reasons for the under-utilisation of the capacity, the Sub-Committee felt that the average output per machine per shift could be around 26,000 to 27,000 vials. In this case also, there were two categories of machines *i.e.* one category of very old machines in which an output of 25,000 vials could be achieved and the other category of relatively less old ones in which output of 28,000 vials could be achieved. Based on this, the Sub-Committee concluded that the following could be achievable capacities with the various machines now existing as given in the Annexure:

(i) Vials		780 lakhs per annum
(ii) Tablets	...	1200 lakhs per annum
(iii) Capsules	..	720 lakhs per annum

The actual capacity utilisation will depend upon the market condition.

(3) *Whether there was any deliberate under-utilisation of capacity by the company and if so, who is responsible for such under-utilisation*

The Sub-Committee observed that the decisions to formulate or to sell the company's products in the form of bulk were taken from time to time keeping in view constraints in formulations brought out in the earlier paragraphs and the Sub-Committee did not find any indication of a deliberate attempt at under-utilisation of the capacities.

(4) *Any other matter pertaining to the above: Remedial measures*

The Sub-Committee noted that a number of measures have been taken by the Company to improve upon the output per machine per shift as a result of which, during the last two years *viz.* 1976-77 and 1977-78, the Company achieved an output of 27,000 to 28,000 vials per machine per shift, as compared to 21,000 to 22,000 during the earlier four years *viz.* 1972-73 to 1975-76. While the company was initiating corrective steps on the technical aspects, the personnel aspects were to be tackled gradually. In addition to the measures already taken, steps were being taken to provide adequate Dehumidifiers, new inverted vial washing machines, improvements in areas down the line such as post inspection by re-aligning the inspection lines, setting up of a separate Quality Assurance Cell etc. A proposal for sterilisation by radiation was also being examined by the Research and Development Wing to restrict the rate of rejections due to sterility. It was also proposed to rationalise the shift timings to obtain continuous working. This would, however, have to be done keeping in view the statutory requirements in respect of shift timings. The Sub-Committee noted that the efforts so far made by the Company to rationalise the operations were not acceptable to the workers and whenever any such steps were suggested, these were resisted. If the Company could tackle both the technical and personnel side, it could be possible to achieve an output of around 36,000 vials per machine shift.

The meeting then terminated with a vote of thanks to the Chair.

Sd/-
CHAIRMAN.

HINDUSTAN ANTIBIOTICS LIMITED

PIMPRI PUNE 411018

Machinery used in vialling of antibiotics and their installation dates

No.	Machinery	Year of installation
1.	AF-1 Filling machine	1961
2.	AF-2 Filling machine	1962
3.	AF-3 Filling machine	1969
4.	AF-4 Filling machine	1969
5.	AF-1 Tunnel and vial washing unit	1961
6.	AF-2 Tunnel and vial washing unit	1962
7.	AF-3 Tunnel and vial washing unit	1959
8.	AF-4 Tunnel and vial washing unit	1959
9.	Autoclave No. 4	1960
10.	Autoclave No. 5	1960
11.	18-2 Drier for Rubber stoppers	1960
12.	18-3 Drier for Rubber stoppers	1960
13.	Washing Rubber stoppers M/c C, C2	1975
14.	Saral Over Printing machine	1977
15.	Carton Veyor (making cartons)	1960
16.	Air conditioning system machinery	1960
17.	Strunck horizonal labelling machine 2	1956
18.	Strunck horizontal labelling machine 2	1958

Equipment used for capsules and tablets

	Equipment used for Pen. V	*Capacity*	*Year of pur.*
1	2	3	4
1.	Mixer (Pen. V)	20 Kg/hr.	1955
2.	Mixer (Excittients)	50 Kg/hr.	1973
3.	Granulator (Pen. V)	50 Kg/hr.	1973
4.	Granulator (Excipetients)	50 Kg/hr.	1973
5.	Stocks Oven	15 Kg/hr.	1955
6.	Sara Oven	30 Kg/day	

1	2	3	4
7.	Ganson Oven	30 Kg/day	197 0
8.	Fluid Bed dryers	75 Kg/shift	1975
9.	Manstry B3A	1 lb/shift	1958
10	Rotapress mark II	12 to 15 lacs/shift	1971
11.	Strip packing (3 machines)	50,000/shift	1970-1973
12.	Mixer (IInd stage)**	machine each **50 Kg/hr.	1973
	Equipment used for Vitamin C Tablets		
1.	Mixer (Vitamin C)	50 Kg./hr.	1955
2.	Mixer (Exceptients)	50 Kg.	1973
3.	Granulator	50 Kg/hr.	1973
4.	Granylator	50 Kg./hr.	1973
5.	Fluid Bed dryers	120 Kg/shift	1975
6.	Fluid Bed dryers	100 Kg/shift	1975
7.	Mixer for final granules	50 Kg/charge/1 hr.	1973
8.	Rotapress mark II (2 machines)	12 Lakhs/shift	1972
	Equipment used for capsulation		
1.	Capsules filling Machine	7200 capsules/hr	1959
2.	Zanasi Capsules filling machine	200 capsules/hr.	1971
3.	Strippacking machine 1	50,000 Nos/shift	1968
4.	Stri ppacking machi ne 2	50,000 Nos/shift	1975

APPENDIX X

[*Vide* reply to recommendation at S. No. 62]

Copy of Ministry of Chemicals and Fertilizers letter No. L-35011(1)/77-DC, dated the 27th September, 1977 to the Managing Director, M/s. Hindustan Antibiotics Ltd., regarding Expansion in the manufacture of Streptomycin, waiver of export commitments.

I am directed to refer to your letter No. AD/IA/Export/25570, dated the 12th January, 1977 and to say that the waiver of export obligation imposed by Government in the former Ministry of Commerce and Industry's letter No. A&I-5(3)/61 of 27th January and 6th may, 1962 towards expansion in the manufacture of streptomycin was considered by Government.

In view of the reasons stated therein, it has been decided to waive the balance of export obligation remaining unfulfilled to the extent of Rs. 18.72 lakhs.

APPENDIX XI

(*Vide* reply to recommendations at S. Nos. 64 to 67)

Summary of progress made during 1975-76 *in the different projects*

Penicillin:

1. Stabilizing the new strain PC-II developed by R. & D.

2. Evolving a strain, PC-12, for Penicillin 6, also developed by R. & D. In fact, all Penicillin strains so far developed for plant use are products of R. & D. No outside collaboration was taken in this work.

3. Recommending the conditions for Penicillin V production based on shake flask and lab. fermenter experiments.

4. Evolving a technology of periodic additions for Penicillin V relating to productivity—achieved about 11,000 u/ml. in lab. fermentors and 2 K.L. fermentors and 9,000 in experimental plant fermentors.

5. Experimenting and suggesting SAG 471 for controlling foaming, resulting in better management of Fermentations.

6. Generally aiding in fermentation problems both in regard to raw materials and parameters standardisation.

7. Testing new strains showing improvements over existing production strains both in the pilot plant and the main plant, about 8,000 strains tested in two years and 10—15 superior strains selected, one of these was even tested in the plant.

8. Adoption of the improved Japanese technology and strain in the pilot plant. All aspects of this are being adopted. Pilot Plant has been equipped to work out and identify the scale-up problems for the production of 30,000 u/ml. in 160 hours, which has been achieved in six batches, the quality of the product is good.

9. A task force at the R. & D. was formed for a close liaison with the production group for improving utilisation, reducing rejection and cutting costs. Several significant improvements suggested in regard to parameters and fermentation conditions have been adopted in the plant.

The R. & D. has aided several items in close liaison with the manufacturing department to overcome sterility problems resulting

in draining of fermentors and high rejection rate in finished sterile products. Post harvest treatment of the fermented broth was improved. One of the important suggestion was to maintain the broth temperature below 18 until extracted which helped in improving the efficiency from about 57 per cent to about 70 per cent by introducing a chiller in line.

On-exchange conversion of 1st crystals (Potassium Penicillin G) to Sodium Penicillin 6 was developed and standardized. This has resulted in reduction of cost, increase in efficiency, reduction in raw materials usage and increased the stability of the material.

