22

PROCUREMENT OF ALLOPATHIC DRUGS IN CGHS

MINISTRY OF HEALTH AND FAMILY WELFARE
(DEPARTMENT OF HEALTH)

PUBLIC ACCOUNTS COMMITTEE
(2015-16)

TWENTY-SECOND REPORT

SIXTEENTH LOK SABHA

LOK SABHA SECRETARIAT
NEW DELHI

PAC NO. 2053

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(SIXTEENTH LOK SABHA)

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MINISTRY OF HEALTH AND FAMILY WELFARE
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Presented to Lok Sabha on: .....

Laid in Rajya Sabha on: ..... 13 AUG 2015

LOK SABHA SECRETARIAT
NEW DELHI
August 2015/ Shravana 1937 (Saka)

CONTENTS

*Not appended to the cyclostyled copy of the report

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(2015-16)

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* Vacant *vice* Dr. M. Thambidurai who has been chosen as Hon'ble Deputy Speaker, Lok Sabha and has since resigned from the membership of the Committee.

INTRODUCTION

I, the Chairperson, Public Accounts Committee (2015-16) having been authorised by the Committee, do present this Twenty-second Report (Sixteenth Lok Sabha) on **"Procurement of Allopathic drugs in CGHS"** based on Paragraph 6.3 of the C&AG Report No. 19 of 2013 related to the Ministry of Health & Family Welfare .

2. The above-mentioned Report of the Comptroller and Auditor General of India was laid on the Table of the House on 6th September, 2013.

3. The Public Accounts Committee (2014-15) took up the subject for detailed examination and report. The Committee took evidence of the representatives of the Ministry of Health and Family Welfare (Department of Health) on the subject at their sitting held on 12th January, 2015. The Committee also took evidence of the representatives of the Ministry of Health and Family Welfare (Department of Health) and Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) on 9th April, 2015. As the examination of the subject could not be completed due to paucity of time, the Public Accounts Committee (2015-16) retained the subject to continue the examination and hereby, present a Report based on the earlier evidences taken by their predecessor Committee. Accordingly, a Draft Report was prepared and placed before the Committee for their consideration. The Committee considered and adopted this Draft Report at their sitting held on 11th August, 2015. The Minutes of the Sittings are appended to the Report.

4. For facility of reference and convenience, the Observations and Recommendations of the Committee have been printed in thick type and form Part- II of the Report.

5. The Committee thank their predecessor Committee for taking oral evidence and obtaining information on the subject.

6. The Committee would like to express their thanks to the representatives of the Ministries of Health and Family Welfare (Department of Health) and Chemicals and Fertilizers (Department of Pharmaceuticals) for tendering evidence before them and furnishing the requisite information to the Committee in connection with the examination of the subject.

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

NEW DELHI;
12th August,2015
21 Shravana, 1937 (*Saka*)

PROF. K.V. THOMAS
Chairperson,
Public Accounts Committee.

REPORT
PART- I

I. INTRODUCTORY

1. The Ministry of Health and Family Welfare provides comprehensive health care facilities through "Central Government Health Scheme" (CGHS) to MPs, ex MPs, serving and retired Judges of Supreme Court and retired Judges of High Courts, Central Government employees and pensioners and their dependents residing in 23 cities covered under CGHS apart from Delhi NCR. The medical facilities are provided through 250 CGHS Wellness Centres (earlier called as dispensaries) across the country. CGHS provide consultation at CGHS Wellness Centres and Government Hospitals, and provides OPD medicines to its beneficiaries. In addition, inpatient treatment facilities and investigations are provided at Government hospitals, and empanelled private hospitals. Medical Stores Organisation (MSO) is entrusted with the task of procurement of drugs and medicines required for CGHS Hospitals and Wellness Centres outside Delhi. The MSO operates through seven Medical Stores Depots (MSD). Government Medical Store Depot (GMSD), Delhi is the nodal centre for procurement, storage and distribution of drugs for all CGHS wellness centres in Delhi.

II. ORGANISATION

2. CGHS is headed by Director CGHS. Additional Director (Headquarters) is the administrative head of MSD Delhi and four zonal Offices of CGHS. The zonal offices exercise administrative control over CGHS wellness centres in their zone, and are responsible for processing and making payments of bills relating to local purchase made by the CGHS wellness centres. In cities outside Delhi, the CGHS is headed by Joint/Additional Director who exercises overall administrative control over the CGHS units and authorises payments to the suppliers of medicines against their bills.

III. PROCEDURE FOR PROCUREMENT OF DRUGS FOR THE CGHS

3. There are four channels of procurement of drugs for the Central Government Health Scheme (CGHS). These are briefly enumerated below:

1) **Pilot Project**: In 2008, based on CGHS data, National Informatics Centre (NIC) identified 272 items (branded drugs) which were being

procured by the dispensaries from the local chemists. In order to get better discounts as compared to those given by the chemists, a pilot project was started to procure them through manufacturers / distributors. The indents of these drugs are placed monthly by the CMO I/c online directly to the suppliers / distributors. The indents themselves are auto generated based on the consumption pattern of the drugs in the preceding 4 months and availability at Wellness Centre .The drugs are delivered at the Wellness Centres. Prior to introduction of this system, these items were being procured through local chemists at a discount of up to 15%, but placing of orders directly on the manufacturers / distributors meant that the discount rate were increased to the range of 30 to 35%. The manufacturer / distributors could give a better discount as they could make a saving on the distribution cost. The new system also improved the availability of medicines at the WCs since the medicines indented through the local chemists had to be collected on the second or third day, whereas under this system the medicines were available at the Wellness Centre itself. Thus, this was an improvement on the existing practice. It is however true that the 272 items were identified on the basis of their brand name rather than on the basis of the drug composition. Hence, there was still an opportunity to go for the cheaper branded drug with the same chemical composition.

2) **Procurement through Medical Store Organization (MSO):** In the normal course, MSO procures drugs for the CGHS. This organization has two separate formularies for branded and generic drugs, and undertakes their procurement through open tender.

For branded drugs, the formulary initially consisted of 504 items. These were reviewed by a Committee headed by the Joint Secretary (which has been referred to in the Audit Para) and 350 items were identified for retention. In addition, the Committee recommended the inclusion of 382 more items. Subsequently, however the 272 items identified as part of the pilot project noted above (instead of the recommended 382) were added to this list making a total of 622 items which continues till date. For generic drugs, the formulary has been reviewed at intervals. It comprised 818 items during the period covered in the audit para, and was increased to 1128 in 2013. It presently covers 1447 items. The audit para mentions that a) these formularies are not broad enough and should be revised more frequently, and b) the rates for many drugs included for formulary could not be finalized in large number of cases, especially in the case of generic drugs. Keeping this in view, a Committee headed by the Director General, Health Services, has considered the revision of the formulary and has identified 1165 drug compositions for inclusion therein. About 2000 formulations could be available from these compositions. Tenders for 1261 items have already been floated.

3) **Procurement of Life Saving Drugs**: These medicines are procured by the Additional Director (Medical Store Depot) in Delhi and by the concerned Additional Directors of CGHS for cities outside Delhi. These drugs are mainly required for the treatment of serious illness such as Cancer, Hepatitis etc. Once a patient approaches MSD / AD with a valid prescription of the Specialist, and the advice of the CMO In-charge of the Wellness Centre, the drug is procured directly from the manufacturer / distributor at rates already finalized. In case a new drug has been prescribed, then the process of rate enquiry from the manufacturers is undertaken and the drugs are provided to the patients directly after purchase.

It is true that in each of the above methods, various brand names of the same drug composition have been included. This has happened probably because at the relevant time, the items to be procured were identified on the basis of brand names rather than on the basis of their drug composition. However, it has now been decided that only the item that emerges as L-1 in the tender floated / to be floated amongst the branded drugs with the same chemical composition will be procured. Hence, multiple brands of the same drug composition will not be procured henceforth.

4) **Local Purchase**: If the required drugs are not obtained through methods (1) & (2) above, these are purchased by the CMO I/c from the authorised local chemists. Each dispensary/group of dispensaries has been assigned a local chemist after following a tender process. Generally a discount of 15% is offered by these chemists. Purchase through local chemists is also resorted to when drugs that are to be procured through MSD do not reach the dispensary in time, due to a variety of reasons. It also becomes necessary when a new drug has been introduced and is recommended by a Specialist, which is not yet included in the formulary.

4. This Report is based on Paragraph 6.3 of Report of the C&AG of India for the year ended March, 2012, Union Government (Civil –Compliance Audit Observations) No. 19 of 2013 relating to the subject "Procurement of Allopathic drugs in CGHS".

IV. Audit Review

5. The Audit covered scrutiny of procurement of allopathic drugs in CGHS by Medical Stores Depots (MSD) and CGHS Wellness Centres in Delhi, Ahmedabad, Jaipur, Chandigarh, Bhopal, Jabalpur, Kolkata, Chennai, Thiruvananthapuram, Hyderabad, Bangalore, Allahabad, Bhubaneswar and Mumbai during 2009-10 to 2011-12. In Delhi, related records were examined in offices of Medical Store Organisation (MSO), MSD and the Ministry. In cities outside Delhi related records were examined at

the offices of concerned Joint/Addl. Director CGHS, Central Medical Stores/Medical Store Depots and at the CGHS Wellness Centres.

V. Audit Findings

6. Some of the important observations made by Audit are as under:

(i) Audit had noted that the Committee which prepare the drug formulary, while identifying the drugs for inclusion in the formulary, opted for commonly prescribed brands of drugs instead of identifying commonly prescribed drug composition. Thus, the methodology adopted by the Committee was predominantly based on the prescription of specific brands by doctors. The selection of items by adopting the drug composition approach would have provided many options that would be cost effective, as there were many brands of same drug composition available in the market at different rates.

(ii) Test check of 21 cases in the Branded drug formulary revealed availability of several low cost brands in the same category of drugs. Audit also noted that even the discounted price of the selected brand was much higher than the MRP of other low cost brands available in the market. Audit compared the prices of these 21 test checked brands with other brands of identical drugs and found that CGHS Delhi incurred avoidable expenditure of ₹ 9.25 crore during 2011-12 by opting for higher priced brands.

(iii) Audit noted that the doctors continued to prescribe drugs outside the formulary despite the adverse recommendations of the Parliamentary Committee. As a result, drugs valuing ₹ 1119 crore were purchased from outside the formulary during 2009-12. The fact that 71 per cent of the expenditure during 2009-12 was spent on drugs outside the formulary points to drug formulary not being comprehensive enough to cover drugs for wide-ranging ailments/diseases.

