

FIFTEENTH REPORT

STANDING COMMITTEE ON
CHEMICALS AND FERTILIZERS
(2015-2016)

(SIXTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

JAN AUSHADHI SCHEME

*[Action Taken by the Government on the Observations/Recommendations
contained in the Fourth Report of the Standing Committee on
Chemicals and Fertilizers (Sixteenth Lok Sabha) on Jan Aushadhi
Scheme of the Ministry of Chemicals and Fertilizers
(Department of Pharmaceuticals)]*

Presented to Lok Sabha on 27.11.2015

Laid in Rajya Sabha on 27.11.2015



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COMPOSITION OF THE STANDING COMMITTEE ON
CHEMICALS AND FERTILIZERS
(2015-16)

Shri Anandrao Adsul – *Chairperson*

MEMBERS

Lok Sabha

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3. Smt. Anju Bala
4. Shri B.N. Chandrappa
5. Shri Sankar Prasad Datta
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Rajya Sabha

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[#]Nominated w.e.f. 28.9.2015.

24. Shri Sanjay Dattatraya Kakade
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29. Shri Palvai Govardhan Reddy
30. Dr. Sanjay Sinh
31. Shri Abdul Wahab

SECRETARIAT

1. Smt. Rashmi Jain — *Joint Secretary*
2. Shri Anil Kumar Srivastava — *Director*
3. Smt. Emma C. Barwa — *Deputy Secretary*

INTRODUCTION

1, the Chairperson, Standing Committee on Chemicals and Fertilizers (2015-2016) having been authorised by the Committee to present the Report on their behalf, present this Fifteenth Report (Sixteenth Lok Sabha) on Action Taken by the Government on the observations/recommendations contained in the Fourth Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2014-2015) on Jan Aushadhi Scheme of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Fourth Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers was presented to Lok Sabha on 4.3.2015. The Action Taken replies of Government to all observations/recommendations contained in the Report were received on 10.8.2015. The Standing Committee on Chemicals and Fertilizers (2015-2016) considered and adopted this Report on Action Taken Replies at their sitting held on 7.10.2015.

3. An analysis of the Action Taken by the Government on the observations/recommendations contained in the Fourth Report (Sixteenth Lok Sabha) of the Committee is given in Appendix-II.

4. For facility of reference and convenience, the observations/recommendations of the Committee have been printed in bold letters in the body of the Report.

NEW DELHI;
07 October, 2015
15 Asvina, 1937 (Saka)

ANANDRAO ADSUL,
Chairperson,
Standing Committee on
Chemicals and Fertilizers.

CHAPTER I

REPORT

This Report of the Standing Committee on Chemicals and Fertilizers (2015-16) deals with the action taken by the Government on the Observations/Recommendations contained in the Fourth Report (Sixteenth Lok Sabha) of the Committee on 'Jan Aushadhi Scheme' of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha and laid in Rajya Sabha on 04.03.2015. In all, the Committee made 09 Observations/Recommendations in the Report.

1.2 The Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) were requested to furnish replies to the Observations/Recommendations contained in the Fourth Report within three months from the date of presentation of the Report, *i.e.*, by 03.06.2015. The Action Taken Replies of the Government in respect of all the 09 Observations/Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) *vide* their O.M. No. F.No. 54012(3)/2015-PI-IV, dated 10.08.2015. These Replies have been examined and categorized as follows:—

- (i) Observations/Recommendations that have been accepted by the Government:

Sl. Nos. 2, 3, 4, 5, 7, 8 and 9

(Total=07)

Chapter II

- (ii) Observations/Recommendations which the Committee do not desire to pursue in view of the Government's reply:

Sl. No. Nil

(Total=Nil)

Chapter III

- (iii) Observations/Recommendations in respect of which replies of the Government have not been accepted by the Committee:

Sl. No. 1

(Total=01)

Chapter IV

(iv) Observations/Recommendations in respect of which final replies of the Government are still awaited:

Sl. No. 6

(Total=01)
Chapter V

1.3. The Committee desire that the Action Taken Notes on the Observations/Recommendations contained in Chapter-I, Chapter IV in respect of which reply of the Government has not been accepted by the Committee and Chapter V for which final reply is still awaited, of this Report, should be furnished expeditiously.

1.4 The Committee will now deal with action taken by the Government on some of their Observations/Recommendations which still require reiteration or merit comments.

A. Need for augmenting Financial Assistance for opening of Jan Aushadhi Stores

Recommendation No. 1

1.5 Stressing the need to increase the one time financial assistance for opening of JASs, the Committee had recommended as under:—

“The Committee note that a one time financial assistance of Rs. 2.00 lakhs as establishment cost and Rs. 50,000/- as an one time start-up cost is given to NGOs/Institutions/Co-operative Societies identified by the State Government. In case of any other entity, such as reputed NGO/Charitable Society/Self Help Group and individuals, financial assistance as incentive linked to sale of medicines at the rate of 10% of the monthly sales amount subject to a ceiling of Rs. 10,000/- per month for a period of 12 months is provided. In case of stores opened in North-Eastern States and other difficult areas *i.e.* naxal affected area, tribal area etc., the rate of incentive would be 15% of monthly sale amount subject to a ceiling of Rs. 15,000/- per month. However, during the course of examination of the subject, it was brought to the notice of the Committee that the one-time grant for opening of Jan Aushadhi Store is not sufficient and the amount should be increased to Rs. 3.5 lakh as the earlier rate was fixed in 2008. The Committee, therefore, recommend that the Department should examine the possibility of increasing one time grant from Rs. 2.5 lakh to Rs. 3.5 lakh as establishment cost for opening Jan Aushadhi Stores in the country. The Committee would like to be apprised of the action taken in this regard.”

Reply of the Government

1.6 In reply to the aforesaid recommendation of the Committee, the Department of Pharmaceuticals has stated as under:—

“The Committee has recommended that the Department of Pharmaceuticals should examine the possibility of increase in one time grant from Rs. 2.5 lakhs to Rs. 3.5 lakhs towards established cost for opening Jan Aushadhi Stores in the country.

It is true that the one time grant for opening of Jan Aushadhi Store *i.e.* Rs. 2.50 lakhs was fixed in 2008 and that too it is extended only to the operating agencies identified and nominated by the State Government for running the JASs located in Government Hospitals. For any JAS proposed outside the Government Hospital premises, no one time grant is permitted. In place of one time grant, incentive @ 10% of the sales value subject to the ceiling of Rs. 10,000/- per month for a period of one year only is included. However, in case of North Eastern States and other naxal affected area and tribal areas, the rate of incentive @ 15% of the monthly sales value subject to the ceiling of Rs. 15,000 per month for a period of one year is offered.

It is also seen that one time financial grant is extended only to those Jan Aushadhi Stores, opened in the Government hospital premises where space is provided free of cost by the State Government Whereas in case of Jan Aushadhi Stores opened outside Government hospital premises run by Private Entrepreneurs, un-employed Pharmacists, NGOs, one time grant is not extended for the commencement of Jan Aushadhi Stores. They are expected to have their own/hired space, establishment cost of the stores as per the layout design of BPPI and other requirement as per the Drug and Cosmetic law.

Suggestion of increasing the one time grant of Rs. 2.5 lakh to Rs. 3.5 lakh was evaluated. It is learnt that the amount of Rs. 2.5 lakh is sufficient to meet the expenses in connection with commencing of operation of JAS. BPPI intends to focus more on ensuring supply of 504 medicines and 161 consumables strengthening supply chain and strengthening BPPI.”