A new method of conversion of Penicillin V acid to re-crystallised potassium Penicillin V was developed and standardised in the plant.

With these improvements use of butyl acetate, a petroleum based solvent was completely eliminated from the re-crystallation area.

R. & D. recommended the use of butyl rubber stoppers particularly for vialled Penicillin products such as Crystalline Sodium benzyl penicillin and procaine benzyl penicillin fortified. This has resulted in increased stability as these products showed premature deterioration when packed in vials with natural rubber stoppers.

Streptomycin:

1. *Carbohydrate source*: A new strain yielding high levels of amyloglucosidase was isolated in the laboratory. The process for production of emyloglucosidase was developed and upscaled in plant. The enzyme was used for hydrolysis of starch in the plant. The use of starch hydrolysate for the production of Streptomycin was standardised while maintaining the productivity which has reduced the cost of sugar utilised in Streptomycin farmentation.

2. X-mannosidase: A process for production of X-mannosidase was developed. The enzyme was used in the Streptomycin fermentor for reducing Streptomycin B levels were reduced by about 50—70 per cent. The process was adopted in the plant and a number of batches were taken. This has resulted in increased production, increasing recovery efficiencies and reducing product cost.

3. *Soluble vegetable protein (SVP)*: Sootafoam SVP which was resulted in low Streptomycin productivity was up-graded by modifications of phosphate levels to near that of the American SVP the preferred raw material.

4. Laboratory process for reduction of non-calcium ash in calcium chloride complex of Streptomycin was developed which is expected to decrease the rejection rate of the product. In addition this process will result in reducing solvent utilisation.

5. Master cultures needed by production which is being supplied by M/s. Glaxo is presumed to be supplied by Research and Development.

Aureofungin:

Main problems:

(a) Obtaining consistent quality in different batches and increasing the shelf-life of formulations.

(b) Establishing its field efficiency against plant diseases.

(c) Establishing a meaningful production programme consistent with market demand.

Work completed and in progress:—

(a) Assay procedures etc., have been standardised and consistent quality could be assured.

(b) product has been stabilised with shelf-life of about 18 months.

(c) Collaborative experiments with different agricultural universities and research stations have underway and already several states have officially recommended the use of aureofungin-sol.

(d) The dove-tailing of having a production programme to meet market demand is in progress. For instance, even as recently as 24th July, 1976 it was decided that HAL would take up continuous production of 12 batchs of aureofungin to meet the immediate market orders.

(e) In collaboration with other laboratories a new method has been developed to separate and distinguish aureofungin from Hamycin and other heptaene antibiotics.

Hamycin:

Several pilot plant 2000 litre batches were taken which storred that the strain and the process yielded product of consistent quality that conformed to all specifications

Neomycin:

1. New strains have been developed which yield around 6000 u/ml. in shake flasks in lab-fermentors.

2. The fermentation and process taken up in the pilot plant at 2000. 1 fermentors yielded standard product with satisfactory yields. The quality of this product was tested in several Indian and International Laboratories.

Semi-synthetic Penicillin:

The American Home Products procedure for synthesizing ampicillin was first standardised in the laboratory. Only when the results in laboratory runs were according to the expected yields the process was scaled up to plant. Scientists in R. & D. then went to plant and helped the production staff to standardise the process on plant scale.

In laboratory, method for synthesizing Ampicillin Trihydrate has been developed. Standardisation of the same in laboratory is going on. This is in view of the fact that the collaboration is for ampicillin anhydrous which is more costly than ampicillin-trihydrate.

Process development of other semi-synthetic penicillins such as Cloxacillin and dicloxacillin has also been undertaken.

A long acting injectable ampicillin derivative is being developed as a substitute for injectable short acting sodium ampicillin.

6-APA:

1. R. & D. developed process for the production of 6-APA in large scale by either soluble enzyme or immobilished enzyme process. Both processes have been patented in India and abroad. The process has shown in the pilot plant that it is capable for quality of product and yields as good as any other process that is currently in use anywhere also.

2. Based on this process, HAL is establishing a plant for 6-APA required for 5 tonnes/year of ampicillin. The plant is expected to be on steam by the end of 1976. The R. & D. and Projects groups are in close liaison for this purpose.

Vitamin 'C':

R. & D. scientists participated in the deliberations of the working group formed by the Task Force which in turn was appointed by Government of India. During several sittings, many suggestions were given; many of which were tried in Laboratory, pilot plant and some have been implemented on the plant. These were mainly in the areas of sorbose recovery, solvent substitution and Vitamin C Re-crystallisation from the point of view of reduction in cost, recovery of solvents and better efficiencies.

Subsequently, Roche scientists also visited the organisation. They also gave several suggestions in the areas of sorbose fermentation, sorbose recovery and Vitamin C recrystallisation. All these have, been successfully tried in the Laboratory and in Pilot Plant and some of these have been implemented in the plant with expected results.

Production Development Unit:

This unit was established in 1968 with only one assistant until 1971 when one more assistant was added. The present strength is one Sr. Scientific Officer Gr. II and 4 assistants. The following formulations have been developed so far and already marketed:—

(1) Penicillin V granules for Syrup (new products)

(2) Penicillin V tablets 65 mg. and 125 mg. (improved formulation)

(3) Penicillin V tablets 250 mg. (new product)

(4) Vitamin 'C' 100 mg. tablets (new product)

(5) Ampicillin capsules 250 mg. (improved formulation)

(6) Hamycin suspension

(7) Hamycin tablets

(8) Aureofungin sol.

The following formulations are ready for marketing:—

(1) Vitamin C 500 mg. tablets (new product)

(2) Ampicillin capsules 250 mg. (alternative formulation from ampicillin trihydrate)

(3) Ampicillin mixture B.P.C. (new product)

(4) Chloramphenicol—Streptomycin capsules 125 mg. each (new product)

The following formulations are under development and it is expected that data on some of them would be ready before 31st December, 1976 so that they could be marketed subsequently:—

(1) Vitamin C drops 100 mg/ml. (new product)

(2) Tetracycline Vitamin C capsules 250 mg. and 100 mg. (new products)

(3) Ampicillin Mixtures B.P.C. (Alternate formulation from Ampicillin Trihydrate)

(4) Ampicillin capsules 500 mg. (new product)

(5) Benzathine Penicillin Gand Procaine Benzyl penicillin 6 lacs units each (new product)

(6) Benzathine Penicillin G, Procaine Benzyl penicillin and Sodium Benzyl penicillin 6 lakhs, 3 lac and 3 lac units/vial (new products)

(7) Chloramphenicol Tetracycline Hydrochloride 125 mg. each (new product)

(8) Tetracycline syrup

(9) Chloramphenicol, Tetracycline Vitamin C 125 mg., and 250 mg. (new products).

(10) Chloroquine tablets 500 mg. (new product)

Pilot Plant:

(1) *Pilot plant Laboratory.*—In order to implement the Toyo Penicillin technology, a microbiological and chemistry process laboratory was established in the pilot plant with existing R&D staff and equipment.

(2) Modificatiohns of 2 K. L. formentors and ancilliary vessel in order to carry out experiments for absorbing Toyo technology and provide scale up information on penicillin fermentation to main plant. Testing and standardising the indigenous raw materials needed to Toyo.

(3) Setting of the PH temp. controlled 6—APA production system in pilot plant which has served as base for the main plant which is under construction.

(4) Improving the sterile air systems.

(5) Modifying and adapting the pilot plant N.B. Lab. fermentors with continuous and staggered addition facilities to provide process information for main plant. Yields of over 15,000 u/ml. in about 160, 180 hours were obtained.

Strengthening R and D Staff:

(1) A chief Pharmacologist (N.D.) was appointed to this newly created post to strengthen the pharmacology and Toxicology work connected with the new products and formulations that are being developed.

(2) The product development group was strengthened through the addition of two more scientific Assistants.

(3) The Pilot Plant and bio-engineering requirements were greatly strengthened through the recruitments of a biochemical Engineer.

Projects that have been dropped:

1. *Antiamoebin.*--This drug showed some initial promise as an effective anthelminthic agent. Subsequent field trials failed to sustain this expectation and except for a small field trial on its lactogenic properties, no further work is in progress at present.