(iv) CGHS procured only 2 to 55 per cent of the generic drugs listed in the formulary. Further, the expenditure on procurement of generic drugs in CGHS, Delhi during 2009-12 constituted a mere 0.19 per cent. Test check also revealed that 59 drugs selected for branded drug formulary were already listed in the generic formulary. Further, a comparison of rates of 30 branded drugs with rates of generic drugs in *Janaushidhi Scheme revealed that an amount of ₹ 11.81 crore could have been saved by CGHS Delhi during 2011-12, had generic drugs been procured instead of branded drugs.

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* Under Janaushidhi Scheme Generic drugs which are available at lower prices but are equivalent in Potency to the Branded expensive drugs are made available to public through Janaushidhi stores.

(v) MSD Delhi is the nodal office which procures drugs for all CGHS Wellness Centres in Delhi. Procurement rates and concerned suppliers of the drug, listed in the approved drug formulary, are finalized by the Ministry. However, MSD procures these drugs through Hospital Service Consultancy Corporation (HSCC) instead of procuring them directly from notified suppliers. MSD paid consultancy charges of 4.5 per cent to HSCC for this procurement till October 2008 and 2.5 percent thereafter. Audit noted that HSCC did not add any value to the procurement process and simply acted as a conduit between the Ministry and the supplier. This is so because the rates and suppliers had already been fianlised for drugs procured through HSCC.

(vi) During 2009-10 to 2011-12, 71 percent of the total expenditure was incurred on procurement of drugs not listed in the formulary. Further, CGHS Delhi procured only 19 percent of items from within the formulary while 81 per cent items were from outside the formulary. In cities outside Delhi covered in Audit, CGHS incurred about 50 percent of the total expenditure on procurement of drugs outside the formulary during 2009-12.

(vii) Audit noted that drugs were received in MSD after a delay of two to six months after communication of the requirement to HSCC. Further, issue of drugs from MSD to CGHS Wellness Centres took another three to five months. In effect the drugs were received in CGHS wellness centres with significant delays. The delays in procurement and non-availability of formulary drugs at CGHS wellness centres led to procurement of these drugs by CGHS centres from local chemists at higher rates leading to an extra expenditure of ₹ 3.05 crore.

(viii) In CGHS Kolkata drugs were issued to the patients before receipt of test reports, which were later reported as sub-standard by GMSD. In CGHS Mumbai, medicines worth ₹ 28.45 lakh received from GMSD during 2009-12 were declared sub-standard. Out of these, medicines worth ₹ 15.66 lakh were already issued to patients. Such instances highlight the absence of a robust mechanism for quality assurance, which exposes the patients to the hazards of sub-standard medicines and drugs.

7. A performance Audit of the procedure of procurement of medicines and medical equipments was earlier taken up and the results included in the Audit Report No. 20 of 2007 of the C&AG of India. The Audit Report, *inter-alia*, had highlighted several deficiencies in management of pharmaceutical procurement procedures, which were examined by the Public Accounts Committee. In the light of Audit findings and evidence tendered before them, the Public Accounts Committee in their 24th Report (15th Lok

Sabha) had examined various shortcomings/lapses in the procedure of procurement of medicines and medical equipment and the Committee had accordingly given their Observations/Recommendations. Some of the important Observations/Recommendations with regard to procurement of medicines as made by the Committee in their 24th Report (15th Lok Sabha) were as under:

(i) Ministry should urgently bring in the Codified Purchase Manual so as to ensure that the entire procurement process becomes more reliable, accountable and transparent.

(ii) Steps should be taken by the Ministry to explore the feasibility of doing away with the local purchases altogether so that exploitation of the system by certain vested interests is prevented and higher payment towards locally procured medicines is checked.

(iii) Monitoring mechanism be strengthened and exemplary action taken against the errant doctors, who take advantage of the helplessness of the patients and frequently prescribe expensive medicines outside the formulary so that superfluous local purchase of medicines is avoided.

(iv) Ministry should codify and adopt a defined process for annual updation of medicine selection and periodical revision of CGHS formularies.

(v) Periodical inspections should be carried out to ensure that all the CGHS hospitals/dispensaries maintain their respective formularies and update them at regular intervals.

(vi) Effective measures need to be taken to make the MSO corruption free as well as adequately staffed so that the organization is able to gradually shift its focus from procurement to management aspects of medicines and medical equipments.

(vii) Supply and distribution of spurious/adulterated drugs are dealt with iron hand to wipe out the menace of such drugs.

8. These recommendations were substantially accepted by the Government. The action taken by the Ministry of Health and Family Welfare on these recommendations are contained in the 84th Report (15th Lok Sabha). Nevertheless, the deficiencies pointed out in the previous Audit Report and the recommendations of the PAC were not

addressed completely. Shortcomings in the drugs procurement system in CGHS remained unresolved.

9. Therefore, the Public Accounts Committee (2014-15) further took up the subject for detailed examination and Report. The representatives of the Ministries of Health and Family Welfare, Chemicals and Fertilizers (Departments of Pharmaceuticals and Petro Chemicals) appeared before the Committee for tendering evidence on 12th January 2015 and 9th April, 2015. Subsequently, the post-evidence replies were also received from the Ministries/Departments. Based on all these written and oral deposition by the aforesaid Ministries/Departments, the Committee examined the subject in detail and identified certain critical issues which are discussed at length in the succeeding paragraphs.

Audit Findings

A. Preparation/revision of drug formulary for Branded drugs

10. Audit observed that the Ministry of Health and Family Welfare constituted (September 2008) a Committee for preparation/revision of the existing drug formulary for Branded drugs. The Committee decided to include new items in the formulary by identifying those drugs which were commonly procured in the CGHS, Delhi during 2008 through local purchase. The inclusion of various drugs was further subject to valid drug licence, registration of the manufacturing firm with MSO. Consequently, the Committee recommended (December 2009) inclusion of 382 more drugs over the existing 350 drugs. Subsequently, a total of 622 drugs were notified in the revised formulary in September 2010.

11. The Committee, while identifying the drugs for inclusion in the formulary, opted for commonly prescribed brands of drugs instead of identifying commonly prescribed drug composition. Thus, the methodology adopted by the Committee was predominantly based on the prescription of specific brands by doctors. The selection of items by adopting the drug composition approach would have provided many options that would be cost effective, as there were many brands of same drug composition available in the market at different rates.

12. Test check by Audit of 21 cases in the Branded drug formulary revealed availability of several low cost brands in the same category of drugs. Audit also noted that even the discounted price of the selected brand was much higher than the MRP of other low cost brands available in the market. Audit compared the prices of these 21 test checked brands with other brands of identical drugs and found that CGHS Delhi incurred avoidable expenditure of ₹ 9.25 crore during 2011-12 by opting for higher priced brands **(Annexure I)**.

13. Further, on being enquired as to whether the lower cost options of brands in the same category of drugs was available, the Ministry replied "Yes".

14. When asked about the reasons for opting the commonly prescribed drugs instead of identifying commonly prescribed drugs composition that would have been more cost effective, the Ministry of Health and Family Welfare in their written submission stated as under:

> "The formulary for proprietary drugs was finalized in 2008-09. At that time it was noticed that local chemists were giving 10-12% discount on the MRP, and it was therefore felt that purchasing the commonly prescribed drugs through MSO would result in large savings.
>
> Following issues were considered while preparing the formulary in 2008.
>
> 1. Expenditure towards local chemist, which was around 85% of the procurement budget.
> 2. Supply of MSO was not adequate based on the then formulary of MSO.
> 3. To reduce the dependency on local chemist.
> 4. To supply all the essential medicines on day zero.
> 5. To reduce the total expenditure on procurement.
>
> Based on the above issues and looking at the prescription pattern at that point of time the formulary was prepared for both Generic items and Branded items. The number of items included in the formulary was 818 and 622 for generic and branded respectively. The idea was to prepare:-
>
> 1. Generic formulary to include in general the medicines with single composition.
> 2. Cover all the commonly prescribed drugs through a formulary of branded medicines.

This position is being rectified and it has now been proposed that only the L-1 out of the tender for branded formulary will be considered and other brands of the same composition will not be purchased. The proposal is under examination in the Ministry."

15. Apprising the Committee about the present position with regard to preparing branded formulary, the Ministry of Health and Family Welfare in their written note submitted as under:

> "The present proprietary (branded) formulary contains different brands having the same salt. The revised proposal is to have rate contract with L1 brand alone, where there are more than one brand having same generic composition. Thus list of 622 brands will get reduced to 469, as 256 brands can be grouped into 103 medicines based on their chemical composition. The proposal has been accepted by the Ministry. Rate enquiry has already been invited and bids received have been opened."

B. <u>Procurement of drugs not listed in the formulary</u>

16. An analysis of the expenditure incurred by the Ministry on procurement of formulary and non-formulary drugs during the years 2009-12 indicated that 71 *per cent* of the total expenditure was incurred on procurement of drugs not listed in the formulary. Further, CGHS Delhi procured only 19 *per cent* of items from within the formulary while 81 *per cent* items were outside the formulary **(Annexure II)**. In cities outside Delhi covered in Audit, CGHS incurred about 50 *per cent* of the total expenditure on procurement of drugs outside the formulary during 2009-12.

17. The Committee sought to know about the rationale for introducing the local purchase system and the measures taken to remove the shortcomings in present system of procurement, distribution and inventory management of drugs so that local purchase of drugs is avoided. In response, the Ministry of Health and Family Welfare, in their written replies stated as follows:

> "The need for introducing the local purchase system arises because of the following:
>
> 1. It is not possible to restrict all prescriptions written by physicians and specialists to the MSO approved drug formulary because no formulary can at all times be extensive enough to cover the whole spectrum of drugs required for treatment of human diseases.

2. Pharmaceutical research is a constant process for introduction of newer and more effective medicines in the market with better results and lesser side effects. For many diseases, particularly chronic ones like Hypertension, Cancer, Heart diseases etc. such drugs are prescribed by doctors.

3. In addition it needs to be pointed out that procurement of all items in the formulary is always not possible because of various reasons such as lack of response etc. Consequently such medicines are not supplied to WCs by MSO, necessitating Local Purchase. However, demand for such local purchase should not be very large.

A certain amount of local purchase may become necessary. However, its quantum can be brought down significantly.

The measures recently taken to improve the system, include the following;

i) the formulary has recently been revised to make it comprehensive,
ii) tenders have been floated for rate contract of more than 1200 items,
iii) computerization both at CGHS and MSO through web based software has been completed.
iv) all deliveries of Pilot Project medicines are at CGHS WCs, thereby minimizing the delivery time."