Comments of the Committee

1.7 The Committee in their earlier recommendation had stated that the one time financial assistance for establishment cost for opening of Jan Aushadhi Stores in the country should be increased from Rs. 2.5 lakh to Rs. 3.5 lakh.

The Department in the Action Taken Reply has stated that one time financial grant is extended only to those Jan Aushadhi Stores, opened in the government hospital premises where space is provided free of cost by the State Government. Whereas in case of Jan Aushadhi Stores opened outside the Government Hospital premises, no one time grant is permitted. In place of one time grant, incentive @ 10% of the sales value subject to the ceiling of Rs. 10,000/- per month for a period of one year is included. However, in case of North Eastern States and other naxal affected areas and tribal areas, the rate of incentive @ 15% of the monthly sales value subject to the ceiling of Rs. 15,000 per month for a period of one year is offered. The Department has further stated that the recommendation of increasing one time grant of Rs. 2.5 lakh to Rs. 3.5 lakh was evaluated and the Department has found that Rs. 2.5 lakh is sufficient to meet expenses in connection with opening up of Jan Aushadhi Stores.

The Committee are not satisfied with the reply given by the Department and are of the view that with increased inflation Rs. 2.5 lakh is not sufficient for opening up of Jan Aushadhi Store. The Committee felt that the quantum of one time financial assistance should be adequate to meet the price rise of infrastructural requirements to make Jan Aushadhi Store operational within the space provided for the purpose. The Committee, therefore once again strongly reiterate its earlier recommendation and state that the Department and BPPI should once again re-evaluate the amount granted and increase the one time grant for opening up of Jan Aushadhi Stores to Rs. 3.5 lakh. This issue should also be periodically evaluated in the context of price rise of furnishing material and other accessories such as computer etc. The Committee would like to be apprised of the action taken in the matter.

B. Utilisation of Funds allocated for Jan Aushadhi Scheme

Recommendation No. 2

1.8 Emphasizing the need for utilization of funds allocated for JASs, the Committee had recommended as under:—

“The Committee are distressed to note that Rs. 20 crore earmarked at BE stage for Jan Aushadhi Scheme was reduced to Rs. 4.50 crore at RE stage during the year 2012-13, out of which only Rs. 1.66 crore were utilized. For the period from 2013-14, Rs. 25 crore was allocated for the Scheme but based on the requirement of BPPI, only Rs. 15.20 crore, was released for the year 2013-14. The Committee also regret to note that for the year 2014-15, Rs. 30 crore

was allocated at BE stage for the Jan Aushadhi Scheme but due to non-utilisation of the allocation till September 2014, the Ministry of Finance reduced the allocation of the Department at RE stage to NIL. The Committee strongly feel that the under-utilisation or non-utilisation of funds is bound to have its cascading effect on the targets set by the Department under the scheme during 12th Plan period. The Committee also feel that the Department does not seem to have undertaken any proactive measures to overcome the bottlenecks which have impeded the optimum utilisation of funds. The very fact that during 2014, only 11 stores could be opened in the country as indicated in the Annexure-I, clearly indicates the slow pace of progress in setting JASs across the country. This also shows the lack of proper planning and concerted and coordinated efforts on the part of the Department to address those constraints which were impeding the implementation of the scheme. The Committee, therefore, recommend that the Department should resolve and take initiative and formulate plan for optimum utilisation of funds for opening of stores as per the plan target. The Committee also recommend that the Department should also monitor timely and full utilization of funds for the purpose. The Committee would like to be apprised of the initiatives taken by the Department in this regard.”

Reply of the Government

1.9 In reply to the aforesaid recommendation of the Committee, the Department of Pharmaceuticals has stated as under:—

“The total budget envisaged in the new business plan for the years 2013-14 and 2014-15 were Rs. 25.00 crore and Rs. 38.21 crore respectively. However, only a total of Rs. 16.86 crore were released as BPPI has utilized only 14.6 crore till 31st May, 2015. BPPI has also submitted a plan of utilization of Rs. 69.35 crore for the current year and Rs. 154.94 crore for the next year 2016-17.

BPPI is in the process of opening another 200 JAS during the current year. They have already initiated various actions required for increasing their basket of products and services. Procurement activities for 504 medicines and 161 consumables against the present level of 361 medicines is in progress. They have also prepared a detailed plan of media activities to be undertaken in and around the existing 111 JAS and also around every JAS being opened through hoardings, bulk SMS, Mobile exhibitions, distribution of pamphlets etc. For achieving the above target BPPI is getting strengthened through augmentation of manpower. All these improvements will ensure the full utilization of funds allotted for Jan Aushadhi Scheme.”

Comments of the Committee

1.10 The Committee in their earlier recommendation had stated that the Department should resolve and take initiative and formulate plan for optimum utilization of funds for opening of store as per the plan target. The Committee further recommended that the Department should monitor timely and full utilization of funds for the purpose.

The Department in the Action Taken Reply has stated that the total budget envisaged in the new business plan for the years 2013-14 and 2014-15 were Rs. 25.00 crore and Rs. 38.21 crore respectively. However, only a sum of Rs. 16.86 crore was released as BPPI has utilized only Rs. 14.6 crore till 31st May 2015. BPPI has also submitted a plan of utilization of Rs. 69.35 crore for the current year and Rs. 154.94 crore for the next year 2016-17. The Department has further stated that BPPI has been taking various initiatives during the current year, such as opening more JAS stores, procurement of more medicines for the store and plan for media activities for advertisement of JAS etc.

The Committee are happy to note that the Department and BPPI are taking various measures to promote Jan Aushadhi Stores and also to strengthen the infrastructure for Jan Aushadhi Scheme making it viable for maximum number of people. The Committee in this regard expect that the Department should completely utilize the funds earmarked for the Jan Aushadhi scheme and the initiative undertaken would give desired and planned results. The Committee would like to be apprised of the progress in the matter.

C. Need to improve the functioning of Bureau of Pharma PSUs of India (BPPI)

Recommendation No. 3

1.11 Stressing the need to improve the functioning of BPPI, the Committee had recommended as under:—

“The Committee note that the Bureau of Pharma Public Sector Undertaking India (BPPI) comprising all the central Pharma PSUs (CPSUs) namely IDPL, RDPL, KAPL, HAL and BCPL was set up on 1st December, 2008 with major objective to have focused and empowered structure to implement the Jan Aushadhi Campaign initiated by Department of Pharmaceuticals. It is a registered society under Societies Registration Act, 1860 with Government of NCT of Delhi on 21.04.2010. BPPI is monitoring the functioning of Jan

Aushadhi Stores. It is also involved in promotion of unbranded generic drugs. The Committee note that one of the main functions of BPPI is to have coordination with the State Governments for opening of Jan Aushadhi Stores. The BPPI takes up the issue with the State Governments and meets the officials concerned for explaining about the scheme and opening of Jan Aushadhi Stores. Further, the nodal officials appointed by BPPI and placed in the State, meet with the State Government officials regularly in matters relating to Jan Aushadhi Scheme Stores. However, the functioning of BPPI does not seem to be satisfactory. The very fact that till date only 170 JAS have been opened and out of that only 99 are functional clearly shows that BPPI has not been very effective in its functioning. The Committee, therefore, recommend that the Department should take remedial measures for improving the functioning of BPPI so that the opening and maintenance of JAS and availability of medicines therein could be done in an effective and efficient manner. The Committee would like to be apprised of the initiatives taken/ being taken by the Department in this regard.”

Reply of the Government

1.12 In reply to the aforesaid recommendation of the Committee, the Department of Pharmaceuticals has stated as under:—

“DoP has initiated few steps to improve the functioning of BPPI. BPPI has submitted a detailed Strategic Action Plan for improving the Jan Aushadhi Scheme. BPPI is getting strengthened with adequate man power and standard operating procedures are being laid down for different activities in BPPI clearly defining the functions and responsibilities of each and every Executive in the organization.