2. *Erythromycin.*—R&D took up strain and process development for this antibiotic which was included in the HAL Vth Plan programme. After thorough evaluation it was decided to discontinue project work as the antibiotic yields of the strains on hand were poor and therefore un-economical.

APPENDIX XII

(*Vide* reply to recommendation at S.O. 56)

Statement laid on the table of the Lok Sabha on 29th March, 1978 by Shri H. N. Bahuguna, Minister of Petroleum, Chemicals and Fertilizers containing Government Decisions on the (Hathi) Committee on Drugs and Pharmaceuticals Industry.

Mr. Speaker, Sir, with your permission, I place on the Table of the House the following Statement containing the decisions of Government on the Report of the Committee on Drugs and Pharmaceuticals Industry, popularly known as the Hathi Committee.

The functioning and growth of the drugs and pharmaceuticals Industry in India over the past few years had been engaging the attention of the Government, particularly with a view to finding out ways and means to meet the growing requirements of drugs and pharmaceuticals in the country as well as the broad social objectives of providing quality drugs at fair prices. Questions about the performance of the public sector units, the role of multi-national firms, licensing policy and prices were prominently raised in Parliament also from time to time. Following a suggestion made in Parliament, Government of India set up, on February 8, 1974, a Committee under the chairmanship of Shri Jaisukhlal Hathi and other Members of Parliament along with various officials and non-officials, to enquire into the various facts of the drugs industry in India. The terms of reference of this Committee were as follows:—

(i) To enquire into the progress made by the industry and the status achieved by it;

(ii) To recommend measures necessary to ensure that the public sector attains a leadership role in the manufacture of basic drugs and formulations, and in research and development;

(iii) To make recommendations for promoting the rapid growth of the drugs industry, and particularly of the Indian and small scale industries sector. In making its recommendations the Hathi Committee will keep in view the need for a balanced regional dispersal of the industry;

(iv) To examine the present arrangements for the flow of new technology into the industry, and make recommendations therefor;

(v) To recommend measures for effective quality control of drugs, and for rendering assistance to small-scale units in this regard;

(vi) To examine the measures taken so far to reduce the prices of drugs to the consumer, and to recommend such further measures as may be necessary to rationalise the prices of basic drugs and formulations.

(vii) To recommend measures for providing essential drugs and common house-hold remedies to the general public, especially in the rural areas; and

(viii) To recommend institutional and other arrangements to ensure equitable distribution of basic drugs and raw materials, especially to the small scale sector.

2. The Hathi Committee submitted its Report to Government in April 1975. The report was laid on the Table of both Houses of Parliament in May 1975. After several discussions with representatives of the industry as well as several high level inter-Ministerial consultations, the views of the Cabinet Committee, designated therefore, were put up to the Cabinet in February 1977, but could not be considered. Immediately after the General Elections of 1977, the Minister for Petroleum, Chemicals and Fertilizers directed that the recommendations should be examined on priority keeping in view the large number of representations received from various Associations of the industry and allied sectors, as well as individual manufacturers.

A series of discussions were held by the Minister with the following Associations:—

(i) Indian Medical Association (IMA).

(ii) Indian Drug Manufacturers Association (IDMA).

(iii) Organisation of Pharmaceutical Producers of India (OPPI).

(iv) All India Manufacturers Organisation (AIMO).

(v) Indian Pharmaceutical Manufacturers Association (IPMA).

(vi) Pharmaceutical and Allied Manufacturers Association (PAMDAL).

(vii) All India Chemists and Druggists Association.

3. A series of inter-Ministerial meetings at high level were also held to review all points of view. The Foreign Exchange Regulation Act (FERA) Committee also met specially to consider the recommendations concerning the future role of the foreign drug manufacturing companies. A special meeting of the Consultative Committee

of the Ministry of Chemicals and Fertilizers convened in November, 1977 discussed exclusively the recommendations of the Hathi Committee at considerable length. The draft recommendations which emerged from all these deliberations were directed by the Cabinet to be considered by a Cabinet Committee on Drugs.

4. The Cabinet considered the conclusions of this Cabinet Committee and have taken a final decision on various recommendations at their meeting held on March 28, 1978.

BACKGROUND OF THE INDUSTRY

5. The drugs and pharmaceuticals industry in India is one of the most important sectors of the Indian economy—of crucial significance to the public health of the Nation. In the last three decades since Independence, the industry has expanded considerably and India today has wide-ranging capability and production in basic drugs and formulations. From a production of Rs. 10 crores 30 years ago, a production of Rs. 150 crores of bulk drugs and Rs. 700 crores of formulations has been achieved in 1976-77. There are over 2500 drug units of which 128 are in the organised sector.

6. The break-up of production of bulk drugs and formulation by various sectors of the industry in 1976-77 is as follows:—

(Rs. in crores)

	Bulk	Formulations
(i) Public Sector	48	47
(ii) Foreign Sector	63	292
(iii) Indian Sector (private) including Small-scale Sector .	39	361
TOTAL . . .	150	700

7. Besides the above indigenous production, bulk drugs of a *c.i.f.* value of Rs. 47 crores were also imported in 1976-77.

Foreign Sector

8. There are, today, 45 foreign drug companies where the direct and indirect foreign shareholding exceeds 40 per cent. The break-up is as follows:—

Foreign equity exceeding 74% . .	14
Foreign equity between 51 to 74%	11
Foreign equity between 40 to 51% .	13

Besides the above 38 foreign companies, there are 7 more companies which are either branches of foreign companies or with foreign equity above 40 per cent in other than organised sector. The break-up of these 45 companies, country-wise, is as follows:—

USA	18
United Kingdom	13
Switzerland	6
Federal Republic of Germany	4
Others	4

9. The share of the foreign companies in the production of bulk drugs in the country in 1976-77 was 42 per cent, as against 40 per cent in 1975-76. In respect of formulations, the percentage was 41.7 in 1976-77 as against 53.8 in 1975-76. Overall, the share of foreign companies in the total production of bulk drugs and formulation was 51 per cent in 1975-76 as against 41.8 per cent in 1976-77.

Public Sector

10. Indian Drugs and Pharmaceuticals Ltd. and Hindustan Antibiotics Ltd. are the two public sector drug manufacturing units. In the year 1976-77, these units produced Rs. 48 crores worth of bulk drugs and Rs. 47 crores worth of formulations, amounting to 33 per cent and 7 per cent respectively of the country's total production. It would, thus be seen that while a third of the country's production of bulk drugs comes from the public sector, its share in formulations is negligible. The total investment in the public sector is, as of 31-3-1977, as follows:—

	Rs. crores
Indian Drugs & Pharmaceuticals Ltd.	116·73
Hindustan Antibiotics Ltd.	15·61

11. *Broad objectives of the New Drugs Policy:*

The broad principles and objectives which Government have kept in view in formulating the new Drugs Policy are as follows:—

(i) To develop self-reliance in drug technology;

(ii) To provide a leadership role to the public sector;

(iii) To aim at quick self-sufficiency in the out-put of drugs with a view to reduce the quantum of imports;

(iv) To foster and encourage the growth of the Indian sector;

(v) To ensure that the drugs are available in abundance in the country to meet the health needs of our people;

(vi) To make drugs available at reasonable prices;

(vii) To keep a careful watch on the quality of production and prevent adulteration and mal-practices;

(viii) To offer special incentives to firms which are engaged in Research and Development; and

(ix) To provide other parameters to control, regulate and rejuvenate this industry as a whole, with particular reference to containing and channelizing the activity of foreign companies in accord with national objectives and priorities.

12. *New Drug Policy*:

The following policy on production and planning in the drugs industry and the role of the public sector therein has been approved by Government:—

(i) The drugs open to licensing for (a) the public sector and (b) the Indian sector and (c) all sectors (including foreign companies) have been listed at Annexure I.

(ii) The rate of growth of each sector will be carefully planned to avoid shortages.

(iii) In considering industrial licence applications, however, preference will be given to Indian companies over MRTP units and foreign companies and in that order. Economy to scale, technology and pricing of products, however, would be the deciding factors.

(iv) In view of the growing export market for Indian Drugs and Pharmaceuticals, the Ministry of Petroleum, Chemicals and Fertilizers will seek to so regulate production that the required surplus for export is also available.