18. When the Committee desired to know as to whether the Ministry had made any analysis of the medicines that they were largely buying from the local chemists and whether those medicines have been entered into formulary list, the Ministry in their post-evidence replies submitted as under:

"In August 2014, an analysis was made to identify the medicines which are commonly indented through Authorized Local Chemists (ALCs). These medicines were not part of the CGHS formulary, could not therefore be procured centrally and were being indented through ALCs against individual prescriptions. Based on the data received from NIC of commonly indented items for 06 months (01/01/2014 to 30/06/2014) from various Wellness Centres from Delhi / NCR, a Committee of the CGHS identified the medicines which are indented in large numbers i.e. 50000 tablets capsules or more during this period. The list of 171 such medicines was submitted to MSO for inclusion under CGHS formulary. This has been done in the proposed revised formulary, and these medicines would now be procured centrally."

19. As regards the steps taken to refrain the doctors from prescribing drugs outside the formulary which led to excessive local purchases, the Ministry informed as under:

"The steps taken by the Ministry generally relate to promotion of generic drugs in place of branded drugs. However, it is felt that compliance with following instructions would also lead to shift to greater prescription of drugs from within the formulary.

1. Use of Generic names of drugs: Medical Council of India (MCI) issued guidelines in this regard that every physician should, as far as possible, prescribe drugs with generic names and he /she shall ensure that there is a rational prescription and use of drugs, vide notification dated 11.3.2002.

2. Ministry of Health & Family Welfare vide F.No. 39-3/2003-04/CGHS/MSD/RS Dt.23.7.2009, on the recommendations of an expert committee and DCGI, decided that:

   a. The products manufactured/marketed as food supplements, cosmetics and Ayurvedic preparations prescribed by allopathic doctors will be inadmissible.
   b. Supply of vitamins and antioxidants will be restricted to CGHS formulary only.
   c. Vaccines in general will be admissible except Hepatitis B, Influenza and Leprovac for high risk.

3. After detailed discussions with the specialists of the Dr RML Hospital & Safdarjung Hospital New Delhi they were advised vide O.M. No. 25-1/09-10/CGHS/MSD/CGHS(P) dt. 30.9.2009 to prescribe only those drugs which are available in the CGHS Wellness Centres, as far as possible, so that immediate availability of drugs to beneficiaries can be ensured. It was also provided that medicines available in CGHS Wellness Centres and having identical formulations and/or therapeutic values may be issued to the beneficiaries.

4. Vide order No. S-11025/45/10-MH-I dt. 26.5.2010 conveyed to all the institutions under the Ministry of Health & Family Welfare, it was enjoined that "must provide only good quality generic medicines. It has therefore, been decided that whenever any branded drug is prescribed in the above mentioned institutions, it shall invariably also be mentioned that any other equivalent generic drug could also be provided".

5. Ministry of Health & Family Welfare has issued guidelines vide Office Memo. No. H-11013/4/2010-DFQC dated 19.5.2011 followed by a circular No. H-11013/7/2012-CGHS (P) dated 8th February 2013 and No. S-11011/16/2012-CGHS(P) dated 8.4.2015 emphasizing the need of prescribing generic drugs. In this regard it was reiterated that all specialists/Doctors working in CGHS were directed to ensure that generic drugs are prescribed to the maximum extent possible with a view to make medical treatment cost effective and affordable."

20. Apprising the Committee about the action initiated against those doctors who are frequently prescribing expensive branded medicines instead of low cost yet equally effective drugs, the Ministry informed that a prescription audit was conducted in one of the Wellness Centres in the last week of August and show cause notices were issued to

two doctors deputed as Medical Specialists, to explain as to why they prescribed medicines out of CGHS formulary. While the case is under process, one of the doctors has resigned. Their deputation as Medical Specialist, was also withdrawn.

21. As regards the keeping an eye on the doctors who prescribe branded drugs, the representative of the Ministry of Health and Family Welfare during his deposition before the Committee on 12th January, 2015 stated that:

> "As far as the Government doctors are concerned, the CGHS, Delhi now has been computerized and we are able to identify as to which doctor has prescribed which medicine. This has been done only recently."

22. Further, as far as private doctors are concerned, DGHS deposed during evidence on 12.01.2015 as under:

> "Whole of the Private hospitals are unregulated and for that purpose only the Government of India brought the Clinical Establishment Act, but that Act is not adopted by many of the States. We are not able to take action against them or de-recognize them."

23. In order to keep check on the prescription pattern of doctors which lead to unnecessary local purchase of medicine, the Committee in Para 5 of the 24th Report of PAC (15th Lok Sabha) had recommended that the monitoring mechanism be strengthened and exemplary action taken against the errant doctors, who take advantage of the helplessness of the patients and frequently prescribe expensive medicines outside the formulary, so that superfluous local purchase of medicines is avoided.

24. While not accepting the Action taken by the Ministry of Health and Family Welfare on the abovesaid recommendation, the Committee in Para 12 of their 84th Report (15th Lok Sabha) had further recommended the Ministry to evolve a transparent and effective mechanism enabling the aggrieved patients to lodge their complaints against the errant Doctors without fear or pressure so that more instances of malpractices are detected and large scale purchase of medicines outside the formulary is avoided. Further, explanation may be obtained from these CGHS doctors who make prescriptions which are regularly at variance.

25. Audit analysed the approved rates of drugs listed in the formulary and found that during 2011-12 the Ministry was able to obtain discounts in the range of 12 to 50 *per cent* on the Maximum Retail Price (MRP) of these drugs. In comparison, CGHS was able to obtain discounts in the range of 10 *per cent* to 30 *per cent* for drugs outside the formulary. Thus the drugs listed in the formulary are substantially cheaper. However, Audit is unable to quantify the exact financial implication on this account as rates of non-formulary drugs are not maintained and therefore are not available for comparison.

26. Specifying the reasons for CGHS for lagging behind the Ministry in obtaining the high discount range from suppliers, the Ministry stated as under:

> "(i) Ministry purchases drugs from the Manufacturer/Importer in bulk quantity through open tender through Medical Store Organization whereas CGHS procures drugs not available in the Wellness Centre/Outside the formulary on a day to day basis.
>
> (ii) Percentages of discounts on drugs procured from Authorised Local Chemists are based on percent of discounts offered by chemists in the tender. These discounts are based on offer from ALCs and only L1 Quotation is selected as per Government guidelines.
>
> (iii) The discounts offered on bulk procurement by Ministry are different as compared to drugs procured from Local Chemists on the following grounds: (a) There is marked difference in quantity procured at the Ministry and Local Chemist level. (b)The delivery is at single point in case of Ministry and in one go while Local Chemist has to provide medicine on daily basis in 90 odd Wellness Centres in small quantity increasing logistic cost. (c) Ministry purchases from the Manufacturer/Importer while Local Chemists fixed by CGHS are retailers."

27. While taking into consideration large scale procurement of medicines through local purchase, the Public Accounts Committee in their 24th Report (15th Lok Sabha) had recommended that steps be taken by the Ministry accordingly to explore the feasibility of doing away with the local purchases altogether so that exploitation of the system by certain vested interests is prevented and higher payment towards locally procured medicines is checked.

28. In their Action Taken Note, the Ministry of Health and Family Welfare stated as under:

"In the period prior to the computerisation of the functioning of the CGHS there was no data base regarding procurement of medicines by the CGHS through local purchase. After the computerisation of the functioning of CGHS, it was possible for the CGHS to monitor the prescriptions made by Government specialists, as a result of which 272 drugs which were not in the formulary of CGHS, but were being commonly prescribed by specialists were identified. CGHS has been able to procure such medicines directly from manufacturers/suppliers at more competitive rates. All Chief Medical Officers in charge of the dispensaries have been authorised to place indents directly on the manufacturers/suppliers on a periodic basis based on the need. This arrangement has resulted in beneficiaries getting upto 90% of their requirement of medicines on the same day. The project, which was attempted as a pilot project in 10 dispensaries, in Delhi, as a result of positive response received, was extended initially to all dispensaries in Delhi and then subsequently to other CGHS cities. With the expanded coverage of scheme, the proportion of local purchase is expected to come down further. Given the need to make medicines available to beneficiaries without delay and taking note of existing prescription practices and newer medicines being introduced from time to time, it is not possible to entirely do away with local purchase, though further effort is being made to further reduce local purchases."

(a) Non-finalization of procurement rates of drugs listed in the formulary

29. One of the most important factors for timely supply of drugs of good quality is the speedy finalisation of the procurement rates of the drugs listed in the formulary by the Ministry. Audit noted that the rates of large number of drugs, particularly during 2009-10 and 2010-11, were not finalised by the Ministry. The details are given below:

Formulary	Year	Total nos. of drug listed in formulary	Drug for which rates finalized	Drug for which rates not finalised	Percentage of drugs of which rate had not been finalised
Branded drugs	2009-10	504	350	154	30.56
	2010-11	504	339	165	32.74
	2011-12	622	592	30	4.82

30. The reasons for non-finalisation of rates of various drugs were attributed to items being de-registered by the Drug Controller, rates of drugs not being negotiable, firms having changed drug composition to bypass National Pharmaceuticals Pricing Authoirty (NPPA)†, the firm not being the manufacturer of the quoted item, etc. Thus non availability of rates of drugs within the formulary is likely to lead to procurement of drugs outside the formulary which in turn would lead to extra expenditure.

31. While observing that one of the reasons for non-finalisation of rates of various drugs is items being de-registered by the Drug Controller, the Committee wanted to know the reasons thereof. In response, the Ministry stated as under:

> "It is submitted that the drugs are not de-registered by the Drug Controller as pointed out in the Audit Note, rather the manufacturing firms are de-registered by the MSO, based on the stipulated guidelines. Drugs when procured, are tested from two Government approved Labs, before they are distributed to CGHS. If the drugs are declared not of standard quality by these two labs then the sample is sent to Central Drug Laboratory (CDL). If drug is declared not of standard quality by CDL then the drug is de-registered for further procurement."

32. Further, when asked as to why the rates of drugs were not negotiable, the Ministry in their written replies submitted as under:

"Issue of non finalization of rates

Sl. No.	Type of formulary	Number of drugs in formulary	Number of drugs for which rate approved
1.	Generic	818	218
2.	Proprietary or Branded	622	532

The reasons for less number of drugs for which rates were approved are:

1. Paucity of valid bidders in tender for generic groups.
2. The rate of a firm/company which had been deregistered cannot be considered in subsequent years.
3. It is seen that some companies stop manufacturing drug of particular brands.

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† National Pharmaceuticals Pricing Authority (NPPA) is an independent body of experts and is responsible for implementing the drug price control order (DPCO). DPCO is an order issue by the Government for fixing the prices of some essential bulk drugs and their formulations.

4. It has also been seen that the requirement under CGHS for some drugs is so small that companies are not interested in finalizing the rate contract for those brands."