The recruitment process has already been initiated through open advertisement in leading newspapers. The recruitment process is expected to be completed by the end of August 2015.”

Comments of the Committee

1.13 The Committee had earlier recommended that the Department should take remedial measures for improving the functioning of BPPI which would facilitate the opening and maintenance of Jan Aushadhi Stores and availability of medicines therein in an effective and efficient manner.

In this regard, the Department in the action taken reply has stated that they have taken various steps to improve the functioning

of BPPI. It has also been stated that BPPI has submitted a detailed Strategic Action Plan for improving the Jan Aushadhi Scheme. The Department has further stated that BPPI is being strengthened with adequate man power and standard operating procedures are being laid down for different activities in BPPI clearly defining the functions and responsibilities of each and every Executive in the organization. Further, the recruitment process has already been initiated through open advertisement in leading newspapers. The recruitment process is expected to be completed by the end of August 2015.

While appreciating the efforts made by the Department based on Strategic Action Plan submitted by BPPI for strengthening BPPI with adequate manpower and laying down standard operating procedure, the Committee recommend that all the requisite formalities in this regard should be finalized expeditiously and the Action Plan may accordingly be implemented in the current financial year. The Committee hope to find some substantial improvement in the functioning of BPPI by the end of this financial year.

D. Implementation of Jan Aushadhi Scheme

Recommendation No. 4

1.14 Noting the need for effective implementation of Jan Aushadhi Scheme, the Committee had recommended as under:—

“The Committee note that access to quality medicines at affordable prices is a key challenge for the Government. The prices of branded medicines are generally higher than generic medicines due to various reasons including limited regulation through Drug Prices Control Order, 1995 etc. A countrywide campaign in the name of ‘Jan Aushadhi Campaign’ was also launched in November 2008 by the Department of Pharmaceuticals for ensuring availability of generic medicines at affordable prices to all in collaboration with the State Governments as a direct market intervention strategy. Under this Campaign, less priced quality generic medicines are being made available through Jan Aushadhi Stores (JAS) which are of same and equivalent quality, efficacy and safety as compared to branded generic medicines. Under this Scheme, the State Government has to provide space in Government Hospital premises for the running of the Jan Aushadhi Stores. Government hospitals, NGOs, Charitable Organizations and public societies like Red Cross Society, Rogi Kalyan Samitis typically constituted for the purpose could be operating agencies for the JAS. The operational expenditure

is met from trade margins admissible for the medicines. The first Jan Aushadhi Generic Drug Store was opened in civil hospital Amritsar on 25th November, 2008. However, the Committee regret to note that the Jan Aushadhi Scheme during the first six year of its implementation, has not been able to make much headway in opening of Jan Aushadhi Stores in each district of the country as was proposed. The poor performance of the scheme is quite evident from the fact that as against the target of opening of one JAS in each of the 630 districts, only 170 stores have been opened so far. However, with a view to remove the shortcomings noticed in the original Jan Aushadhi scheme, a revised New Business Plan has been worked by the Department. The Committee were informed that various steps were being undertaken under the New Business Plan to remove/rectify bottlenecks in implementation of the campaign. The steps include relaxation of eligibility conditions for operating entities, review of existing list of medicines, improving supply chain management, sourcing of drugs, working capital, prescription of generic medicines health policies and media campaign etc. The Committee also note that the Department proposes to issue advertisements calling for applications from interested parties for opening of Jan Aushadhi Stores in all the States. The Committee also note that New Business Plan envisage to open 3000 new JAS by 2016-17. Against this backdrop, the Committee hope that the New Business Plan would take care of bottlenecks in effective and efficient implementation of the scheme and the Department would take proactive measures and make co-ordinated efforts with all concerned to open maximum JASs as envisaged under New Business Plan by 2016-17 so that the benefits of low cost improved generic drugs are reached to maximum number of common people. However, the Committee recommend that the execution and progress of the scheme should be monitored at regular intervals so that the target to open 3000 JASs by 2016-17 under New Business Plan could be achieved. The Committee would like to know the initiatives taken by the Department and progress made under the New Business Plan from time to time.”

Reply of the Government

1.15 In reply to the aforesaid recommendation of the Committee, the Department of Pharmaceuticals has stated as under:—

“BPPI has prepared and submitted their Strategic Action Plan which elaborates various steps and plans undertaken by the BPPI for revamping the Jan Aushadhi Scheme. As per the plan, it is proposed to open 200 Stores during 2015-16 and 3000 Stores during 2016-17.

It is also proposed that Jan Aushadhi Stores can be opened not only inside the hospital but also anywhere outside the hospital premises too. The sole objective is to improve the accessibility of JAS for the poor people. The report includes the relaxation of eligibility conditions for operating agencies.”

Comments of the Committee

1.16 The Committee in their earlier recommendation had noted that the Department has envisaged New Business Plan to open 3000 new Jan Aushadhi Stores by 2016-17. Against this background the Committee had hoped that New Business Plan would take care bottlenecks and be more effective in the implementation of the scheme. The Committee had also recommended execution and progress of Jan Aushadhi Scheme should be monitored at regular intervals for its effective implementation.

The Department in the Action Taken Reply has stated that BPPI has prepared and submitted their Strategic Action Plan which elaborates various steps and plans undertaken by the BPPI for revamping the Jan Aushadhi Scheme. As per the plan, it is proposed to open 200 Stores during 2015-16 and 3000 Stores during 2016-17. The Department has also proposed that Jan Aushadhi Stores can be opened not only inside the hospital but also anywhere outside the hospital premises too. The sole objective is to improve the accessibility of Jan Aushadhi Stores for the poor people. The report includes the relaxation of eligibility conditions for operating agencies.

In the light of above, while appreciating the initiatives taken by the Department, the Committee are of the opinion that BPPI and the Department should take steps to expedite the revamping of Jan Aushashi Scheme and ensure that the Strategic Action Plan which includes opening of 200 stores during 2015-16 and opening of 3000 stores in 2016-17 is implemented without fail and meets its target within a fixed time frame. The Committee would like to be apprised of the action taken by the Department in this regard.

E. Availability of Medicines in Jan Aushadhi Stores (JASs)

Recommendation No. 5

1.17 Emphasizing the need for availability of medicines in Jan Aushadhi Stores, the Committee had recommended as under:—

“The Committee note during oral evidence of non-official witnesses that major complaint of the general public has been the non-availability of all the listed medicines in JASs. The Committee

also note that the in-house production of medicines manufactured by the CPSUs is able to cover approximately 138 medicines out of the existing range of 361 medicines committed by them. Now to mitigate the situation of non-availability of medicines in the JAS, rate contracts/price fixation have been finalized in respect of 249 products which covers 144 items produced by CPSUs and 105 items produced by private manufacturers. In addition, finalization of rate contract, in respect of 20 more products through open tender is under process. The Committee are, therefore of the view that the very purpose for which JASs were opened is defeated if adequate number of listed medicines are not available with them. The Committee, therefore, recommend that BPPI and the Department should take immediate steps to increase the production of medicines listed for JASs by the CPSUs and also to expedite the process of undertaking contracts for acquiring medicines from private pharma manufacturers. The Committee also recommend that the Department should expedite the revival of sick CPSUs and increase production capacity of working CPSUs to increase the production of medicines specially those listed for JASs. The Committee would like to be apprised of the initiatives taken in this regard.”