(v) The Public Sector will be assigned a leading role in the production and distribution of drugs and pharmaceuticals. Adquate outlays will be be provided to achieve this objective.

(vi) The Public Sector will be permitted to obtain the best technology available to improve productivity.

(vii) The Public Sector would be encouraged to earmark a suitable percentage of their net turn-over for R and D activities.

(viii) Formulation capacity in the Medical Stores Organisation under the Ministry of Health and Family Welfare will be suitably augmented.

(ix) Institutes like the C.R.I., Kasauli, B.C.G. Vaccine Institute, Madras, Haffkine Institute, Bombay, which are producing

vaccines, sera and antigens would be activised to accept a wider role for production and supply of these categories of medicines.

(x) Public Sector units shall be planned to meet major requirements of drugs for public health services.

(xi) The Indian drug manufacturers will be allowed formulation licences upto 10 times of the value of their bulk drug production. In order to encourage consumption of indigenously produced bulk drugs, such formulation capacity would be sanctioned, provided the formulation turnover is based on a ration of 2 : 1 between consumption of indigenous bulk drug and imported/canalised bulk drugs.

(xii) However, a case-by-case approached will be adopted in applying the these ratios where Indian companies have made substantial investments for production of bulk drugs but actual production has yet to be achieved, because of the gestation periods, time-span for perferction of technology, etc.

(xiii) The question whether Indian companies may be allowed to expand formulation capacity freely, based on consumption of indigenous bulk drugs and whether restriction on expansion of formulation capacity may be applied only whether the Indian companies are seeking imported bulk drugs, will be reviewed after a year.

(xiv) At present, certain units in the organised sector are exempt from obtaining industrial licences, but are required to register their activities with the D.G.T.D. with a view to ensure the implementation of the entire complex of decisions on licensing etc. in the drugs industry, it is proposed that all units which are carrying on so far with DGTD registration only would be required to obtain industrial licences and the registration scheme shall cease, in so far as the drug industry is concerned.

Role of Foreign Companies

13.1. The first view of a majority of the members of the Hathi Committee was that the multi-national units in the field of drugs and pharmaceuticals should be taken over by Government. A second view was that there was no case, at this stage, to justify such drastic measures. In the second view the economic case for take-over has to be based on the advantages accuring to the community from such a stop and in this, it would be difficult to make a distinction between foreign and Indian companies. If there is a case for nationalisation,

the argument would be equally applicable to the units in the Indian sector above a certain size. A third view endorsed the second view but added that the wholly Indian units to be nationalised may be at least with annual turn-over of Rs. 2 crores and above and those which are determined as sick units need not be nationalised and paid unnecessary compensation.

13.2. The Hathi Committee could not come to any unanimous decision though the majority of the members were of the view that foreign firms should be taken over, as set out in the first view. However, the Hathi Committee was unanimous that the measures set out in the succeeding para should be taken.

13.3. Under the Guidelines issued for administering Section 29 of the Foreign Exchange Regulation Act, 1973, (FERA) Indian Companies having more than 40 per cent foreign shareholding and branches of foreign companies engaged in the production of items specified in Appendix I of the Industrial Licensing Policy of February 1973 of which 'Drugs' and Pharmaceuticals is one, are required within a specified period to associate Indian participation to not less than 26 per cent of the equity of the Company. The Hathi Committee recommended that having regard to the present stage of development of the drug industry, for the purpose of FERA Guidelines, this industry should not be eligible for the preferential treatment given to items specified in Appendix I of the Industrial Licensing Policy of 1973. In the view of the Hathi Committee, foreign undertakings operating in this country should be directed to bring down their equity to 40 per cent forthwith and further it progressively to 26 per cent. This, however, is without prejudice to other concessions to which they are eligible as a result of the industry being in Appendix I of the Industrial Licensing Policy of 1973. The Hathi Committee further recommended that the dilution of foreign equity as suggested above, should not take the form of dispersed holding of the shares by large number of Indian nationals. This is because such widely dispersed holding will not in any way, reduce the effective control of the foreing equity holders. In order to serve national objectives, it would be desirable for Government to purchase these shares either by public sector undertakings which are directly or indirectly connected with the manufacture of drugs/chemicals or by public financial institutions or by Government itself.

14. Keeping in view the need to sustain a high level of drug production in the country and in view of the fact that several other measures of control are included in the new drug policy, which will direct the activities of foreign drug companies to subserve national objectives and interest, Government have decided to redefine "drugs

and pharmaceuticals" listed at 14 of Appendix I of Industrial Licensing Policy in a comprehensive manner. The new definition would be as follows:—

"(a) Drug intermediates from the basic stages for Production of high technology bulk drugs; and

(b) High technology bulk drugs from stage and formulations based thereon with an overall ratio of bulk drugs consumption (from own manufacture) of formulation from all sources of 1.5".

15. Government have further decided that, so far as foreign companies engaged only in the manufacture of formulations of bulk drug not involving high technology or both are concerned, they should be directed to bring down their foreign equity forthwith to 40 per cent, so that 66 per cent of the balanced equity currently in the hands of the foreign share-holders is disinvested in favour of Govt. financial or public sector institutions and the rest in favour of Indian investors, preference in the letter case being given to Indian employees of such companies.

16. As there are frequent allegations of unduly large profits by foreign companies, Govt. have decided to set up Committees to carry out an investigation in this regard and suggest measures, where appropriate, to regulate the profits of foreign companies.

16.2. Identification of foreign drug companies engaged only in the manufacture of formulations is simple. However, for the purpose of identifying foreign companies engaged in the manufacture of "bulk drugs not involving high technology," detailed exercises will be carried out through a high level Committee consisting of Secretaries to the Government in the Departments of Chemicals and Fertilizers, Industrial Development, Technical Development and Science and Technology, assisted by experts.

17. In respect of foreign drug companies currently engaged in Appendix I activity on drugs and formulations, the value of turnover which will be considered as such Appendix I activity, will consist of (a) the value of bulk drugs sold by them to non-associated formulators, plus (b) the value of formulations not exceeding 5 times the value of their total bulk drug production.

18. For the purposes of FERA, a drug company will be deemed to be a foreign companies if the direct foreign equity in it is above 40 per cent. The FERA guidelines and dilution formula applicable to all other industries would be applicable to the drugs and pharmaceuticals industry also.

19. Government have also decided that, in respect of foreign drug companies other than those featured in para 15, as a result of reduction of foreign shareholding under FERA Guidelines or on expansion, Government financial and public sector institutions should aim to acquire, to the extent possible, 66 per cent of the balance equity, the rest being disinvested in favour of Indian investors, preference in the latter case being given to Indian employees of such companies.

20. Foreign companies engaged in the manufacture of household proted bulk or producing bulk drugs from penultimate stage will they be allowed to take up such activity as additional items hereafter.

21. Foreign companies producing drug formulators based on imported bulk or producing bulk drugs from penultimate stage will have to manufacture, within a period of two years, the bulk drugs concerned from the basic stage.

22. Existing foreign companies will be given formulation licences in future only if they are linked with the production of high technology bulk drugs from the basic stage.

23. The Small-scale sector will be a prohibited area for foreign companies.

24. No foreign companies will be given loan licence for operating in the drugs field. The turn-over of the foreign companies based on the existing loan licences will not be treated as Appendix I activity, but purely as trading activity.

25. Application for industrial licences (including expansion of capacity over the level existing on 31-12-1977) by foreign drug companies for the manufacture of high technology lines of bulk drugs will be considered, subject to the overall condition of their supplying 50 pet cent of their production of such bulk drugs to non-associated formulators and subject further to their restricting their overall ratio of bulk drug consumption (from own manufacture) to formulation from all sources to 1:5.

26. The condition of release to non-associated formulators, in similar circumstances, in respect of Indian companies; the pubic sector and MRTP companies will be 30 per cent, 40 per cent and 50 per cent respectively.

REGULARISATION OF CAPACITY

27.1. With regard to the capacities approved for the manufacture of bulk drugs against permission letters and C.O.B. licences, the Hathi Committee recommended that having regard to the national

need for bulk drugs, the permission letters and C.O.B. licences issued to such firms, may be regularised on the condition that:

(a) all bulk drugs are manufactured from the basic stages, and

(b) 50 per cent of the production of basic drugs should be made available to non-associated Indian formulators.