33. Upon noticing that the Ministry of Chemicals and Fertilizers (D/o Pharmaceuticals) has been assigned the role of fixing rate on certain drugs, the Committee desired to know the reasons thereof, number of drugs for which they have been fixing the rates and why this role was not assigned to the Ministry of Health and Family Welfare being the nodal Ministry for healthcare. In response the Ministry of Chemicals and Fertilizers (D/o Pharmaceuticals) stated as follows:

> "As per the business allocation the prices of medicines are controlled/monitored by the Department of Pharmaceuticals through National Pharmaceutical Pricing Authority (NPPA). The Government notified Drugs Prices Control Order (DPCO), 2013 vide which all the medicines specified in the National List of Essential Medicines 2011 (NLEM) have been brought under price control. There are 614 formulations specified in the first schedule of DPCO, 2013 covering 27 therapeutic groups including medicines used in the treatment of cancer, Heart and Kidney. Further, it may be mentioned that while healthcare is under the domain of Ministry of Health and Family Welfare, making available essential medicines at affordable prices is under purview of Department of Pharmaceuticals."

34. Apprising the Committee about the existing mechanism to fix rates of drugs and coordination mechanism with Ministry of Health and Family Welfare, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) in their written replies stated as follows:

> "Under DPCO 2013, prices are fixed based on market data. National List of Essential Medicines (NLEM), 2011, published by Ministry of Health and Family Welfare and included in the 1st Schedule of DPCO 2013, forms the basis for fixation of ceiling prices. For calculation of ceiling prices, all brands and generic version of the medicines having market share of more than or equal to 1 percent of the total market turnover is taken into account. The prices are fixed by NPPA in its Authority meetings which *inter-alia* has an ex-officio Member from the Ministry of Health and Family Welfare. This Department also coordinates with Ministry of Health and Family Welfare for revision/updation of the NLEM. Whenever required, technical input is also taken from Ministry of Health & Family Welfare."

(b) <u>Inadequate and incomplete drug formulary</u>

35. Audit pointed out the doctors continued to prescribe drugs outside the formulary despite the adverse comments of the Parliamentary Committee. Drugs valuing ₹ 1119

crore were purchased from outside the formulary during 2009-12. The fact that 71 *per cent* of the expenditure during 2009-12 was incurred on drugs outside the formulary points to drug formulary not being comprehensive enough to cover drugs for wide-ranging ailments/diseases.

36. Explaining about the reasons for prescribing drugs outside the formulary despite adverse remarks of PAC, the Ministry of Health and Family Welfare in their written replies stated that :

> "Medical science is an evolving scientific field. Newer drugs/combinations/brands are added frequently for the treatment of ailments and older brands/drugs become out dated. Newer drugs are superior to the available drugs in one or the other aspects like lesser side effects, better efficacy, requirement of lesser number of dosage per day, shorter duration of treatment etc. In a large number of cases the patients are either referred to the Specialist or consult the Specialist directly for advice. Often, it has been observed that the Specialists of the Central/State/Private Recognized Hospitals prescribe medicines which are not included in the existing CGHS formulary. It becomes difficult for the GDMOs of the Wellness Centres to overrule the decision of the Specialists due to ethical and administrative reasons. This is the major cause of increase of expenditure through local chemist."

37. When asked as to whether the present formulary is comprehensive enough to cover drugs for wide ranging ailments, the Ministry replied that :

> "Present formulary is not comprehensive enough to cover drugs for wide ranging ailments in view of development of new pharmaceutical products in the world. A Committee under the Chairmanship of DGHS is reviewing the generic formulary.
>
> In fact, during a recent meeting of the above Committee, it was seen that there are 397 generic drugs which are generally used in the Wellness Centres, but are not included in the present formulary."

38. In response to other related query, the Ministry of Health & Family Welfare in their written submission stated as under:

> "The CGHS formulary is quite broad, but it cannot be said that it is fully comprehensive in view of the constant evolution of new drug formulations required to treat disease. The recent one prepared at the level of DGHS will make the formulary more comprehensive. However, there will always be some individual beneficiaries requiring medicines, which are not part of the formulary since new medicines get added rapidly. In addition it needs to be pointed out that

actual procurement of all items in the formulary is always not possible because of various reasons such as lack of response, etc., consequently such medicines are not supplied to WCs by MSO, necessitating local purchase. However, demand for such local purchase should not be very large."

39. Apprising the Committee about the process adopted by the Ministry for periodical updating of formulary list and when the last revision of formulary list was undertaken, the Ministry in their written replies stated as under:

"Updating the formulary is generally carried out by a Committee specially constituted for this purpose. The Committee comprises Specialists from different fields as well as representatives of DCG(I) and CGHS. It considers the existing formularies and recommends inclusion / deletion of items based on recent advances in medical field, and also the experience of specialists. The last revision of the generic formulary was done in June 2013 by a Committee headed by Addl. Secretary & DG, CGHS. Its revision has been proposed by a Committee headed by the DGHS. This formulary is approved at the level of Secretary. The formulary for Branded drugs was finalized by a Committee headed by a Joint Secretary in the Ministry. The final approval was given by the HFM in September 2010. It was inadvertently, through a typographical mistake, mentioned in the reply dated the 27th February 2015 that the Branded formulary was finalized in 2008-09. Actually the process was begun in this year and as mentioned above (and also in the Audit Note of May 2013 itself) the approval was given in September 2010. This error is deeply regretted."

40. On being enquired as to whether any definite time frame has been fixed for regular revision of formulary list, the Ministry stated as under:-

"There are no specific instructions on this issue. The generic formulary was however revised in 2008, then in 2011 and again in 2013. Further revision has now been done. The branded formulary was last revised in 2010."

41. When the Committee sought to know about the existing mechanism of inspection in the Ministry so as to ensure that all the CGHS Wellness Centres maintain their formularies and update them at regular intervals for identifying purchasing essential drugs, the Ministry of Health and Family Welfare submitted as follows:-

The broad mechanism for identifying drugs for purchase is as follows:-

i) MSO procures medicines centrally from the drugs included in the formulary based on the indents received from CGHS. Addl. Directors of Cities compile the requirements from CGHS Wellness Centres for provisioning of medicines and place online indents to MSO. MSO arranges for delivery of medicines in two installments in a year.

ii) The indents for pilot project medicines are calculated through NIC software and indents are placed to suppliers based on the consumption pattern and the inventory available.

iii) Life saving medicines are procured on case to case basis by Addl.Director,CGHS(MSD) in Delhi and by Addl. Director of concerned city in other cities.

iv) Procurement through Authorized Local Chemist is done by CMO i/c of CGHS Wellness Centre and medicines are procured against individual prescriptions.

100% Stock verification of CGHS Wellness Centres is done annually, and the inventory of medicines is also verified."

42. In response to a query regarding by what time the complete drug formulary would be made, Director General of Health Services in his deposition before the Public Accounts Committee on 12th January, 2015 stated as under:-

"In another three months we will be getting the complete formulary made and tender done."

43. He further stated that "now we have made it that it should be looked after every three months."

44. Upon noticing that no defined process has been adopted by the Ministry to update the medicine selections, the Committee in Para 6 of their 24th Report (15th Lok Sabha) had urged upon the Ministry to codify and adopt a defined process for annual updation of the medicine selection and periodical revision of the CGHS formularies so as to ensure that the intended purpose of economical and efficient procurement of medicines is well served and the emerging therapeutic options and needs are appropriately catered to.

45. In response thereto, the Ministry in their Action Taken Note stated as follows:

"The Ministry is reviewing/updating the formularies periodically. Current formulary for Proprietary drugs is approved for one year. To revise the proprietary drug formulary a committee has been constituted on 19.12.2011. The validity of the current proprietary formulary is extended upto 23.12.2012. The Generic formulary was revised on 23.05.2011 and is valid for three years. All efforts were taken to complete the exercise of updating the formulary in time. However, in case some time gap was there in updating the current formulary, it was extended with the approval of the competent authority at existing rate contracts. Hence, the procurement made by the Ministry was always economical and efficient."

46. While commenting on the above said Action Taken Notes the Committee had in their 84th Report (15th Lok Sabha) had desired that a defined process and definite time-frame be prescribed for mandatory annual updation of the medicines.

C. Procurement of Generic drugs

a) Generic and Branded Drugs

47. A Generic drug is defined as any drug marketed under its chemical name without advertising; therefore Generic drugs are listed as the name of the constituent drug only e.g. Paracetamol. A Branded drug on the other hand is a drug /medication sold by a pharmaceutical company under a trademark-protected name, e.g. Crocin, Metacin, etc. – these are tablets of Paracetamol sold under proprietary names.

48. Audit further noted that many drugs are available in both Generic and Branded version. Generic drugs are substantially cheaper than the Branded version. The Minister of Health and Family Welfare while approving (September 2010) the revised formulary of Branded drugs, expressed serious concern on prescribing of Branded drugs by doctors instead of Generic versions and directed for a complete shift towards Generic drugs, within one year, both in prescriptions and supplies. In order to promote Generic drugs the Ministry, in May 2011, revised its Generic drug formulary from 818 to 1128 drugs.

49. As generic and non-branded drugs are effective enough and cheaper than the branded drugs, the Committee wanted to know as to what steps have been taken by the Ministry to instill faith in the doctors/patients in the efficacy of those drugs. In their reply, the Ministry of Health and Family Welfare responded as under:-

> "The Ministry has consistently held that generic drugs, of good quality, are as effective as branded drugs. The following steps have been taken in this regard:
>
> 1. After detailed discussions with the specialists of the Dr RML Hospital & Safdarjung Hospital, New Delhi, O.M. No. 25-1/09-10/CGHS/MSD/CGHS(P) dt. 30.9.2009 was issued with the following directions/advice:
>
>   a. Specialists of these hospitals were advised to prescribe only those drugs which were available in the CGHS Wellness Centres, as far as possible, so that immediate availability of drugs to beneficiaries can be ensured.

b. Medicines available in CGHS Wellness Centres and having identical formulations and/or therapeutic values may be issued to the beneficiaries.
c. It is for information of the CGHS beneficiaries that proprietary /branded drugs manufactured by different manufacturers and having same generic composition have same therapeutic effect.

2. The order No. S-11025/45/10-MH-I dt. 26.5.2010 conveyed to all the institutions under the Ministry of Health & Family Welfare, stipulated that they "must provide only good quality generic medicines. It has therefore, been decided that whenever any branded drug is prescribed in the above mentioned institutions, it shall invariably also be mentioned that any other equivalent generic drug could also be provided.

3. Director, CGHS has also issued instructions in this regard to Addl.Director(HQ),Addl.DDG (HQ) and Addl.Director(MSD) to analyze and take necessary steps for better utilization of generic drugs."