Reply of the Government

1.18 In reply to the aforesaid recommendation of the Committee, the Department of Pharmaceuticals has stated as under:—

“BPPI has initiated various steps to increase the basket of products and services with a list of 504 medicines and 161 consumables. Rate contract for 314 medicines has already been finalized and the tender for remaining 190 medicines has already been published. 131 medicines have already been identified for PSUs and a list of 173 medicine has already been forwarded to Pharma PSUs with a request of exploring the possibility of undertaking the manufacturing the same. As per the Strategic Action Plan in place of existing 40% advance extended to PSUs, 50% advance is proposed thereby expediting the revival of sick PSUs and also it can improve the utilization of their existing plant. The BPPI is planning to include all the products being manufactured by the Central Pharma PSUs in their basket of products.”

Comments of the Committee

1.19 Noting that the very purpose of opening of Jan Aushadhi Stores was defeated when adequate numbers of listed medicines were not available with them, the Committee, therefore,

recommended that BPPI and the Department should take immediate steps to increase the production of medicines for Jan Aushadhi Stores by the CPSUs and also expedite the process of undertaking contracts for acquiring medicines from private pharma manufacturers.

The Department in the Action taken Reply has stated that BPPI has initiated various steps to increase the basket of products and services with a list of 504 medicines and 161 consumables. Rate contract for 314 medicines has already been finalized and the tender for remaining 190 medicines has already been published. 131 medicines have already been identified for PSUs and a list of 173 medicines has already been forwarded to Pharma PSUs with a request of exploring the possibility of undertaking the manufacturing the same. As per the Strategic Action Plan in place of existing 40% advance extended to PSUs, 50% advance is proposed thereby expediting the revival of sick PSUs and also it can improve the utilization of their existing plant. The BPPI is planning to include all the products being manufactured by the Central Pharma PSUs in their basket of products.

The Committee are happy to note that the BPPI and the Department are taking various steps to increase the number of medicines available in JASs. The Committee further hope that BPPI would increase the basket of products and services with a list of 504 medicines and 161 consumables. The Committee also hope that BPPI would pursue CPSUs to increase the production of medicines and supply of the same to JASs. The Committee, however, once again reiterate that the Department should expedite the revival of the sick CPSUs and increase the capacity of production of medicine specially the medicines being supplied to Jan Aushadhi Stores. The Committee would like to be apprised of the progress made by the Department in this regard.

F. Timely Supply of Medicines

Recommendation No. 6

1.20 Stressing the need for timely supply of medicines to JASs, the Committee had recommended as under:—

“It has also come to the notice of the Committee that supply of listed medicines to far-flung JAS stores takes very long time specially to States such as Jammu & Kashmir. The Committee, therefore, strongly feel that warehouses should be opened in every State for stocking of medicines so that the same are timely supplied to the

JASs. The Committee also feel that the supply chain for timely provision of JAS medicines should be strengthened and streamlined as envisaged under the New Business Plan and periodical inspection of the JASs should be conducted by BPPI to ascertain the availability of medicines and the Action Taken Report thereon should be placed on the website of the Department. In this regard, the Department in coordination with State Governments and stake holders may also work out the feasibility of introducing mobile vans for supply of medicines to the people at far flung areas of the State.

In this context, the Committee were informed that an IT based management information system software has been installed to keep track of availability of medicines at the JASs as well as super market. This has become partially operational and the same is expected to become fully operational by 31 January 2015. The Committee hope that the system might have become fully operational by this time to maintain an efficient supply chain to distribute the generic medicines to all the JASs seamlessly specially in the far flung and remote areas of the country. However, the Committee would like to be apprised of the progress made in this regard.”

Reply of the Government

1.21 In reply to the aforesaid recommendation of the Committee, the Department of Pharmaceuticals has stated as under:—

“BPPI has initiated various steps for improving the supply chain like selection and appointment of C&F agents/Distributors in various States. The administration of the Central Warehouse in Gurgaon has already been handed over to experienced operating agency. The BPPI has also appointed nodal officers at different locations for close monitoring of the availability of medicine in JAS ensuring timely supply and distribution to C&F and JAS.

IT based MIS software has already been established at CWH, C&F and distributors level to keep track of availability of medicine at different levels. The IT-based retail software has also been provided to every JAS for accounting retail sale. Integration of the above two software’s is in progress and is expected to be completed by end of Aug 2015.

The recommendations regarding the feasibility of introducing mobile vans for supply of medicine to the people at far flung areas of J&K and also remote villages in other State is being looked into as per the Drug and Cosmetic Act 1940 and rules 1945.”

Comments of the Committee

1.22 The Committee in its earlier recommendation had observed that an IT based management information system software has been installed to keep a track on the availability of medicines at the JASs as well as in the super market and the same was expected to be fully operational by 31.01.2015. The Committee hoped that the system might have become fully operational by this time to maintain an efficient supply chain to distribute the generic medicines to all the JASs seamlessly specially in the far flung and remote areas of the country.

The Department in its Action Taken Reply has stated that the administration of central warehouse in Gurgaon has already been handed over to experienced operating agency. Further, BPPI has appointed nodal officers at different locations for close monitoring of availability of medicine in Jan Aushadhi Store. Also, IT based MIS software has already been established at Central Ware Housing (CWH), Carry and Forwarding (C&F) and distributors level to keep track of availability of medicines at different levels. IT based retail software has been provided to every Jan Aushadhi Stores for accounting retail sale and also integration of both the software is expected to be completed by August 2015. Further, the Department has stated that the feasibility of mobile vans for supply of medicine to far flung areas and remote areas are being looked into.

The Committee are satisfied to note that the progress has been made to ensure timely supply of medicines to various Jan Aushadhi Stores in various parts of the country. The Committee have also noted that the Department is looking into the feasibility of introducing mobile vans for supply of medicines to far flung areas. The Committee hope that the IT based software both at Central Ware Housing (CWH)/ Carry and Forwarding (C&F)/distributor level of Jan Aushadhi Scheme might have been integrated by now. The Committee are now hopeful that the steps being taken by BPPI and the Department would yield results and improve the timely supply of medicines and that the Department would keep up the pace of supplying medicines to Jan Aushadhi Stores at regular and timely intervals. The Committee would like to be apprised of the steps being taken in this regard.

G. Media Campaign for Jan Aushadhi Scheme

Recommendation No. 8

1.23 Emphasizing the need to increase the media campaign for JASs, the Committee had recommended as under:—

“A large population of poor people in the country find it difficult to afford the expensive branded medicines and therefore, the key

objective of the Jan Aushadhi campaign is to provide low cost and quality controlled unbranded generic drugs to the common man. However, the Committee are disappointed to note that the media campaign or creation of awareness for Jan Aushadhi Scheme has not been very significant. Jan Aushadhi medicines are apparently not being accepted either by the public or the drugs under the scheme are not being prescribed by the doctors to the patients. Even after six years, no concerted efforts have been made by the Government to educate the people and to reach out to the doctors' community in this regard. The Committee, therefore, recommend that a vigorous campaign should be launched by the Department to create awareness among the people about the generic drugs and its quality, efficacy and safety comparable with branded medicines and to reach out to the doctors' community by way of conferences to impress upon them to prescribe generic drugs to the patients. An effective mechanism for media campaign for Jan Aushadhi medicines on the lines of campaigning of "Jago Garhak Jago" should be worked out by the Department/BPPI. The Committee would like to be apprised of the initiatives taken by the Department in this regard.

The Committee further note that JAS toll free helpline functions for limited time of the day and days of the week. The Committee feel that the purpose of JAS is not served if the toll free number is functioning for limited time of the day and days of the week. The Committee, therefore, strongly recommend that the Department should take effective steps to improve the working of toll free helpline number. The Committee would like to be apprised of the initiatives being taken in this regard."