27.2. The Hathi Committee also recommended that, so far as formulations converted by C.O.B. licences/permission letters are concerned, foreign firms should be asked to switch over within one year to the manufacture of bulk drugs and formulations to the extent of 50 per cent of the production of basic drugs by them, and the balance 50 per cent to be supplied to non-associated formulators.

27.3. Government have decided that the criterion for regularisation of production in excess of licensed capacity or capacity based on COB licences, permission letters, registeration certificates, no objection certificate etc. will be the highest production actually achieved in any year during the three year period ending March 31, 1977. If the companies had expanded beyond licensed capacity or done any other acts in violation of the conditions attached to the specific industrial licences or other authority granted to them or of any other laws whether during the period 1973—77 or prior to that, action may be taken against them on the same lines as applicable to all companies in other sectors of industry which may have committed similar violations.

28. In the case of foreign drug companies, regularisation of excess production on the above criterion will be done (a) subject in their making over to non-associated formulators 50 per cent of their total production of such bulk drugs (including that regularised) and (b) subject further to their restricting the value of their formulations to five times the value of their total bulk productions.

29. In the case of Indian public sector and MRTP companies, regularisation of excess production on the above criterion will be done on the condition that they make available 30, 40 and 60 per cent respectively of their total production (including that regularised) to non-associated formulators and subject to the further condition that they restrict production of their formulations to 10 times the value of their bulk drug production.

30. Excess production in formulations which fall within the decontrolled category will not be regularised and the companies will have to reduce their production in this category to the level of authorised capacity within a period of 6 months from the promulgation of policy.

31. If excess production of price controlled categories of formulations is regularised on the above criterion and such formulations are based on imported bulk drugs, the company will not acquire a prescriptive right to obtain imported/canalised bulk drugs to a sustain such excess production and Government bulk reserves the right to reduce supplies of imported/canalised bulk drugs to the level of original authorised capacity.

32. On the excess production so regularised, Government will also have the right to receive supplies at rate fixed by them.

33. *The excess production in household remedies produced by the foreign sector will not be regularised.*

34. However, in the case of foreign companies which have a ratio of bulk to formulations of less than 1:5 (or 1:10 in the case of Indian companies), regularisation of excess production of decontrolled formulations and household remedies may also be permitted up to the ceiling of these ratios.

35. Excess production in any category will be regularised, if the company undertakes to export such excess for a period of 5 years from the promulgation of the policy.

36. *No unauthorised production (that is production not authorised by industrial licences, COB licence permission letter or DGTD registration) shall be regularised.*

Consolidation of Industrial Licences:

37. *A fresh consolidated licence will be issued to each company replacing all earlier licences issued under various licensing authorisations like industrial licence, COB licences permission letter, registeration certificate etc. This consolidated* licence will indicate *inter alia*, the names and descriptions of bulk drugs, the quantity licensed the percentage of production required to be supplied to non-associated formulators and export obligation, along with (a) the approved formulation, and (b) the bulk drugs (with quantity) required for the production of such formulations.

38. In regard to licences where the capacities for bulk drugs or formulations have not been specified so far, capacities will be fixed depending on the nature of items produced and their essentialities, subject to the highest production achieved in any one year during the three years ending March 31, 1977.

IMPORT OF TECHNOLOGY

39. The import of technology for new bulk drugs by the foreign drug companies will have to be on such terms as may be determined by Government.

40. The foreign drug companies should undertake transfer of technology laterally to public sector units where national interests justify the setting up of additional capacity.

R & D export obligation and offer of guality control facilities.

41. Foreign companies whose turnover in drugs in the excess of Rs. 5 crores per annum shall be obliged (a) to have R & D facilities within the country on which capital investment should be at least 20 per cent their net block, and (b) to spend at least 4 per cent of their sales turnover as recurring expenditure on R & D facilities.

42. To correct the present situation where industrial licences do not prescribe the export obligation of foreign companies a suitable export obligation based on the total sales turnover in formulations may be prescribed for foreign companies while consolidating their licences under the proposed policy, after a case by case review.

43. Foreign companies should be encouraged to offer quality control facilities to the small scale sector on a no profit no loss basis.

Pricing Policy

44. The Hathi Committee had recommended that a return post-tax between 12 to 14 per cent on equity, i.e. paid-up capital *plus* reserves, may be adopted as the basis for price fixation, depending on the importance and complexity of the bulk drug. In the case of formulation, the Hathi Committee felt that the principle of selectivity could be introduced in terms of (a) the size of the units, (b) selection of items, and (c) controlling the prices only of market leaders, in particular, of products for which price control is contemplated. The Hathi Committee considered that units (other than MRTP units) having only turnover of less than Rs. 1 crore may be exempted from price control. Alternatively, all formulations (other than those marketed under generic names) which have an annual sale in the country in excess of Rs. 15 lakhs (inclusive of excise duty) may be subject to price control, irrespective of whether or not the total annual turn-over of the unit is in excess of Rs. 1 crore. The ceiling price will be determined taking into account the production costs and a reasonable return for the units which are the market leaders. Yet another variant of selectivity, according to the Hathi Committee, would be to identify product groups which individually are important and which collectively constitute the bulk of the output of the industry. In respect of each item of this list, it would be possible to identify the leading producers who account for about 60 per cent of the sales between them. On the basis of the cost analysis in respect of those units, maximum prices may be prescribed and all other units may be free to fix their prices within this ceiling. On balance, the Hathi Com-

mittee was of the view that this particular variant selectivity may be administratively simpler.

45. The Hathi Committee also felt that the recommendations of the Working Group on pricing of formulations under the alternative scheme of pricing could be adopted with the revised rate of ceilings on profits ranging from 8 to 13 per cent on sales turnover--listing the firms under large, medium and small groups. The Hathi Committee also suggested further that as an alternative criterion, the ceiling on profit may also be specified as between 10 to 12.5 per cent post-tax on net worth.

46. After an exhaustive examination of all aspects of these recommendations, the Government have decided that all bulk drugs which are used in the production of price controlled formulations will be subject to price control. The post-tax return on bulk drug required for production of Category I and II formulations which are highly essential and life-saving will be kept at 14 per cent and on other bulk drugs, at 12 per cent on net worth i.e. equity plus free reserves.

47.1. However, price of about 100 bulk drugs whose cost structure has already been studied by the Bureau of Industrial Costs and Prices (BICP) will be frozen, initially for one year.

47.2. In regard to those bulk drugs where no such cost study has been made so far, their current declared prices would be reviewed quickly by the BICP on the above criterion.

47.3. The prices of new bulk drugs introduced into the market after the promulgation of the new policy will also be governed by the above criterion.

48. Where the indigenous bulk drug is produced by more than one manufacturer, a common selling price for sales to all formulators will be fixed initially on the basis of average costs of relatively more efficient firms which account for a large percentage of out-put.

49. The prices of bulk drugs notified by Government would be inclusive of the cost of transportation and transit insurance, but exclusive of local taxes.

50. Government have also decided that price control on FORMULATIONS WILL BE APPLIED on a selective basis and for this purpose, four categories will be established, as at Annexure II.

51. The pricing of formulations in Category I and II will be worked out on the basis of product groups of equivalent the reputic value. Such pricing will be based on the "Leader product" of leading producers whose price will serve as a ceiling for all other formulators,

within that group. The mark-ups shall be 40 per cent and 55 per cent respectively.

52. In so far as Category III is concerned, separate pricing for each producer will be done, as was being done hitherto. However, wherever possible on the basis of standard composition "leader products" would be sought to be indentified here also and prices notified for such formulations, which may, at the option of the concerned manufacturers, be adopted by them, under advice to Government. The mark-up for this category shall be a miximum of 100 per cent the manufacturer being free to choose his own mark-up upto the limit of this ceiling.

53. *In respect of Category IV, there will be no price control.*

54. The gross of profit of the individual manufacturers would be contained as follows:—

(A) *Large units with turnover exceeding Rs.* 6 *crores per annum and pre-tax return on sales turnover exclusive of excise duty.*

(a) having no basic drug manufacturing activity nor any research activity 8 per cent.