50. As the Minister of Health and Family Welfare in September, 2010 had directed for a complete shift towards Generic drugs, within one year, both in prescriptions and supply, the Committee desired to know about the action taken by the Ministry in this regard. In response, the Ministry submitted as under:

> "It is felt that a complete shift towards generics in prescriptions is not possible presently. More complex medicines, involving more than 3 ingredients, are now being developed and are giving good results in the fight against disease. Such drugs are almost always proprietary in nature. It would be unfair to deny patients the benefits of new advances in medical science by insisting on an absolute reliance on generic drugs. It is nevertheless correct that there should be a greater reliance on generic drugs."

51. Audit further noted that many drugs are available in both Generic and Branded version. Generic drugs are substantially cheaper than the Branded version. The following example would illustrate the point:

Generic drugs					Branded Drugs		
Generic name	Strength	Type	Pack	Price	Brand	Manufacturer	Price
Nimesulide	100mg	Tab	10	2.70	Nimulid	Panacea Biotech	29.00
					Nise	Dr. Reddy Lab	32.00
Amikacin	100mg/2ml	vial	2ml vial	6.25	Zycin	Zydus Cadila	19.50
					Amexel	Nicholas Piramal	15.10
Source :www. janaushidhi.gov.in							

I. The Minister of Health and Family Welfare while approving (September 2010) the revised formulary of Branded drugs, expressed serious concern on prescribing of Branded drugs by doctors instead of Generic versions and directed for a complete shift towards Generic drugs, within one year, both in prescriptions and supplies. In order to promote Generic drugs the Ministry, in May 2011, revised its Generic drug formulary from 818 to 1128 drugs.

II. Audit further noted that the Ministry did not finalise procurement rates of most of the drugs listed in the Generic formulary as detailed below:

Formulary	Year	Total nos. of drug listed in formulary	Drug for which rates finalised	Drug for which rates not finalised	Percentage of drugs of which rate had not been finalised
Generic drugs	2009-10	818	264	554	67.73
	2010-11	818	127	691	84.47
	2011-12	1128	279	849	75.26

III. The reason for non-finalisation of the rates of Generic drugs was mainly attributed to poor response from the drug manufacturers.

IV. As a result, CGHS procured only 2 to 55 *per cent* of the Generic drugs listed in the formulary as detailed in the Table below:

Name of city covered in audit	Year	Percentage of drugs procured from Generic list
Delhi	2009-10	2.08
	2010-11	2.20
	2011-12	5.14
Ahmedabad	2009-10	54.5
	2010-11	8.17
	2011-12	4.43
Kolkata	2009-10	27.63
	2010-11	9.90
	2011-12	8.43
Chennai	2009-10	14.18
	2010-11	3.45
	2011-12	4.26
Mumbai	2009-10	40.61
	2010-11	16.78
	2011-12	24.59
Bhubaneswar	2009-10	6.80
	2010-11	6.80
	2011-12	5.07

Further, the expenditure on procurement of Generic drugs in CGHS, Delhi during 2009-12 constituted a mere 0.19 *per cent*.

52. It is seen from above that the percentage of generic drugs procured in Delhi was only 2 to 5 percent and in Bhubaneswar around 5 to 7 percent during 2009 to 2012. Further in major cities like Ahmedabad, Kolkata, Chennai and Mumbai graph of percentage of generic drugs procured has drastically come down from nearly 50 percent during 2009-10 to below 10 percent in 2011-12. While specifying the reasons thereof, the Ministry of Health and Family Welfare in their written replies stated as under:

> "Drugs procured in bulk after provisioning depend on the availability of drugs for which rates have been approved. As per records, procurement of medicines in 2013-14, through GMSDs was based on the previous formulary containing – 818 generic and 622 Proprietary Medicines. Out of these, rates were approved for 218 generic and 532 Proprietary Medicines. The approved rates of 99 generic medicines are through 99 PSU companies, and the rest 119 are through other companies. One of the main reasons for less procurement of generic drugs by CGHS was that rates were approved by MSO for only 25 percent of the generic drug formulary and also many of the drugs listed in the generic formulary were

only for hospital use and not required in the Wellness Centres. Also MSO could not supply many of the drugs that were indented by CGHS."

53. Further, with regard to the corrective measures taken by the Ministry to increase the procurement of generic drugs by CGHS, the Ministry of Health and Family Welfare informed as under:

"A committee under the Chairmanship of DGHS has been constituted to revise the generic formulary of 1447. The Committee in its meeting held on 19.01.2015 has decided as follows:-

(a) All the drugs, which are presently being procured through local indent, are to be included in the generic formulary.

(b) MSO to take up tendering process for finalization of rate-contract of drugs. Priority in tendering is to be given to drugs which are presently being procured through local indent.

The open bid has already been invited in generic form for 27 most commonly prescribed compositions & technical bid will be opened on 19.02.2015. The open tender process for over 800 other drugs has already been initiated, and tender will be floated in the next few weeks."

54. The details indicating the current status of percentage of drugs procured from generic drugs list as submitted by the Ministry of Health and Family Welfare are given as under:

"Procurement of medicines in 2013-14, through GMSDs was based on the previous formulary containing – 818 generic and 622 Proprietary Medicines. Out of these, rates were approved for 218 generic and 532 Proprietary Medicines. The approved rates of 99 generic medicines are through 99 PSU companies, and the rest 119 are through other companies."

55. Test check also revealed that 59 drugs selected for Branded drug formulary were already listed in the Generic formulary **(Annexure III)**. Further, a comparison of rates of 30 Branded drugs with rates of Generic drugs in Janaushidhi scheme revealed that an amount of ₹ 11.81 crore could have been saved by CGHS Delhi during 2011-12, had Generic drugs been procured instead of Branded drugs. **(Annexure IV)**.

56. When asked by the Committee as to whether the Ministry have explored the possibility of nexus between doctors and pharma companies to refrain the doctors from prescribing generic drugs and whether it is a fact that even foreign trips are sponsored

by the pharma companies as a quid pro-quo, the Ministry of Health and Family Welfare in their post-evidence information submitted as follows:

> "Two cases have come to the notice of CGHS.
>
> A complaint was received against the then Addl. Director, CGHS, Patna. The matter is under investigation and the CBI is conducting a Preliminary Enquiry (PE). In the meantime, the then Addl. Director, CGHS (Patna) has been relieved of his charge. Another complaint has been received against Addl. Director, CGHS, Thiruvananthapuram and the matter is under examination. The Deptt. of Pharmaceuticals issued Uniform Code of Conduct for Pharma Companies for voluntary compliance for a period of 6 months vide OM No 5/3/2009-PI/P-II (Vol.III) dated the 12th December, 2014."

57. The Committee then asked the Ministry about the measures initiated by them to break the nexus between pharmaceutical companies and doctors. In response the Secretary, Department of Pharmaceuticals informed the Committee as under:

> "From January, 2015, the Department of Pharmaceuticals has sent new guidelines to all the pharmaceutical companies that they should follow this uniform code of conduct for pharmaceutical companies to break this nexus between pharmaceutical companies and doctors. They are barred from conducting many training programmes, sponsoring doctors to foreign tours and giving them costly gifts and all other things. But this particular Code is to be adopted voluntarily by all these companies. The MD has to give the statement saying that we are following this particular Code and we are not giving costly gifts and all that to doctors. That they have to give every year. This is for the initial six months' period. For the first six months' period, we will see how this particular system works 'voluntarily code'. After six months, we will review this scheme and we will see that this is statutorily met for followings in the country. This is what we have done. Medical Council has also given separate guidelines to all the doctors. So we are working in close coordination. We are having a meeting very shortly with MCI to see that both these regulations – regulations given by pharmaceutical companies and MCI – got together to see that there is very good impact in the society."

58. Apprising the Committee about the steps taken by the Ministry to promote generic drugs, the Secretary, Department of Pharmaceuticals during evidence stated as under:

> "All our past efforts to promote generic drugs in a big way did not give that much yield. Today, we are working on our revised programme to see that for six therapeutic segments we want to give 500 generic drugs to all our public. First of all, we want to introduce this scheme even in ten different States from June. The first scheme failed to a great extent because we never approached the doctors to prescribe the generic drugs. That big flaw was there. Now, we want to see that doctors are approached, trained and informed about the advantage of having

generic drugs. That is one important strategy that we want to take. Secondly, we want to educate the patients and common public about the advantages of taking generic drugs. These two strategies were missing to a great extent in the first phase programme that we had earlier. Now, with these changes, we are very confident that we will be able to complete the entire country with *jan aushadhi* drugs in a very big way."

59. In this regard, Secretary, Ministry of Health and Family Welfare also informed the Committee during evidence that "as far as prescription of generic drugs is concerned, that proposal is also under consideration that doctors can only prescribe the generic medicines.

b) <u>Delays in procurement of drugs listed in formulary</u>

60. Hospital Service Consultancy Corporation (HSCC) places the supply orders on vendors at rates already finalized by the Ministry. HSCC provides 60 days to the suppliers for making drugs ready for inspection and testing. Audit noted that drugs were received in MSD after a delay of two to six months after communication of the requirement to HSCC. Further, issue of drugs from MSD to CGHS Wellness Centres took another three to five months (**Annexure V**). In effect the drugs were received in CGHS Wellness Centres with significant delays. Similarly in CGHS Chennai, Jaipur, Kolkata, Chandigarh, Thiruvananthapuram, Hyderabad and Bhubaneswar, drugs were received from respective MSDs after a delay of two to ten months from placing the orders. In CGHS Hyderabad, Thiruvananthapuram, Chandigarh, Mumbai and Bhubaneswar there was a short supply/non-supply up to 85 *per cent* of drugs indented to the GMSD during 2009-10 to 2011-12.

The delays in procurement and non-availability of formulary drugs at CGHS Wellness Centres led to procurement of these drugs by CGHS centres from local chemists at higher rates leading to an extra expenditure of ₹ 3.05 crore as detailed below:

(₹ in lakh)

Name of CGHS covered city	Amount of extra expenditure incurred
Delhi	231.83
Kolkata	0.18
Hyderabad	12.77
Jaipur	14.44
Chennai	45.58
Total	**304.80**

61. On being asked about the steps taken by the Ministry of Health and Family Welfare to obviate the delays in procurement as well as non-availability of formulary drugs at CGHS Wellness Centres, the Ministry stated as under:

(a) "To obviate the delay in procurement of drugs, the procurement of drugs for CGHS Delhi has been given to MSO from HSCC.

(b) 272 drugs are being procured directly from manufacturer (at the rates finalized by MSO) by CMOs In-Charge of CGHS Wellness Centres on monthly requirement basis through NIC developed software. These drugs are being directly supplied to the Wellness Centres.

(c) Generic formulary is being revised by a Committee under the Chairmanship of DGHS and tender is being floated by MSO for finalization of rate contract of generic drugs shortly."