Reply of the Government

1.24 In reply to the aforesaid recommendation of the Committee, the Department of Pharmaceuticals has stated as under:—

"The Committee has recommended that Media campaign shall be launched by the Deptt. to create awareness among the people regarding Jan Aushadhi Scheme. BPPI has initiated various media and publicity campaigns around each Jan Aushadhi Store through hoardings, bulk SMS, Mobile exhibitions, distribution of pamphlets etc. Production of an appropriate 30 sec. TV spot (Jago Grahak Jago) is also being taken up through DAVP. Telecast through DD and other TV Channels in regional languages for a period of 30 days is also being planned at the time of re-launching of Jan Aushadhi

Scheme. A campaign through social media is also being taken up. The required fund for the above referred campaign has been included in the revised budget for the year 2015-16 & 2016-17 and submitted to the Ministry.

The existing toll-free help line is functioning only on Monday to Saturday from 9.30 A.M. to 5.30 P.M. BPPI has taken up the matter of extending helpline to 24 x 7 days basis with the present operating agency, Consumer Online Foundation.”

Comments of the Committee

1.25 The Committee with a view to create more awareness among the public about Jan Aushadhi Scheme had recommended that vigorous media campaign on the lines of campaigning of “Jago Grahak Jago” should be worked out by Department and BPPI. The Committee had also recommended that the Department should take effective steps to improve the working of toll free helpline number.

The Department in the action taken reply has stated that BPPI has initiated various media and publicity campaigns around each Jan Aushadhi Store through hoardings, bulk SMS, Mobile exhibitions, distribution of pamphlets etc. Production of an appropriate 30 sec. TV spot (Jago Grahak Jago) is also being taken up through DA VP. Telecast through DD and other TV Channels in regional languages for a period of 30 days is also being planned at the time of re-launching of Jan Aushadhi Scheme. A campaign through social media is also being taken up. The required fund for the above referred campaign has been included in the revised budget for the year 2015-16 and 2016-17 and submitted to the Ministry. The existing toll-free help line is functioning only on Monday to Saturday from 9.30 A.M. to 5.30 P.M. BPPI has taken up the matter of extending helpline to 24 x 7 days basis with the present operating agency, Consumer Online Foundation.

The Committee though appreciative of the steps being taken by BPPI to create mass awareness among the people about Jan Aushadhi Scheme through hoardings, SMS, TV, Social media etc., however, feel that more efforts should be made with regard to the media campaign for Jan Aushadhi Scheme specially for the rural and far flung areas of the country. The Committee also reiterate its earlier recommendation that the Jan Aushadhi Scheme helpline should be made compulsorily available 24x7 as it would be more helpful to persons in emergency circumstances. The Committee would like to be apprised of the progress achieved in the matter.

H. Quality Control of Jan Aushadhi Medicines

Recommendation No. 9

1.26 Noting the need for quality control of Jan Aushadhi medicines, the Committee had recommended as under:—

“The Committee note that BPPI is vested with the responsibility to ensure that only quality drugs are supplied through Jan Aushadhi Store and samples should be sent for testing on a regular basis. The Committee recommend that the Department should strictly monitor the quality of drugs before it comes out of the manufacturing units of the company and after that it should again be checked by a national level laboratory. The Company should also upgrade all its manufacturing units conforming WHO-GMP standards. The Department should also work in close co-ordination with Central Drug Standard Control Organisation which comes within the purview of the Ministry of Health and Family Welfare and State Drug Control Authority to monitor and keep strict vigilance over circulation of spurious drugs in the market. In this regard, the Committee reiterate its recommendation contained in its 29th Report of the Committee (15th Lok Sabha) that quality control and regulatory mechanism should come under the Department of Pharmaceuticals. The Committee would like to be apprised of the action taken by the Department in this regard.”

Reply of the Government

1.27 In reply to the aforesaid recommendation of the Committee, the Department of Pharmaceuticals has stated as under:—

“BPPI is assuring receipt of in-house test reports along with medicines. Besides, when material is received in Central Warehouse, our Quality control Department draws sample of each batch of each medicine at random basis and send to NABL accredited labs for testing. Medicines will be dispatched to distributor/JASs only on receipt of test reports which indicate of standard quality from empanelled NABL accredited laboratory.

The steps to be taken by the CPSU in upgrading its manufacturing units conforming WHO/GMP standards: Rs. 11.39 crore has been released to RDPL in two installments as grant in aid for making the company WHO/GMP compliant.

Comments of the Committee

1.28 The Committee in their earlier recommendation had impressed upon strict monitoring of quality of drugs and also stated that BPPI should ensure the quality of the drugs being supplied through Jan Aushadhi Stores. The Committee had also recommended that the company should upgrade all the manufacturing units conforming to WHO-GMP standards.

The Department in the Action Taken Reply has stated that BPPI is ensuring receipt of in house test reports along with the medicines. Further, the medicines are dispatched to Jan Aushadhi Stores only when test reports from empanelled NABL accredited laboratory indicate the standard quality. It has also been stated that Rs. 11.39 crore has been released to RDPL in instalments for making the company WHO/GMP compliant.

In view of the above, the Committee once again reiterate its recommendation that the Department and BPPI should ensure strict compliance with the quality control of the medicines being supplied to Jan Aushadhi Stores. The Department should also ensure that all medicine producing manufacturing units comply with WHO-GMP standards. The Committee would like to be apprised of the action taken by the Department in this regard.

CHAPTER II

OBSERVATIONS/RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

A. Utilisation of Funds allocated for Jan Aushadhi Scheme

Recommendation No. 2

The Committee are distressed to note that Rs. 20 crore earmarked at BE stage for Jan Aushadhi Scheme was reduced to Rs. 4.50 crore at RE stage during the year 2012-13, out of which only Rs. 1.66 crore were utilized. For the period from 2013-14, Rs. 25 crore was allocated for the Scheme but based on the requirement of BPPI, only Rs. 15.20 crore, was released for the year 2013-14. The Committee also regret to note that for the year 2014-15, Rs. 30 crore was allocated at BE stage for the Jan Aushadhi Scheme but due to non-utilisation of the allocation till September 2014, the Ministry of Finance reduced the allocation of the Department at RE stage to NIL. The Committee strongly feel that the under-utilisation or non-utilisation of funds is bound to have its cascading effect on the targets set by the Department under the scheme during 12th Plan period. The Committee also feel that the Department does not seem to have undertaken any proactive measures to overcome the bottlenecks which have impeded the optimum utilisation of funds. The very fact that during 2014, only 11 stores could be opened in the country as indicated in the Annexure-I, clearly indicates the slow pace of progress in setting JASs across the country. This also shows the lack of proper planning and concerted and coordinated efforts on the part of the Department to address those constraints which were impeding the implementation of the scheme. The Committee, therefore, recommend that the Department should resolve and take initiative and formulate plan for optimum utilisation of funds for opening of stores as per the plan target. The Committee also recommend that the Department should also monitor timely and full utilization of funds for the purpose. The Committee would like to be apprised of the initiatives taken by the Department in this regard.

Reply of the Government

The total budget envisaged in the new business plan for the years 2013-14 and 2014-15 were Rs. 25.00 crore and Rs. 38.21 crore respectively. However, only a total of Rs. 16.86 crore were released as

BPPI has utilized only 14.6 crore till 31st May 2015. BPPI has also submitted a plan of utilization of Rs. 69.35 crore for the current year and Rs. 154.94 crore for the next year 2016-17.