(b) having basic drug manufacturing activity corresponding to 5 per cent or more of turn-over but no research activity 9 per cent.

(c) having basic drug manufacturing activity at 5 per cent or more of the turnover and engaged in approved research and development work relating to new drug 10 per cent.

(B) *Medium size units with turnover between Rs.* 1 *crore to Rs.* 6 *crores per annum and*

(a) having no basic drug manufacturing activity nor any research activity. 9%

(b) having basic drug manufacturing activity corresponding to 5% (or more) of turnover but no research activity. 11%

(c) having basic drug manufacturing activity at 5% or more of turnover and engaged in approval research and development work relating to new drugs. 13%

(C) *Other units with turnover of less than Rs.* 1 *crore per annum.*

(a) having only formulation capacity. 12%

(b) having basic drug manufacturing activity at 5% or more of turnover. 13%

55. While the Government would take a final view on the mark ups to be allowed in respect of Category I, II, III, it has also been decided that:—

(a) For an initial period of one year, prices of existing formulations in categories I and II would be frozen, with the leader prices operating as a ceiling.

(b) Where, however, the current prices of individual manufacturers in respect of such formulations are lower than the ceiling, no increase in prices will be allowed.

(c) BICP would, within a period of one year, scrutinise the costing of existing formulations for fixing leader prices. The basis of costing would be settled by BICP in consultation with the Ministry of Petroleum, Chemicals and Fertilizers.

(d) If any increase in leader prices for existing formulations were to be suggested as a result of the BICP's scruting these would be brought before the Cabinet.

(e) The prices of formulations in category III would also be frozen at the existing level for the initial period of one year.

(f) The prices of category IV formulations would be decontrolled with immediate effect.

(g) However, the overall ceiling on profitability as given above would apply.

56. In respect of new formulations, including formulations arising from new bulk drugs mentioned earlier at para 47.3 while the general principles enumerated above would be applicable, the following mark ups would be permitted:—

Category I 40% } 'Subject to the over all.
Category II 50% } 'Ceiling on profitability.
Category III not to exceed 100% as above.
Category IV not subject to price control.

57. The gross profit beyond 8 to 13 per cent for the group listed earlier shall be funded separately for such purposes including R&D, as may be specified by Government.

58. While the existing exception limit of a turn-over of Rs. 50 lakhs in respect of small-scale drug units will continue for exemption from price control, the leader price will be followed by the small-scale sector also in respect of categories I and II formulations.

59. It will be ensured progressively that at least 20 per cent of the turnover of an individual drug company is in Categories I and II formulations.

60. For Government purchases of drugs and medicines, other things being equal, preference will be given to producers in the public sector, considering the leadership role being assigned to the public sector in the manufacture of drugs and pharmaceuticals.

61. The present provision under the Drugs (Prices Control) Order, 1970 regarding marking of equal retail prices shall continue to apply to both the controlled and decontrolled drugs produced both by the exempt and non-exempt manufacturers.

62. *Incentive for original development*—In the case of entirely new or original bulk drugs developed through indigenous R&D efforts and which have not been produced elsewhere, there will be no price control on the bulk drug and its formulations for a period of 5 (five) years. The condition of supply of part of the production to no-associated formulators shall not also apply to such bulk drugs during this period. The Department of Science & Technology will certify claims made in this regard.

63. Appropriate packaging costs necessary for retaining the efficacy of drugs will be allowed. A Committee will be set up by the Ministry of Petroleum, Chemicals and Fertilizers to standardise and lay down norms for the packaging required for various types of formulations. The Committee will consist of experts drawn from the drug industry (both public and private sectors), the packaging industry, doctors, representatives of consumer interest and officials of the Ministries of Health and Family Welfare, Petroleum, Chemicals and Fertilizers and the BICP.

64. *Notifications of norms.*—The norms of (a) process loss (b) convesion cost of bulk drugs into formulations and (c) packing charges shall continue to be notified by the Government.

65. *Trade Margins.*—The existing trade margin for whole-salers and retailers will continue, that is:

(a) minimum of 2 per cent and 10 per cent for wholesaler and retailer respectively for non-ethical formulations; and

(b) minimum of 2 per cent and 12 per cent for wholesalers and retailers respectively for enthical formulations.

66. *Price control on Intermediate.*—Ministry of Petroleum, Chemicals and Fertilizers will fix, from time to time, in consultation with BICP, the prices of intermediates produced the public sector undertakings.

67. The following 8 (eight) critical drug intermediates will also be brought under the purview of price control, while ensuring a return of 12—14 per cent on net worth as in the case of bulk drugs:—

(i) Meta-Amino-Phenol.

(ii) Para-Nitro-Chlorobenzene.

(iii) Picolines.

(iv) Para-Nitro-Benzoic Acid.

(v) Methyl Imidazole.

(vi) Dextrose.

(vii) Acetanilide, and.

(viii) Ethylene Oxide.

68. This list of critical drug intermediates could, if necessary, be amended by notification by Government from time to time.

69. Sole selling agencies for drugs and formulations where such arrangements exist, should ultimately disappear. Where existing leader prices are based on sole selling agency commissions of more than 5 per cent BICP would review such leader prices and reduce them appropriately with immediate effect.

NATIONAL DRUG AUTHORITY, BRAND NAMES, QUALITY CONTROL ETC.

70.1. The Hathi Committee had recommended the setting up of a National Drug Authority—an autonomous body which would handle all matters concerning the future expansion of the drug industry licensing, imports, exports, technological development. Government has given careful consideration to this recommendation and has come to the conclusion that it would not be possible to establish a totally independent authority on the lines suggested by the Committee. Government recognize, however, the need for close co-ordination in the formulation of drug policy and in the implementation of expansion programmes. Government have, therefore, approved of the following advisory/administrative/organisational set up.

70.2. A field organisation in the Department of Chemicals and Fertilizers under a Development Commissioner (Drugs Industry) with the following prime functions:—

(i) To operate the scheme of pricing under the Drugs (Prices Control) Order (Essential Commodities Act),

(ii) To recommend a policy for release of raw materials (indigenous, imported and canalised) and to supervise their distribution so as to ensure that the raw materials allocated to the drug manufacturing units are utilised effectively,

(iii) To review the list of canalised items as also to review the availability and distribution thereof in the context of prevailing international economic situation from time to time, with a view to help formulate the ITC policy,

(iv) To inspect selectively with a view to prevent the misuse of canalised and imported materials,

(v) To review the shortages of drugs and to take measures to anticipate such shortages as well as obviate them if they do emerge, and

(vi) To operate as a counselling organisation for development of the drug industry so that new entrepreneurs may be assisted to establish new units in accordance with the policy of the Government.

70.3. A high level Committee on Drugs and Pharmaceuticals called "Policy and Planning Committee for Drugs Industry" (PPDIC) will be constituted to advise the Department of Chemicals and Fertilizers from time to time.

70.4. The Development Council for Drugs and Pharmaceuticals will be activised under the Chairmanship of the Minister for Petroleum, Chemicals and Fertilizers.

70.5. Within the policy guidelines laid down, various Committees like LC & FERA Committee will continue to deal with their various operational functions as hithertofore.

70.6. While the pricing of drugs will be continued to be examined by the BICP, decisions on pricing will be notified by the Department of Chemicals and Fertilizers, as hitherto.

ABOLITION OF BRAND NAMES

71.1. Brand names shall be abolished in the first instance in respect of the following five drugs:—

Analgin

Aspirin

Chlororomazine

Ferrous sulphate

Piperazine and its salts such as adipate, nitrate and phosphate.

71.2. All single ingradient dosage forms of the above drugs shall be marketed only under generic names.

71.3. Drugs which are to be exported will be allowed to bear brand names.

71.4. This decision will be kept under constant review in the light of actual experience.

71.5. Drugs formulations marketed under generic names will also be subject to price control.

71.6. Such amendments as might be necessary would be carried out immediately in the relevant Acts like the Trade and Merchandise Act, 1958 and Drugs and Cosmetics Acts Rules.