62. The Committee also desired to know about the reasons for procuring drugs through HSCC instead of MSO. In response, the Ministry submitted as under:

"M/s HSCC is public sector undertaking of Ministry of Health and Family Welfare and has been set up specifically to provide consultancy services in the health sector. Being a specialized organization, they were assigned the task of procurement of drugs for the CGHS in Delhi in the year 2003. At that time there were certain complaints regarding the functioning of MSO also.

MSO is now capable of procuring drugs and has been entrusted with the same. It may be noted that GMSD has supplied around 78% of generic and 94% of Proprietary Medicines indented by the different indentors against the indent of 2013-14."

63. When enquired about the reasons for giving back the procurement of drugs for CGHS to MSO from HSCC and when such decision was taken , the Ministry replied as under:

> "Procurement of drugs for CGHS, Delhi was given back to MSO from 2014 onwards due to the following reasons:
>
> i) Delay in payment to suppliers by HSCC
> ii) Consultation fee being paid to HSCC
> iii) Imposition of additional terms and conditions by HSCC, due to which suppliers were reluctant to quote.
> iv) Inspection & testing of drugs procured through MSO is carried out after the consignments are received at the GMSDs, whereas in case of HSCC inspection and testing were done at the manufacturers/suppliers' site since HSCC did not have storage space. It could not therefore be ensured that the supplier was supplying the same stocks which had been inspected and tested. Therefore, quality check in case of HSCC was not fool proof."

64. Asked to state as to when the Ministry was not satisfied with the functioning of HSCC, why the services of the same were not terminated earlier, the Ministry did not reply satisfactorily.

65. When asked as to why the procurement of medicines through MSO instead of HSCC was made applicable only for CGHS Delhi and what is the present position in regard to other CGHS centres, the Ministry of Health and Family Welfare replied as under:

> "At that time, it was felt that since MSO had a distribution network outside Delhi also they would be in a better position to take up supplies to CGHS units outside Delhi, whereas HSCC could be made responsible for supply to CGHS units in Delhi. A decision to this effect was taken on 1.3.2003 under the Chairmanship of HFM."

D. Avoidable Expenditure of ₹ 13.52 crore in procurement of formulary drugs in Delhi through HSCC

66. In terms of Rule 165 of General Financial Rules and Para 1.2.1 of Manual of Policies and Procedure of Employment of Consultants issued by Ministry of Finance; the consultants may be employed in the condition of absence of required expertise in–house and when it is felt absolutely essential. MSD Delhi is the nodal office which procures

drugs for all CGHS wellness centres in Delhi. Procurement rates and concerned suppliers of the drug, listed in the approved drug formulary, are finalized by the Ministry. However, MSD procures these drugs through HSCC instead of procuring them directly from notified suppliers. MSD paid consultancy charges of 4.5 *per cent* to HSCC for this procurement till October 2008 and 2.5 *per cent* thereafter. Audit noted that HSCC did not add any value to the procurement process and simply acted as a conduit between the Ministry and the supplier. This is so because the rates and suppliers had already been finalised for drugs procured through HSCC. Thus, MSD Delhi incurred avoidable extra expenditure of ₹ 13.52 crore on consultancy charges paid to the HSCC during 2002-03 to 2010-11.

67. Upon asking as to whether the Ministry had initiated any measures to procure the drugs directly from the suppliers at any time for economizing the cost of procurement, the Ministry of Health and Family Welfare in their written submission stated as under:

"There are four avenues for procurement of drugs in CGHS:

1. Procurement through GMSD: Demand is uploaded by CGHS to GMSD, based on the formulary of MSO and CGHS and supply is made by GMSD.
2. Procurement through Pilot Project for 272 most commonly branded items from the manufacturer directly by CGHS: Rates of these drugs were negotiated and since then these items are being procured by different CGHS Wellness Centres on monthly basis through NIC developed programme. Demand is auto generated by the system based on last four months consumption.
3. Procurement through Local Chemists: Those items which are not included in either MSO list or in the Pilot Project or have been exhausted at the Wellness Centre level are being procured through Local Chemists.
4. Purchase of costly medicines: Procured through MSD CGHS on case to case basis.

All drugs included in the generic & proprietary formularies are being procured directly from manufactures after finalizing the rate-contract. For further economizing the cost of procurement, 272 drugs are being procured directly from the manufacturer by CMOs I/c of CGHS Wellness Centres on monthly requirement basis through NIC developed programme."

E. Pilot Project to Streamline procurement of drugs

68. CGHS proposed (January 2007) to implement a Pilot Project to streamline procurement of drugs in CGHS. The project envisaged assessment of monthly consumption of drugs at CGHS centres. Requirements, thus assessed, were to be intimated to the supplier at the end of month. The drugs were to be delivered at the beginning of each month directly to the CGHS Wellness Centre by the supplier. This project was supposed to eliminate delays in supply of drugs present in the prevailing central procurement system through HSCC in Delhi and through GMSDs in cities outside Delhi. Audit, however, noted that contrary to the proposal, which envisaged procurement of both formulary and non-formulary drugs, the approved list under pilot project contained only non-formulary drugs. It included 235 drugs that were stated to be commonly prescribed drugs purchased locally in CGHS. The project was extended to all the CGHS centres by September 2009. Later the list of drugs in the pilot project was revised to 272 drugs and were included in the Branded formulary of the Ministry (September 2010). Audit also noted that MSD submitted (September 2010) that all the 622 drugs in the new drug formulary as approved by the Ministry may be included in the Pilot Project. This was meant to cut down delays in procurement through HSCC as well as to effect savings of commission of 2.5 *per cent* being paid to HSCC. The proposal was, however, not approved by the Ministry, the reasons for which were not on record. Audit also noted that in CGHS Chennai, Kolkata, Jaipur and Hyderabad, even the drugs included in the Pilot Project were procured through local purchase at higher rates leading to an extra expenditure of ₹ 85.22 lakh.

F. Procurement of Life Saving drugs

69. MSD finalizes procurement rates of these drugs on the basis of quotations received from the manufacturers. MSD procures the drugs based on the prescription made by the CGHS doctors, on approved rates. As noted in the case of other Branded drugs, there were more than one brand of the same drug composition. Audit noted that there were 206 such brands of 72 drug compositions in the list of life saving drugs as on December 2011. Further, prices of the different brands having same drug composition varied substantially. Test check of records related to procurement of life saving drugs in

CGHS Delhi, Thiruvananthapuram, Allahabad and Kolkata revealed that CGHS incurred avoidable extra expenditure of ₹ 6.26 crore on procuring higher priced drug brands despite availability of low cost brands within the list itself **(Annexure VI)**. CGHS did not accord reasons for including several brands of the drug of the same composition in the list of life saving drugs. This led to procurement of drugs in an arbitrary manner. In CGHS Hyderabad, it was observed that life saving drugs were purchased at rates higher than the authorised list resulting in avoidable extra expenditure of ₹ 20.22 lakh. Audit further noted that the MSD Delhi initiated (June 2009) an open tendering process for procurement of Generic drugs. However, the tender documents could not be finalised due to issues relating to modification of clauses in the tender documents. Thus, the MSD failed to implement the proposal of procuring life saving drugs through open tender as of July, 2012.

70. Apprising the Committee about the reasons for delay in finalization of tender documents process of generic life saving drugs, the Ministry stated as under:

> "An open tender for finalizing rate-contract of generic drugs was invited in October, 2013, but the tender could not be finalized since the response from the Pharmaceutical industry was very poor. A Committee was constituted to review the tender conditions with a view to encourage the industry to participate in the tender. Revised terms & conditions of tender recommended by the Committee have been approved with the concurrence of IFD. A tender for finalizing rate-contract for 27 drugs has already been floated, and for another 800 drugs tender would be floated within the next few weeks."

71. Further, with regard to present position of opening the technical bid for 27 drugs and floating the tender for another 800 drugs, the Ministry submitted as follows:

> "Regarding the tender of 27 drugs it is submitted that the Technical Evaluation Committee, under the Chairmanship of Spl. DGHS, held its meeting on 9/4/2015, and the matter is under process. As on 20.4.2015 tenders have been floated for more than 1200 drugs."

72. Providing information regarding current procedure adopted for procurement of life saving drugs, the Ministry of Health and Family Welfare in the replies stated that:

> "The procedure for purchase of Life Saving Drugs has now been streamlined. Currently the Life Saving Drugs are being procured on L_1(lowest) rate after inviting sealed enquiries. Further to have rate contract of Life Saving Drugs, a list

of 268 drugs has been finalized after invitation of Expression of Interest (EOI). The list has been approved by a clinical expert committee and forwarded to the competent authority for approval for initiating E-tender through MSO."

73. When asked as to whether the said list has been approved by the competent authority and E-tendering has been floated, the Ministry stated that the list of medicines to be tendered has been approved by the competent authority, and the tendering is under process.

G. **Quality Assurance**

74. The drugs procured by MSD are subject to mandatory testing in laboratories before supply to CGHS. In CGHS Kolkata drugs were issued to the patients before receipt of test reports, which were later reported as sub-standard by GMSD. In CGHS Mumbai medicines worth ₹ 28.45 lakh received from GMSD during 2009-2012 were declared sub-standard. Out of these, medicines worth ₹ 15.66 lakh were already issued to patients. Such instances highlight the absence of a robust mechanism for quality assurance, which exposes the patients to the hazards of sub-standard medicines and drugs. In CGHS Hyderabad drugs worth ₹ 21.39 lakh procured from GMSD did not have prescribed shelf life and the shortfalls in shelf life were in the range of one to three months. In Chandigarh drugs valuing ₹ 13.53 lakh expired between April 2009 and November 2011 implying that the requirement of drugs was not assessed properly.

75. Providing details of drugs quality assurance mechanism prevalent in CGHS, the Ministry submitted as under:

> "The medicines procured through MSO have inbuilt quality assurance mechanism. In house laboratory test reports are provided by the manufacturers. On receipt of supplies in GMSD (unit of MSO), samples are sent for laboratory testing. On receipt of OK test reports, supplies from GMSD are received in CGHS (MSD) for distribution of medicines to the Wellness Centers."

76. On this aspect, the Ministry have also stated that:

> "Quality assurance mechanism exists for drugs procured in bulk. No lab testing is done on drugs purchased through local chemists since drugs are procured through local chemists on day to day basis and issued to beneficiaries on the next working day. No additional quality is indented for quality / laboratory testing. However all manufacturers have an in house testing system. Drug Controller of India also keeps lifting random samples for drugs testing."

77. The details of sub-standard medicines found in lab testing on all India level during last three years as provided by the Ministry of Health and Family Welfare are given as under:

"Financial year	No. of Samples drawn	Found of Standard Quality	Found of Sub-standard Quality
2011-12	1481	1468	13
2012-13	1446	1441	5
2013-14	2066	2066	Nil

Drugs when procured, are tested from two Govt. approved Labs, before they are distributed to CGHS. If the drugs are declared not of standard quality by these two labs then the sample is sent to Central Drug Laboratory (CDL). If drug is declared not of Standard Quality by CDL then the manufacturers of the said drug is de-registered for further supply of the said drug."