BPPI is in the process of opening another 200 JAS during the current year. They have already initiated various actions required for increasing their basket of products and services. Procurement activities for 504 medicines and 161 consumables against the present level of 361 medicines is in progress. They have also prepared a detailed plan of media activities to be undertaken in and around the existing 111 JAS and also around every JAS being opened through hoardings, bulk SMS, Mobile exhibitions, distribution of pamphlets etc. For achieving the above target BPPI is getting strengthened through augmentation of manpower. All these improvements will ensure the full utilization of funds allotted for Jan Aushadhi Scheme.

[Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals),
OM No. F.No. 54012(3)/2015-P1-IV, dated 10.08.2015]

Comments of the Committee

(Please see Para No. 1.10 of Chapter-1 of the Report)

B. Need to improve the functioning of Bureau of Pharma PSUs of India (BPPI)

Recommendation No. 3

The Committee note that the Bureau of Pharma Public Sector Undertaking India (BPPI) comprising all the Central Pharma PSUs (CPSUs) namely IDPL, RDPL, KAPL, HAL and BCPL was set up on 1st December, 2008 with major objective to have focused and empowered structure to implement the Jan Aushadhi Campaign initiated by Department of Pharmaceuticals. It is a registered society under Societies Registration Act, 1860 with Government of NCT of Delhi on 21.04.2010. BPPI is monitoring the functioning of Jan Aushadhi Stores. It is also involved in promotion of unbranded generic drugs. The Committee note that one of the main functions of BPPI is to have coordination with the State Governments for opening of Jan Aushadhi Stores. The BPPI takes up the issue with the State Governments and meets the officials concerned for explaining about the scheme and opening of Jan Aushadhi Stores. Further, the nodal officials appointed by BPPI and placed in the State, meet with the State Government officials regularly in matters relating to Jan Aushadhi Scheme Stores. However, the functioning of BPPI does not seem to be satisfactory. The very fact that till date only 170 JAS have

been opened and out of that only 99 are functional clearly shows that BPPI has not been very effective in its functioning. The Committee, therefore, recommend that the Department should take remedial measures for improving the functioning of BPPI so that the opening and maintenance of JAS and availability of medicines therein could be done in an effective and efficient manner. The Committee would like to be apprised of the initiatives taken/being taken by the Department in this regard.

Reply of the Government

DoP has initiated few steps to improve the functioning of BPPI. BPPI has submitted a detailed Strategic Action Plan for improving the Jan Aushadhi Scheme. BPPI is getting strengthened with adequate man power and standard operating procedures are being laid down for different activities in BPPI clearly defining the functions and responsibilities of each and every Executive in the organization.

The recruitment process has already been initiated through open advertisement in leading newspapers. The recruitment process is expected to be completed by the end of August 2015.

[Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals),
OM No. F.No. 54012(3)/2015-P1-IV, dated 10.08.2015]

Comments of the Committee

(Please see Para No. 1.13 of Chapter-1 of the Report)

C. Implementation of Jan Aushadhi Scheme

Recommendation No. 4

The Committee note that access to quality medicines at affordable prices is a key challenge for the Government. The prices of branded medicines are generally higher than generic medicines due to various reasons including limited regulation through Drug Prices Control Order, 1995 etc. A countrywide campaign in the name of 'Jan Aushadhi Campaign' was also launched in November 2008 by the Department of Pharmaceuticals for ensuring availability of generic medicines at affordable prices to all in collaboration with the State Governments as a direct market intervention strategy. Under this Campaign, less priced quality generic medicines are being made available through Jan Aushadhi Stores (JAS) which are of same and equivalent quality, efficacy and safety as compared to branded generic medicines. Under this Scheme,

the State Government has to provide space in Government Hospital premises for the running of the Jan Aushadhi Stores. Government hospitals, NGOs, Charitable Organizations and public societies like Red Cross Society, Rogi Kalyan Samitis typically constituted for the purpose could be operating agencies for the JAS. The operational expenditure is met from trade margins admissible for the medicines. The first Jan Aushadhi Generic Drug Store was opened in civil hospital Amritsar on 25th November, 2008. However, the Committee regret to note that the Jan Aushadhi Scheme during the first six year of its implementation, has not been able to make much headway in opening of Jan Aushadhi Stores in each district of the country as was proposed. The poor performance of the scheme is quite evident from the fact that as against the target of opening of one JAS in each of the 630 districts, only 170 stores have been opened so far. However, with a view to remove the shortcomings noticed in the original Jan Aushadhi scheme, a revised New Business Plan has been worked by the Department. The Committee were informed that various steps were being undertaken under the New Business Plan to remove/rectify bottlenecks in implementation of the campaign. The steps include relaxation of eligibility conditions for operating entities, review of existing list of medicines, improving supply chain management, sourcing of drugs, working capital, prescription of generic medicines health policies and media campaign etc. The Committee also note that the Department proposes to issue advertisements calling for applications from interested parties for opening of Jan Aushadhi Stores in all the States. The Committee also note that New Business Plan envisage to open 3000 new JAS by 2016-17. Against this backdrop, the Committee hope that the New Business Plan would take care of bottlenecks in effective and efficient implementation of the scheme and the Department would take proactive measures and make co-ordinated efforts with all concerned to open maximum JASs as envisaged under New Business Plan by 2016-17 so that the benefits of low cost improved generic drugs are reached to maximum number of common people. However, the Committee recommend that the execution and progress of the scheme should be monitored at regular intervals so that the target to open 3000 JASs by 2016-17 under New Business Plan could be achieved. The Committee would like to know the initiatives taken by the Department and progress made under the New Business Plan from time to time.

Reply of the Government

BPPI has prepared and submitted their Strategic Action Plan which elaborates various steps and plans undertaken by the BPPI for revamping the Jan Aushadhi Scheme. As per the plan, it is proposed to open

200 Stores during 2015-16 and 3000 Stores during 2016-17. It is also proposed that Jan Aushadhi Stores can be opened not only inside the hospital but also anywhere outside the hospital premises too. The sole objective is to improve the accessibility of JAS for the poor people. The report includes the relaxation of eligibility conditions for operating agencies.

[Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals),
OM No. F.No. 54012(3)/2015-P1-IV, dated 10.08.2015]

Comments of the Committee

(Please see Para No. 1.16 of Chapter-I of the Report)

D. Availability of Medicines in Jan Aushadhi Stores (JASs)

Recommendation No. 5

The Committee note during oral evidence of non-official witnesses that major complaint of the general public has been the non-availability of all the listed medicines in JASs. The Committee also note that the in-house production of medicines manufactured by the CPSUs is able to cover approximately 138 medicines out of the existing range of 361 medicines committed by them. Now to mitigate the situation of non-availability of medicines in the JAS, rate contracts/price fixation have been finalized in respect of 249 products which covers 144 items produced by CPSUs and 105 items produced by private manufacturers. In addition, finalization of rate contract, in respect of 20 more products through open tender is under process. The Committee are, therefore of the view that the very purpose for which JASs were opened is defeated if adequate number of listed medicines are not available with them. The Committee, therefore, recommend that BPPI and the Department should take immediate steps to increase the production of medicines listed for JASs by the CPSUs and also to expedite the process of undertaking contracts for acquiring medicines from private pharma manufacturers. The Committee also recommend that the Department should expedite the revival of sick CPSUs and increase production capacity of working CPSUs to increase the production of medicines specially those listed for JASs. The Committee would like to be apprised of the initiatives taken in this regard.