R & D IN PUBLIC SECTOR

72. The recommendations that the public sector should set an example in respect of R & D activity by setting apart 5 per cent of their net turn-over will be implemented to the extent possible, depending upon the funds available for such investment.

CESS

73. The Ministry of Industry propose to introduce a Bill for the amendment of the IDR Act, 1951, so as to empower the Government to levy a cess up to 1 per cent of the value of goods produced by any scheduled industry and that Bill will provide for the establishment of a Central Research and Development Coordination Authority and Research Direction Committee for different sectors of industry The proposal to set up five regional laboratories pilot plant and toxicological laboratory will be considered further in the light of this.

QUALITY CONTROL

74. The quality control functions will continue to be looked after by the Ministry of Health and Family Welfare. There will be need to intensify arrangements for guality control. The Ministry of Health and Family Welfare will strengthen the organisation set up with the aim of ensuring that spurious or sub-standard products are not manufactured or marketed by drug manufacturers. Additional funds which may be required therefore will be met to the extent possible from the cess proposed above.

75. The setting up of a laboratory for testing sera, vaccines and immunological products will be expedited, in consultation with CSIR/ICMR.

PATENTS

76.1. A subject index of pending application will be prepared and maintained by the Patent Control Office which may be of help to intending entrepreneurs. The patent control office will also being out a list of rejected patent applications.

76.2. The Recommendation of the Hathi Committee that wherever an Indian entrepreneur has set up any basic production within a certain specified period which might infringe on the coverage claimed in the pending applications, a suitable solution should be found out

whereby entrepreneurs could continue with their manufacturing operations, would be considered separately in consultation with the Department of Science and Technology, Ministry of Law and Controller General of Patents, Designs and Trade Mark.

RESEARCH AND DEVELOPMENT

77. The setting up of a strong centre for for R&D in enzymology and enzyme technology by the Department of Science and Technology/CSIR will be considered after a view is taken on the Report on the present status of research in the field of applied microbiology in the CSIR laboratories.

78. All efforts would be made to prevent avoidable duplication of R&D activities between public sector units. While efforts are usually made in agreements currently being entered into for foreign technology by public sector units to provide for horizontal transfer of technology, a case by case view will be taken on existing Agreement within the parameters of those Agreements.

79. Public Sector units will maintain the closed liaison with the R&D units of national laboratories, State institutions/other educational institutions. Appropriate facilities will also be created in the identified institutions, where necessary, to promote time-bound completion of individual projects.

80. The Indian Council of Medical Research will be requested to concentrate their attention particularly on the discovery of newer drugs for tropical diseases.

81. Highest priority will be accorded to centrally directed research aimed at discovery of newer drugs for treatment of tropical diseases anti-malarials, anti-filarials, anthelmintics and anti-leprotics. Research will be accelerated for new drugs for cardio-vascular ailments, metabolic disorders and contraception.

82. Integrated development of basic chemical raw materials and intermediates by the industries and R&D institutions in the country will be encouraged.

83. In respect of imported technologies, concurrent purchase of equipment to the extent not covered by indigenous manufacturers or by other competitive offers will alone be provided for.

TECHNOLOGY

84. Efforts will continue to be made to step up production of existing units by improvement of technology and of imported processes through R&D activities and the efforts of the State owned research laboratories. This should not, however, preclude obtaining crucial technology wherever necessary.

85. The development of technology for steroids in the public sector would be taken up in the overall context of their existing production lines as well as expansion plans.

86. Development of indigenous technology wherever possible will be encouraged in respect of the drugs highlighted by the Hathi Committee—including Chloramphenicol-involving NCL, CDRI and RRL Hyderabad, etc. Import of technology will be permitted wherever necessary and where available without onerous conditions, taking the entire complex of factors into consideration, such as demand, availability of indigenous technology, success of pilot plant trials etc. In order to reduce dependence on import of technology in general, urgent steps will be taken to equip the public sector units as also the national laboratories with such R & D and pilot equipment as may be necessary Public Sector units will also ensure that they have a strong design and engineering component in their R & D structure, so that chemical processes that may be developed may be indigenously tested and scaled up with the necessary complement of competent indigenous design and engineering skill. Wherever necessary, public sector units may also obtain assistance from other public sector or private design and engineering organisations in respect of up-scaling of a given process.

87. Import of technology for the economic production of ergot alkaloids and therapeutically active steroids, if these have not been worked out by the national laboratories, will be resorted to.

POWER

88. State Electricity Boards will be requested not to subject industrial units to power cuts, if such units are engaged in the production of drugs which are thermo-labile and are sensitive to heat such as sera, vaccines and other immunological products and antibiotics, as also generally ensure uninterrupted supplies to the drug industry.

GRANDULAR PRODUCTS

89. Modern slaughter houses and other facilities for collection and storage of glands, extraction of active principles etc. will be encouraged in order to prevent the wastage of valuable raw materials that could be used profitably for biological products etc.

DRUG COMPLEXES AT INDUSTRIAL COAL CONCENTRATIONS

90. The Hathi Committee have made several recommendations for non-user of valuable chemicals like Benzene, Toluene as fuel, recovery of these chemicals from coke oven of steel plants, usage of acids sludge, establishment of new drug units using chemicals recovered from coal-tar distillation at Durgapur, development of coal carbonisation complexes in Andhra Pradesh and Maharashtra, recovery of aromatics from naphtha etc. All these recommendations will be considered in the context of all factors concerning economic viability including the factor of locational advantage.

MEDICINAL PLANTS

91.1. In the order of importance, the Hathi Committee had identified 14 plants having medicinal value, out of which 8, namely dioscorea species, cinchona, poppy, ergot, digitalis, ipecac, dubesia (or atropa), and lemon grass are the sources for essential drugs identified by this Committee. The Hathi Committee had endorsed the recommendations of the NCST for increased cultivation of the 14 plant materials and also production of active principles obtainable therefrom with updated technology.

91.2. The recommendations of the Hathi Committee on medicinal plants will be reviewed in the light of the conclusions of the Agro-Herbal Advisory Group constituted in the Ministry of Health and Family Welfare.

DISTRIBUTION

92. Possibilities of enlarging, rationalising and decentralising the distribution system in the public sector, with special reference to rural areas, making use of unconventional agencies for the distribution of household remedies and commenly used medicines will be explored, keeping in view the requirements of the Drugs and Cosmetics Act and Rules.

93. The Hathi Committee had recommended that in order to enable the establishment of pharmacies specially in small towns in rural areas, immediate steps should be taken to revise the present syllabus of training of pharmacists. The Pharmacy Council should be approached to tailor the course to suit our country's needs. An intensive need oriented course of a short duration should be instituted for the training of dispensers. The Pharmacy Council of Indian would be requested to actively consider these recommendations.

94. The Ministry of Health and Family Welfare will consider the recommendation concerning provision of proper quality drugs in adequate quantities through Primary Health Centres in rural areas, keeping in view the standards for urban areas.

MONITORING

95. Registration and monitoring of the activities of drug and formulation units in the small scale sector will be done by the development Commissioner, Drug Industry.

PUBLICITY AND ADVERTISEMENT

96. The Ministry of Health and Family Welfare will keep in mind the view of the Hathi Committee that, because of the importance of educating the rural population about the use of household remedies, advertisements may have to be permitted to serve this limited need.

97. Adequate availability of alcohol, particularly for chemical based industries, will be kept under constant watch.

MISCELLANEOUS

98. All supplies of single ingredient drugs and drugs included in Indian Pharmacopoeia should be tendered by Central and State Government institutions and local bodies and supplies made to them under generic names.

99. All single ingredient drugs and drugs included in the Indian Pharmacopoeia other than those in respect of which brand names have been abolished shall bear lables displaying entlythe genric names. Brand names may be shown on lables in less conspicuous manner.

100. Drug Controller should not, while granting permissions, give recognition to brand names of new single ingredient drugs, not should such drugs be allowed to be marketed under brand names when first into this country.

101. The Drug Control Administration should immediately go into the various drug combinations and take prompt measures to eliminate irrational drug combinations or use of ingredients far in excess of what is required. No firm should be allowed to incorporate excessive quantities of any drug over and above the requirements for therapeutic and prophylatic purposes. The Pharmacopoeial Committee will be requested to give new/generic names for multiple ingredient preparations.