78. Apprising the Committee about the steps initiated to ensure proper quality assurance of drugs procured both centrally and locally, the Ministry submitted as under:

a. "Selection of only those manufacturers, for entering into rate contract, who fulfill following eligibility criteria:-

   i. Annual turnover of more than ₹ 100 crore in manufacturing and sale of drugs in case of group A drugs (drugs required for cardiovascular, respiratory, endocrine diseases, cancer and higher antibiotics) and ₹ 50 crore in case of other drugs
   ii. Having three manufacturing and marketing experience of drugs
   iii. Having WHO-GMP/GMP under schedule-M
   iv. Not being convicted under Drugs and Cosmetics Act
   v. Having R&D facilities/own drug testing facilities

b. Registration of manufacturing unit before supply of drugs to GMSD. Registration is based on inspection of manufacturing unit by a team consisting a member from State Drug Controller's office, a member from Pharmacy college/ Deptt. of Pharmacology, and a member from GMSD.

c. Testing of all batches of drugs before accepting the supplies from two different drug testing labs.

d. De-registration/debarment of manufacturer/rate contract holding firm based on following criteria

Medicines procured through ALCs are against individual beneficiary requirements, and are therefore tested only as and when complaints are received."

79. On being asked as to what extent spurious drugs are prevalent in the Indian Market, the Ministry of Health and Family Welfare provided the following details :

"The results of drug samples tested all over the country in the last six years as received from State Drug Controllers, reveals that only about 0.1% to 0.3% of around 58,000 samples per annum (on an average) fall within the category of spurious drugs.

Earlier, a survey to assess the extent of Spurious and Sub-standard drugs in the country was conducted in the year 2009 by the Ministry of Health, through the Central Drug Standards Control Organisation (CDSCO). Under this survey 24,136 samples of 62 brands of drugs belonging to 9 therapeutic categories of 30 manufacturers, were collected from over 100 different Pharmacy outlets in different regions of the country and located in each stratum viz. metros, big cities, district, towns and villages. The survey has revealed that the extent of drugs found to be spurious was 0.046% only. The report on the countrywide survey on Spurious Drugs is available on the CDSCO website www.cdsco.nic.in.

YEAR-WISE DATA OF SPURIOUS DRUGS AND THE ACTION TAKEN FOR LAST FIVE YEARS AND CURRENT YEAR (till September, 2014)

- Details of no. of samples tested declared not of Standard Quality, No. of Samples declared Spurious in the country since 2009-10 to 2014-15 (till September 2014) are as under:

Percentage of Not of Standard quality drugs and Spurious/ Adulterated drugs for the years of 2009-10, 2010-11, 2011-12, 2012-13, 2013-14 and 2014-15(upto September, 2014) as per the feedback available from the States

Sl. No.	Year	No. of drugs samples tested	No. of drugs samples declared not of standard quality	% of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	% of drugs samples declared spurious/ adulterated
1.	2009-10	39248	1942	4.94	117	0.29
2.	2010-11	49682	2372	4.77	95	0.19
3.	2011-12	48082	2186	4.54	133	0.27
4.	2012-13	58537	2362	4.03	70	0.11
5.	2013-14	72712	3028	4.16	118	0.16
6.	2014-15 (upto September)	38655	1823	4.7	25	0.06

A statement showing No. of samples tested, No. of Samples declared not of Standard Quality, No. of samples declared spurious, No. of Prosecution Launched, and No. of cases decided, No. of persons arrested and approximate value of drugs seized States / UTs wise during the last five years i.e. 2009-10, 2010-11, 2011-2012, 2012-13, 2013-14 and current year 2014-15 (upto September, 2014), as per the information made available by the States is at **(Annexure VII).**

Recently, a countrywide survey regarding the extent of Spurious and Not of Standard Quality (NSQ) drugs is being conducted by Ministry of Health & Family Welfare, Govt. of India under the guidance and supervision of Director I/c, National Institute of Biologicals (NIB), Noida and has already been rolled out from 6th April, 2015. Almost 47,000 drugs samples are expected to be drawn under this survey from Retailers, Govt. Hospitals & Dispensaries which would include 15 therapeutic categories of drugs listed in National List of Essential Medicines (NLEM), 2011. The survey is being conducted on the basis of statistical design provided by Indian Statistical Institute (ISI), Hyderabad & NSSO, New Delhi"

80. While providing a copy of the WHO's Report on spurious drugs scenario in India and measures taken by Government to identify and stop spurious drugs in the Indian market, the Ministry submitted as follow:

(a) "Clarification on WHO report

- Reports in the media have been projecting problem of spurious drugs in the country in a manner which does not provide a balanced perspective and have, therefore, caused misgivings.

- The figures quoted in the media range from 10% to 25% of drugs in the country being spurious drugs. These are unsubstantiated reports.

- For example, on the basis of an alleged WHO report, the media frequently reports that 35% of fake drugs produced in the world come from India. However, the WHO has denied its authenticity. In this regard WHO has also clarified that "...there is no such study conducted by WHO regarding fake drugs menace in the past several years." vide letter dated 31st August 2012.

(b) The measures taken to identify & stop spurious drugs in the Indian market are given below:

i. WHISTLE BLOWER SCHEME:-

Whistle Blower Scheme was announced by Government of India to encourage vigilant public participation in the detection of movement of spurious drugs in the country. Under this policy the informers would be suitably rewarded for providing concrete information in respect of movement of spurious drugs to the regulatory authorities. The salient features of the aforesaid reward scheme are as follows:-

- The reward scheme shall be applicable for whistleblowers in the area of drugs, cosmetics and medical devices.
- Reward is to be given to the whistleblowers i.e. the informers / officials only when there is a confirmation of the seizure of spurious, adulterated and misbranded drugs, cosmetics and medical devices by the designated officers of the CDSCO.
- The reward of maximum of upto 20% of the total cost of consignments seized will be payable to the informer /officials which should not in any case exceed ₹ 25 Lakh in each case.
- In respect of an officer of the Government / CDSCO, the reward should not in any case exceed ₹ 5 Lakh for one case and a maximum of ₹ 30 Lakh in his / her entire service.
- With a view to ensuring that the informers are not made to wait till the final disposal of the matter, 25% of the amount will be given at the time of filing of the charge sheet in the Court of Law.
- Further, with a view to ensure that the informers do not turn hostile during the trial of the case and continue to assist the court in deciding the matter in favour of the Government, 25% of the amount will be given to them at the time of disposal of the case in favour of the Government in the first Court of Law.
- The remaining 50% amount will be paid only when the case has been finally disposed off and no appeal with respect to the matter is pending in any other Court of Law in the country.

ii. GUIDELINES FOR TAKING ACTION ON CASES OF SUB-STANDARD DRUGS:-

In the 40th meeting of Drugs Consultative Committee (DCC) consisting of the DCGI and all State Drug Controllers held on 29.6.2009, guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were adopted for the purpose of uniform implementation of the Drugs and Cosmetic Act in the country. The guidelines have also been placed on the web site of CDSCO.

iii. STRENGTHENING OF DRUGS TESTING LABORATORIES

Under a Capacity Building Project through World Bank, assistance has been provided to upgrade testing facilities and to establish new drug testing laboratories so as to enhance the capacity of the laboratories to test large number of samples. Under this project 23 States and 6 Central Drug Laboratories have been strengthened through renovations, extensions and equipments.

iv. GOOD MANUFACTURING PRACTICES

Schedule M to the Drugs and Cosmetics Rules, 1945, pertaining to Good Manufacturing Practices was amended in 2001 and made applicable to all manufacturers in June, 2005 to make it at par with the international standards

and it is mandatory for the manufacturers of drugs to comply with the requirements of this Schedule for quality control of the drugs manufactured by them.

v. **INTRODUCTION OF GOOD LABORATORY PRACTICES**

Schedule L-1 specifying the rules relating to Good Laboratory Practices & Requirements of Premises & Equipment for testing laboratories have become operative since 1st day of November, 2010.These rules provide for Good housekeeping and safety provisions for the maintenance of the laboratory. The manufacturers having in-house laboratories are required to conform to the provisions of the said Schedule.

vi. **STRENGTHENING OF DRUG REGULATORY SYSTEM IN THE COUNTRY**

The Government has decided to strengthen both the Central and States' drug regulatory system during the 12th Five Year Plan enabling them to keep more effective watch on these unscrupulous elements indulging in unlawful activities. The infrastructure facilities at the head quarter as well as other offices of CDSCO are being enhanced. In April, 2008 CDSCO had a total of 111 regular posts. The number of sanctioned posts in Central Drugs Standard Control Organisation (CDSCO) has been increased from **111**(as on April, 2008) to **474** (as on February, 2015)."

81. As regards the mechanism put in place to monitor the menace of spurious drugs, Secretary Ministry of Health and Family Welfare stated during evidence:

"……about this spurious drug, there is a scheme called 'trace and track' which we have to notify in our rules. That scheme has been prepared. It is a software and it will basically allow that the batch number could be given and from the website anyone can find out whether this is the original medicine or not. That software has been developed. Now, the pharmaceutical companies have to do that. For that, we have to formally put it under our rules. This is currently under the consideration of the Drug Technical Advisory Board."

82. As regards the steps initiated to impose stringent penalties on the manufacturing supply and sale of spurious and adulterated drugs, the Ministry in their written replies submitted as follows:

"**MEASURES TAKEN TO CHECK THE MENACE OF SPURIOUS DRUGS AND STRENGTHENING OF DRUGS CONTROL INFRASTRUCTURE**

AMENDMENTS IN DRUGS AND COSMETICS ACT

The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 and had come in force since 10th August, 2009. The salient features of the amended Act are as under:

(a) Under this Act , any drug deemed to be adulterated or spurious when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any

disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more.

(b) The fines realized will be paid to the relative of the deceased or the aggrieved person.

(c) Offence for sale and manufacture of spurious and adulterated drugs have been made cognizable and non bailable.

(d) A provision of compounding of minor offences has been introduced to dispose of them expeditiously.

(e) Designating special courts for trial of offences relating to Drugs and Cosmetics Act. So far, 16 States and UTs namely, Karnataka, Madhya Pradesh, Delhi, Tripura, Lakshadweep, Arunachal Pradesh, Goa, Meghalaya, Bihar, Mizoram, J&K, Daman & Diu, Dadra & Nagar Haveli, Tamil Nadu, Haryana and Andhra Pradesh have set up designated Special Courts for trial of offences related to adulterated and spurious drugs.