Reply of the Government

BPPI has initiated various steps to increase the basket of products and services with a list of 504 medicines and 161 consumables. Rate contract for 314 medicines has already been finalized and the tender

for remaining 190 medicines has already been published. 131 medicines have already been identified for PSUs and a list of 173 medicine has already been forwarded to Pharma PSUs with a request of exploring the possibility of undertaking the manufacturing the same. As per the Strategic Action Plan in place of existing 40% advance extended to PSUs, 50% advance is proposed thereby expediting the revival of sick PSUs and also it can improve the utilization of their existing plant. The BPPI is planning to include all the products being manufactured by the Central Pharma PSUs in their basket of products.

[Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals),
OM No. F.No. 54012(3)/2015-P1-IV, dated 10.08.2015]

Comments of the Committee

(Please see Para No. 1.19 of Chapter-I of the Report)

E. Sale of Surgical Items through JASS

Recommendation No. 7

The Committee note that one of the suggestions made by the non-official witnesses is that other OTC (Over the counter) items, including essential surgical goods such as dispo-Syringes, Dextrose, Drip sets etc. should be provided through Jan Aushadhi Stores so that the consumer gets most of essential medical items at affordable rates with in the hospital premises. In this context, the Department informed the Committee that presently surgical items are not supplied through Jan Aushadhi Stores but the matter would be examined in consultation with BPPI. The Committee feel that sale of low cost surgical items through JASs would largely benefit the poor and the common people. It would also be convenient for the patients if surgical items are also available for sale through JASs along with the medicines so that they need not to go in search for surgical items in chemist shops. The Committee, therefore, recommend that the Department should explore the feasibility of selling low cost surgical items through JASs specially through those stores which are within the premises of Government Hospitals. It has also been brought to the notice of the Committee that prices of some of the Jan Aushadhi medicines are higher than the MRP or higher than other branded medicines. While explaining the position in this regard, the Department has assured the Committee to look in to it and to take corrective action in this regard. The Committee would like to be apprised of the initiatives taken in the matter.

Reply of the Government

A list of 161 surgical items and other consumables have been finalized. Tender for 29 items out of these has already been floated and same will be finalized by end of July 2015. Tender for remaining 132 items will be published by 1st week of August. BPPI is planning to complete the procurement process of all these items by October 2015.

The formula for MRP has been scrutinized, modified and finalized. Comparison of MRP with that of branded medicines has been completed and it is ensured that MRP of JAS medicines are always less than of other branded available in the market.

[Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals),
OM No. F.No. 54012(3)/2015-P1-IV, dated 10.08.2015]

F. Media Campaign for Jan Aushadhi Scheme

Recommendation No. 8

A large population of poor people in the country find it difficult to afford the expensive branded medicines and therefore, the key objective of the Jan Aushadhi campaign is to provide low cost and quality controlled unbranded generic drugs to the common man. However, the Committee are disappointed to note that the media campaign or creation of awareness for Jan Aushadhi store has not been very significant. Jan Aushadhi medicines are apparently not being accepted either by the public or the drugs under the scheme are not being prescribed by the doctors to the patients. Even after six years, no concerted efforts have been made by the Government to educate the people and to reach out to the doctors' community in this regard. The Committee, therefore, recommend that a vigorous campaign should be launched by the Department to create awareness among the people about the generic drugs and its quality, efficacy and safety comparable with branded medicines and to reach out to the doctors' community by way of conferences to impress upon them to prescribe generic drugs to the patients. An effective mechanism for media campaign for Jan Aushadhi medicines on the lines of campaigning of "Jago Garhak Jago" should be worked out by the Department/BPPI. The Committee would like to be apprised of the initiatives taken by the Department in this regard.

The Committee further note that JAS toll free helpline functions for limited time of the day and days of the week. The Committee feel that the purpose of JAS is not served if the toll free number is functioning for limited time of the day and days of the week. The Committee,

therefore, strongly recommend that the Department should take effective steps to improve the working of toll free helpline number. The Committee would like to be apprised of the initiatives being taken in this regard.

Reply of the Government

The Committee has recommended that Media campaign shall be launched by the Department to create awareness among the people regarding Jan Aushadhi Scheme. BPPI has initiated various media and publicity campaigns around each Jan Aushadhi Store through hoardings, bulk SMS, Mobile exhibitions, distribution of pamphlets etc. Production of an appropriate 30 sec. TV spot (Jago Grahak Jago) is also being taken up through DAVP. Telecast through DD and other TV Channels in regional languages for a period of 30 days is also being planned at the time of re-launching of Jan Aushadhi Scheme. A campaign through social media is also being taken up. The required fund for the above referred campaign has been included in the revised budget for the year 2015-16 & 2016-17 and submitted to the Ministry. The existing toll-free help line is functioning only on Monday to Saturday from 9.30 A.M. to 5.30 P.M. BPPI has taken up the matter of extending helpline to 24 x 7 days basis with the present operating agency, Consumer Online Foundation.

[Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals),
OM No. F.No. 54012(3)/2015-P1-IV, dated 10.08.2015]

Comments of the Committee

(Please see Para No. 1.27 of Chapter-I of the Report)

G. Quality Control of Jan Aushadhi Medicines

Recommendation No. 9

The Committee note that BPPI is vested with the responsibility to ensure that only quality drugs are supplied through Jan Aushadhi Store and samples should be sent for testing on a regular basis. The Committee recommend that the Department should strictly monitor the quality of drugs before it comes out of the manufacturing units of the company and after that it should again be checked by a national level laboratory. The Company should also upgrade all its manufacturing units conforming WHO-GMP standards. The Department should also work in close co-ordination with Central Drug Standard Control Organisation which comes with in the purview of the Ministry of Health and Family Welfare and State Drug Control Authority to monitor and keep strict vigilance

over circulation of spurious drugs in the market. In this regard, the Committee reiterate its recommendation contained in its 29th Report of the Committee (15th Lok Sabha) that quality control and regulatory mechanism should come under the Department of Pharmaceuticals. The Committee would like to be apprised of the action taken by the Department in this regard.

Reply of the Government

BPPI is assuring receipt of in-house test reports along with medicines. Besides, when material is received in Central Warehouse, our Quality control Department draws sample of each batch of each medicine at random basis and send to NABL accredited labs for testing. Medicines will be dispatched to distributor/JASs only on receipt of test reports which indicate of standard quality from empanelled NABL accredited laboratory.

Steps to be taken by the CPSU in upgrading its manufacturing units conforming WHO/GMP standards: Rs. 11.39 crore has been released to RDPL in two installments as grant in aid for making the company WHO/GMP compliance.

[Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals),
OM No. F.No. 54012(3)/2015-P1-IV, dated 10.08.2015]

Comments of the Committee

(Please see Para No. 1.30 of Chapter-I of the Report)

CHAPTER III

OBSERVATIONS/RECOMMENDATIONS WHICH THE COMMITTEE DO NOT
DESIRE TO PURSUE IN VIEW OF THE GOVERNMENT'S REPLY

—NIL—

CHAPTER IV

OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT HAVE NOT BEEN ACCEPTED BY THE COMMITTEE

Need for augmenting Financial Assistance for opening of Jan Aushadhi Stores

Recommendation No. 1

The Committee note that a one time financial assistance of Rs. 2.00 lakhs as establishment cost and Rs. 50,000/- as an one time start-up cost is given to NGOs/Institutions/Co-operative Societies identified by the State Government. In case of any other entity, such as reputed NGO/Charitable Society/Self Help Group and individuals, financial assistance as incentive linked to sale of medicines at the rate of 10% of the monthly sales amount subject to a ceiling of Rs. 10,000/- per month for a period of 12 months is provided. In case of stores opened in North-Eastern States and other difficult areas *i.e.* naxal affected area, tribal area etc., the rate of incentive would be 15% of monthly sale amount subject to a ceiling of Rs. 15,000/- per month. However, during the course of examination of the subject, it was brought to the notice of the Committee that the one-time grant for opening of Jan Aushadhi Store is not sufficient and the amount should be increased to Rs.3.5 lakh as the earlier rate was fixed in 2008. The Committee, therefore, recommend that the Department should examine the possibility of increasing one time grant from Rs. 2.5 lakh to Rs. 3.5 lakh as establishment cost for opening Jan Aushadhi Stores in the country. The Committee would like to be apprised of the action taken in this regard.