While reviewing the policy of abolition of brand names in respect of more drugs in future, the recommendations of the WHO from time to time on non-proprietory names may also be kept in mind.

103. An endeavour will be made to create facilities for bio-availability studies, so that the industry, both large and small scale, can use them to plan and conduct bio-availability and pharmaco-kinetic studies.

104. Immediate steps to revise the Indian National Formulary and make it uptodate and to publish journals on the lines of the Prescribers' Journals, UK; Medical Letter, USA; or Formulary Notes of Sri Lanka will be taken.

Annexure I

Indicative list of lines of production for Public Sector, Indian Sector and Open for all sectors (including foreign Sector)

Public Sector	Indian Sector	Open for all Sectors
(1)	(2)	(3)
1. Penicillin	1. Ampicillin	1. Chloramphenicol
2. Streptomycin	2. Doxycycline	2. Neomycin
3. Tetracycline	3. Sulphacetamide	3. Rifamycin
4. Oxy-tetracycline	4. Vitamin C	4. Phthalyl Sulfathiazole
5. Erythromycin	5. Nicotinamide	5. Sulphadizine
6. Ampicillin	6. Halogenated-oxy-quinolines	6. Sulphaphenazole
7. Doxycycline	7. Metronidazole	7. Sulphamethoxazole
8. Griseofulvin	8. Glybenclamide	8. Sulphasomidine
9. Gentamycin	9. Chlorpropamide	9. Sulphamoxole
10. Sulphaguanidine	10. Thiacetazone	10. Vitamin A
11. Sulphadimidine	11. Sodium PAS	11. Vitamin B-6
12. Sulphacetamide	12. INH	12. Vitamin B-2
13. Sulphamethoxy-Pyridazine	13. Baphenium-Hydroxy-Nepthoate	13. Vitamin D-3
14. Sulphadimethoxine	14. Phenacetin	14. Panthenols
15. Vitamin B-1	15. Paracetamol	15. Vitamin-K
16. Vitamin B-2	16. Pethidine	16. Diloxamide-Furoai
17. Folic Acid	17. Diethyl-carbamazine-citrate	17. Tolbutamide
18. Metronidazole	18. Xylocaine	18. Insulin
19. Piperazine & its salts	19. Phenyl Butazone	19. Ethambutol
20. Quinine	20. Oxy-phenyl-Butazone	20. Primaquin
21. Analgin	21. Caffeine (Natural)	21. Amodiaquin
22. Amidopyrine	22. Vaccines & Toxoids	22. Chloroquin
23. Phenobarbitone	23. Diazepam	23. Aspirin including salicylin Acid

(1)	(2)	(3)
24. Morphine		24. Indomethacin
25. Polio Vaccine		25. Pheniramine
		26. Chlorpheniramine
		27. Procaine
		28. Chlorpromazine
		29. Caffeine (Synthetic)
		30. Xanthinol-Nicotiname
		31. Theophyline
		32. Aminophyline
		33. Epnedriac
		34. Nitrofurantoin
		35. Fuxazalidine
		36. Nitrofurazone
		37. Succinyl Choline-Chloride
		38. Hydro-chlorothiazide
		39. Clofazimine
		40. D.D.S. (Dapsone)
		41. Prednisolone
		42. Dexamathasone
		43. Betamathosone & all other corticostere
		44. Ibuprofen
		45. Dextropropoxyphen
		46. Thiabendazone
		47. Tetramisone
		48. Framycetin
		49. Bacitracin
		50. Cyclophosphamide
		51. Mepacrin
		52. Imipiramine
		53. Amitryptilene
		54. Diphenyl Hydantoin

(1)	(2)	(3)
		55. Methyl Dopa
		56. Triamcinolone
		57. Phenyl Ephedrine
		58. Salbutamol
		59. Oxytocin
		60. Rutin
		61. Prenylamine Lactate
		62. Thioridazine
		63. Phenothiazine
		64. Allopurinol
		65. Trimethoprim
		66. Furosemide

CATEGORY I—FORMULATIONS

1. Aspirin tablets
2. Digoxin tablets
3. DDS tablets
4. DPT Vaccines
5. Insulin injection (all sorts)
6. Hydro-chlorthiazide tablets
7. Indo-chloro-hydroxy-quinoline tablets and Di-iodi-oxy-quinoline tablets
8. INH tablets
9. INH plus Thiacetazone tablets
10. Morphine sulphate injection
11. Penicillin injection including procaine Penicillin G and Benzathine Penicillin all strength
12. PAS and its salts, granules and tablets
13. Phenoxymethyl penicillin tablets
14. Streptomycin injection all strengths plus combination with penicillin
15. Pethidine Injection.

CATEGORY II—FORMULATIONS

1. Analgin tablets
2. Amodiaquin tablets
3. Chloramphenicol oral preparations including chloramphenicol palmitate suspension and syrup and chloramphenicol sodium
4. Chloramphenicol in combination with Streptomycin
5. Chloroquin salts
6. Primaquin tablets
7. Calcium Benzoyl PAS tablets
8. Diethyl carbamazine citrate tablets
9. Fur-semide tablets, injection
10. Glycaryl Trinitrate tablets
11. Phthayl Sulphathiazole tablets
12. Prednisolone tablets and injection
13. Phenobarbitone tablets
14. Piperazine and its salts—tablets, syrup
15. Sulphadimidine tablets
16. Tetracyclines, capsules, tablets, syrup, injection, eye ointment (including Oxy-demathylchloro and Pyrrolidine Methyl Tetracylines)
17. Tolbutamide tablets
18. Tetanus Toxoid Injection
19. Diphtheria tetanus toxoid injection
20. Quinine salts, tablets and injections

CATEGORY II—FORMULATIONS

Formulations based on drugs falling under the following categories excluding the formulations included in Category I and II.

1. Anaesthatics, General and Local
2. Analgesics and Antipyretics
3. Anthelimintics
4. Antiameobics
5. Tnti asthmetic drugs and Enteric Antiseptics
6. Antibiotics
7. Anticancer Drugs
8. Anticoagulants
9. Anticonvulsants
10. Antidiabatics
11. Antihistaminics
12. Antileprotic Drugs
13. Antimalarial Drugs
14. Antirheomatic Drugs
15(a). Antiseptics
15. Antisepasmodics
16. Antitubercular Drugs
17. Cardiovascular
    - (i) Antihypertensives
    - (ii) Anginal Drugs and Coronery Vasodilator
    - (iii) Peripheral Vasodilators
    - (iv) Cardiac glycosides
    - (v) Others
18. Corticosteroids
19. Diuretics
20. Drugs used for Calcium therapy
21. Haematinics
22. Oral Contraceptives

23. Ophthelmological Preparations
24. Oxytocies
25. Plasma Expanders and Transufusion Solutions
26. Sera and Vaccines
27. Urinary
28. Vitamins
29. Ampicillin capsules, tablets, syrups and injections
30. Erythromycin capsules, tablets and syrup
31. Metronidazole tablets
32. Antacids
33. Antidiarrhoeals
34. Antigout drugs
35. Disinfectants
36. Antitussives and Expectorants
37. Dental products other than those containing local anesthetics
38. Dermatological preparations not containing antibiotics Sulphonamides and Corticosteriods
39. Otic preparations not based on antibiotics
40. Parasympathomimetics

CATEGORY IV—FORMULATIONS

Categories of Drugs, the formulations falling under which will be exempt from price control

1. Anabolics
2. Antidopressants
3. Antidotes
4. Antiobesity Drugs
5. Aphrodisiacs
6. C. N. S. Stimulants
7. Cholagues
8. Dietotics
9. Enzymes and Digestants
10. Haemorrihoidal preparations
11. Haemostatics
12. Hormones used for menstrual disorders and sterility
13. Laxatives, Purgatives and Lubricants
14. Male Hormones
15. Mouth washer
16. Nasal Decongostants
17. Surgical Dressings
18. Sweetenera
19. Throat Lozangea, paints, etc.
20. Thyroid and Tntithyroid preperations
21. Diagnostic aids
22. Anti Parkinsonian Drugs
23. Muscle Relaxants
24. Sedatives and Hypnotics
25. Tranquiliners

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