Reply of the Government

The Committee has recommended that the Department of Pharmaceuticals should examine the possibility of increase in one time grant from Rs. 2.5 lakhs to Rs. 3.5 lakhs towards established cost for opening Jan Aushadhi Stores in the country.

It is true that the one time grant for opening of Jan Aushadhi Store *i.e.* Rs. 2.50 lakhs was fixed in 2008 and that too it is extended only to the operating agencies identified and nominated by the State Government for running the JASs located in Government Hospitals. For

any JAS proposed outside the Government Hospital premises, no one time grant is permitted. In place of one time grant, incentive @ 10% of the sales value subject to the ceiling of Rs. 10,000/- per month for a period of one year only is included. However, in case of North-Eastern States and other naxal affected area and tribal areas, the rate of incentive @ 15% of the monthly sales value subject to the ceiling of Rs. 15,000 per month for a period of one year is offered.

It is also seen that one time financial grant is extended only to those Jan Aushadhi Stores, opened in the Government hospital premises where space is provided free of cost by the State Government. Whereas in case of Jan Aushadhi Stores opened outside Government hospital premises run by Private Entrepreneurs, un-employed Pharmacists, NGOs, one time grant is not extended for the commencement of Jan Aushadhi Stores. They are expected to have their own/hired space, establishment cost of the stores as per the layout design of BPPI and other requirement as per the Drug and Cosmetic law.

Suggestion of increasing the one time grant of Rs. 2.5 lakh to Rs. 3.5 lakh was evaluated. It is learnt that the amount of Rs. 2.5 lakh is sufficient to meet the expenses in connection with commencing of operation of JAS. BPPI intends to focus more on ensuring supply of 504 medicines and J61 consumables strengthening supply chain and strengthening BPPI.

[Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals),
OM No. F.No. 54012(3)/2015-P1-IV, dated 10.08.2015]

Comments of the Committee

(Please see Para No. 1.7 of Chapter-I of the Report)

CHAPTER V

OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH FINAL REPLIES OF THE GOVERNMENT ARE OF INTERIM NATURE

Timely Supply of Medicines

Recommendation No. 6

It has also come to the notice of the Committee that supply of listed medicines to far-flung JAS stores takes very long time specially to States such as Jammu & Kashmir. The Committee, therefore, strongly feel that warehouses should be opened in every State for stocking of medicines so that the same are timely supplied to the JASs. The Committee also feel that the supply chain for timely provision of JAS medicines should be strengthened and streamlined as envisaged under the New Business Plan and periodical inspection of the JASs should be conducted by BPPI to ascertain the availability of medicines and the action Taken Report thereon should be placed on the website of the Department. In this regard, the Department in coordination with State Governments and stakeholders may also work out the feasibility of introducing mobile vans for supply of medicines to the people at far flung areas of the State.

In this context, the Committee were informed that an IT based management information system software has been installed to keep track of availability of medicines at the JASs as well as super market. This has become partially operational and the same is expected to become fully operational by 31 January, 2015. The Committee hope that the system might have become fully operational by this time to maintain an efficient supply chain to distribute the generic medicines to all the JASs seamlessly specially in the far flung and remote areas of the country. However, the Committee would like to be apprised of the progress made in this regard.

Reply of the Government

BPPI has initiated various steps for improving the supply chain like selection and appointment of C&F agents/Distributors in various States. The administration of the Central Warehouse in Gurgaon has already been handed over to experienced operating agency. The BPPI has also appointed nodal officers at different locations for close monitoring of the availability of medicine in JAS ensuring timely supply and distribution to C&F and JAS.

IT based MIS software has already been established at CWH, C&F and distributors level to keep track of availability of medicine at different levels. The IT-based retail software has also been provided to every JAS for accounting retail sale. Integration of the above two software's is in progress and is expected to be completed by end of August 2015.

The recommendations regarding the feasibility of introducing mobile vans for supply of medicine to the people at far flung areas of J&K and also remote villages in other State is being looked into as per the Drug and Cosmetic Act 1940 and rules 1945.

[Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals),
OM No. F.No. 54012(3)/2015-P1-IV, dated 10.08.2015]

Comments of the Committee

(Please see Para No. 1.22 of Chapter-I of the Report)

NEW DELHI;
07 October, 2015

15 Asvina, 1937 (Saka)

ANANDRAO ADSUL,
Chairperson,
Standing Committee on
Chemicals and Fertilizers.

APPENDIX I

MINUTES OF THE THIRD SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2015-16)

The Committee sat on Wednesday, the 07th October, 2015 from 1500 hrs. to 1600 hrs. in Committee Room 'D', Parliament House Annexe, New Delhi.

PRESENT

Shri Anandrao Adsul—*Chairperson*

MEMBERS

Lok Sabha

2. Smt. Anju Bala
3. Shri B.N. Chandrappa
4. Shri Sankar Prasad Datta
5. Shri K. Ashok Kumar
6. Shri S. Rajendran
7. Dr. Kulamani Samal
8. Dr. Krishna Pratap Singh
9. Shri Tasleemuddin
10. Shri Kotha Prabhakar Reddy

Rajya Sabha

11. Shri Narayan Lal Panchariya
12. Shri K. Parasaran
13. Shri Garikapati Mohan Rao
14. Shri Palvai Govardhan Reddy
15. Shri Mansukh L. Mandaviya
16. Shri Abdul Wahab

SECRETARIAT

1. Smt. Rashmi Jain — *Joint Secretary*
2. Shri Anil Kumar Srivastava — *Director*

2. At the outset, the Hon'ble Chairperson welcomed the members of the Committee.

3. The Committee thereafter took up for consideration the following draft Reports:—

- (a) Action Taken Report on Demands for Grants (2015-16) of the Ministry of Chemicals and Fertilizers (Department of Fertilizers); and
- (b) Action Taken Report on the subject “Jan Aushadhi Scheme” of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

4. Both the draft Action Taken Reports were adopted by the Committee without any amendment.

5. The Committee then authorised the Chairperson to make consequential changes, if any, arising out of the factual verification of the Reports by the Department of Fertilizers and the Department of Pharmaceuticals of the Ministry of Chemicals and Fertilizers and present the same to both the Houses of Parliament.

The Committee then adjourned.

APPENDIX II

[Vide Para 3 of the Introduction)

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE FOURTH REPORT (16TH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2015-16) ON 'JAN AUSHADHI SCHEME' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

I. Total No. of Recommendations	09
II. Observations/Recommendations which have been accepted by the Government:—	07
(Vide Recommendation Nos. 2, 3, 4, 5, 7, 8 and 9)	
Percentage of Total	77.77%
III. Observations/Recommendations which the Committee do not desire to pursue in view of the Government's reply:—	0
(Vide Recommendation No. Nil)	
Percentage of Total	0%
IV. Observations/Recommendations in respect of which replies of the Government have not been accepted by the Committee and which require reiteration:—	1
(Vide Recommendation No. 1)	
Percentage of Total	11.11%
V. Observations/Recommendations in respect of which replies of the Government are still awaited:—	1
(Vide Recommendation No. 6)	
Percentage of Total	11.11%