DETAILS OF ENHANCEMENT OF PENALTIES THROUGH AMENDMENTS IN DRUGS & COSMETICS ACT IN 2008

Offence	Penalties before Amendment in 2008	Enhanced Penalties after Amendment 2008
27(a) any drug deemed to be adulterated or spurious is likely to cause his death or is likely to cause such harm as would amount to grievous hurt	imprisonment for a term which shall not be less than five years but which may extend to a term of life and with fine which shall not be less than ten thousand rupees;	imprisonment for a term which shall not be less than ten years but which may extend to a term of life and with fine which shall not be less than ten lakh rupees; or three times values of the drugs confiscated, whichever is more. The fine realized shall be paid to the victims/relatives.
27(b) any drug adulterated but not being a drug referred to in clause (a), or without a valid licence.	imprisonment for a term which shall not be less than one year but which may extend to three years and with fine which shall not be less than five thousand rupees	imprisonment for a term which shall not be less than three years but which may extend to five years and with fine which shall not be less than one lakh rupees; or three times of value of drug confiscated, whichever is more.
27(c) any drug deemed to be	imprisonment for a term which shall not be less than three	imprisonment for a term which shall not be less than 7 years but which may extend to imprisonment for life

spurious under section 17B, but not being a drug referred to in clause (a)	years but which may extend to five years and with fine which shall not be less than five thousand rupees.	and with fine which shall not be less than three lakh rupees or three times the value of the drug confiscated, whichever is more
27(d) any drug, other than a drug referred to in clause (a) or clause (b) of clause (c), in contravention of any other provision of this Chapter or any rule made thereunder,	imprisonment for a term which shall not be less than one year but which may extend to two years and with fine.	imprisonment for a term which shall not be less than one year but which may extend to two years and with fine which shall not be less than 20 thousand rupees.

83. On being asked during evidence on (12.01.2015) as to why the Ministry of Health and Family Welfare do not have control on the drug manufactures, DGHS admitted before the Committee as follows:

> "We do not have a control on the drug manufacture. Up to first five years, when the drug comes in the country for the first time, at that time, it is under the control of the Drug Controller, Government of India. Once the period of five years expires, then we do not go and evaluate it. Then anybody can manufacture that drug and that drug license is given by the State Government. The number of inspectors for checking these drugs is much less. The Government is now taking a step to strengthen the Drug Regulatory Authority of the State Government. We are going to fund them. The EFC has been completed. We will be giving more inspectors to the State Governments so that the drug is regulated".

PART – II

OBSERVATIONS AND RECOMMENDATIONS

1. The Ministry of Health and Family Welfare provides comprehensive health care facilities through Central Government Health Scheme (CGHS) to MPs, Ex MPs, serving and retired Judges of Supreme Court and retired Judges of High Courts, Central Government employees and pensioners and their dependents residing in 24 cities covered under CGHS apart from Delhi NCR. The medical facilities are provided through 250 CGHS Wellness Centres (earlier called as dispensaries) across the country. CGHS provides consultation at CGHS Wellness Centres and Government Hospitals and provides OPD medicines to its beneficiaries. In addition inpatient treatment facilities and investigations are provided at Government hospitals and empanelled private hospitals. Medical Stores Organisation (MSO) is entrusted with the task of procurement of drugs and medicines required for CGHS Hospitals and Wellness Centres outside Delhi. The MSO operates through seven Medical Stores Depots (MSD). Government Medical Store Depot (GMSD) is the nodal centre for procurement, storage and distribution of drugs to all CGHS Wellness Centres in Delhi. The MSO procures, through open tender, drugs as per two separate formularies for branded and Generic drugs covering 622 and 1447 items respectively at present, which are reviewed and revised periodically. CGHS, undoubtedly was launched with a laudable objective to provide basic medical facilities to Central Government employees and pensioners together with their dependents, sitting and ex-Members of Parliament etc. However, Audit scrutiny of procurement of allopathic drugs in CGHS by MSD and CGHS Wellness Centres in Delhi, Ahmedabad, Jaipur, Chandigarh, Bhopal, Jabalpur, Kolkata, Chennai, Thiruvananthapuram, Hyderabad, Bangalore, Allahabad, Bhubaneswar and Mumbai during 2009-10 to 2011-12 revealed several lacunae/shortcomings in the procurement and distribution of

medicines such as opting for commonly prescribed brands of drugs instead of identifying commonly prescribed drug composition, procurement of drugs not listed in the formulary, non-finalisation of procurement rates of drugs listed in the formulary, inadequate and incomplete drug formulary, delays in procurement of drugs, procuring higher priced branded drugs despite availability of low cost brands, branded drugs continue to be preferred over Generic drugs etc. The Committee's examination is based on the Audit findings as contained in paragraph 6.3 of the Report of the C&AG of India for the year ended March 2012, Union Government (Civil-compliance Audit observations) No. 19 of 2013 relating to the subject "Procurement of Allopathic drugs in CGHS". The Committee's examination has revealed glaring lapses as discussed in the succeeding Paragraphs in the procurement and distribution of drugs resulting in huge infructuous and avoidable expenditure which entails light hearted and skewed approach on the part of the authorities concerned and call for deprecation. Their observations/recommendations to bring about systematic improvements are contained in the succeeding Paragraphs.

2. This is not for the first time that irregularities in CGHS like the rampant local purchase of medicines, prescription of branded medicines instead from approved formulary of medicines, spurious/adulterated medicines/drugs etc were brought to light by the C&AG and the Public Accounts Committee examined the same in detail and made serious observations/recommendations. In fact, a performance Audit of the procedure of procurement of medicines and medical equipment was done earlier by Audit and the results included in the C&AG's Report No. 20 of 2007. The subject was thoroughly examined by the Public Accounts Committee and reported upon in their 24th Report (15th Lok Sabha) on "Procurement of Medicines and Medical Equipment", wherein the Committee had deliberated upon various shortcomings in the procedure of procurement of medicines/medical equipment and given observations/recommendations such as bringing in the Codified Purchase

Manual, exploring the feasibility of doing away with the local purchase of drugs altogether, strengthening the Monitoring mechanism, initiating exemplary action against the errant doctors, codifying and adopting a defined process for annual updation of medicine selection and periodical revision of CGHS formularies in order to make the MSO corruption free and wipe out the menace of spurious/adulterated drugs etc. These recommendations though were accepted by the Government as contained in the 84th Report of PAC (15th Lok Sabha), yet the Committee are inclined to conclude from the audit findings and subsequent examination of the subject that their earlier recommendations on the subject have not been addressed in the right earnest and the shortcomings in the drugs procurement system in CGHS as discussed threadbare in the succeeding Paragraphs remained unresolved. Expressing serious displeasure over the state of affairs and non-fulfillment of the commitments made and assurances given, the Committee feel that the administrative Ministry owes an explanation to them as to why the CGHS beneficiary still suffer due to unavailability or poor quality of medicines. They exhort the Ministry to urgently address the deficiencies pointed out and initiate the requisite and urgent measures so as to effectively resolve the shortcomings in the drugs procurement system in CGHS.

3. A Committee was constituted by the Ministry of Health and Family Welfare in September, 2008 for preparation/revision of the existing drug formulary for branded drugs. This Committee decided to include new items in the formulary by identifying those drugs which were commonly procured in the CGHS, Delhi during 2008 through local purchase. Consequently, in December, 2009 inclusion of 382 more drugs over the existing 350 drugs was recommended. Therefore, a total of 622 drugs were notified in the revised formulary in September, 2010. The Committee are concerned to note that while identifying the drugs for inclusion in the formulary, they simply opted for commonly prescribed brands of drugs instead of identifying commonly prescribed chemical compositions. The Committee

are of the firm opinion that the selection of items by adopting the chemical composition approach would definitely and comprehensively provide varied and competitive options that would be cost effective as there are many brands offering same chemical composition available in the market at different rates.

The Committee are concerned to note that test check by Audit of 21 cases in the Branded drug formulary revealed availability of several low-cost brands in the same category of drugs. It was also found that even the discounted price of the selected brand was much higher than the MRP of other low cost brands available in the market. The Committee are utterly dismayed to find that the comparison of price of these 21 test checked brands with other brands of identical available drugs indicated that CGHS Delhi incurred avoidable expenditure of ₹ 9.25 crore during 2011-12 by opting for higher priced brands. The Ministry have conceded that the lower cost options of brands in the same category were available. The Committee wonder what restrained the Ministry for opting for lower cost options of brands in the same category. The fact remains that the standards of financial propriety as stipulated under Rule 21 of General Financial Rules were not adhered to as the Ministry opted for higher priced brands despite the availability of low cost brands in the market. The Committee are also deeply distressed that if test check of only 21 brands has revealed as much as ₹ 9.25 crore of avoidable expenditure in just one year, the amount of loss in respect of all varieties of medicines for the past several years if checked, might result in a staggering amount of such expenditure. Now, it has been proposed that only L-I (lowest priced) out of the tender for branded formulary will be considered and other brands of the same composition will not be purchased. The proposal is stated to have been accepted by the Ministry and rate enquiry has already been invited and bids received have been opened. While appreciating the steps taken by the Ministry in this direction, the Committee feel that still there is ample scope for further improvement in the procurement system. The Committee, therefore, impress

upon the Ministry to formulate a comprehensive and more reliable policy for procurement of drugs in CGHS so as to ensure that the entire procurement process becomes more transparent.

4. The Committee are surprised to note that during the years 2009-12, 71 percent of the total expenditure was incurred on procurement of drugs not listed in the formulary. Further, CGHS Delhi procured only 19 percent of items from within the formulary, while 81 percent items were outside the formulary. In cities outside Delhi covered in Audit, CGHS incurred about 50 percent of the total expenditure on procurement of drugs outside the formulary during 2009-12. This clearly indicates that the drug formulary is not comprehensive enough to cover drugs for wide-ranging ailments/diseases. The Committee are given to understand that it is not possible to restrict all prescriptions written by physicians and specialists to the MSO approved drug formulary because no formulary can at all times be extensive enough to cover the whole spectrum of drugs required for treatment of various diseases. However, some measures are stated to have been taken by the Ministry so as to avoid local purchase for instance, the formulary has been revised to make it comprehensive, tenders have been floated for rate contract of more than 1200 items, computerization both at CGHS and MSO through web based software has been completed and all deliveries of Pilot Project medicines (i.e. 272 branded medicines procured through manufacturers/distributors under the pilot project, 2008) are at CGHS Wellness Centres, thereby minimizing the delivery time. Further in August, 2014, an analysis was made to identify the medicines which are commonly indented through Authorized Local Chemists (ALCs). The list of 171 such medicines was submitted to MSO for inclusion under CGHS formulary. This has been done in the proposed revised formulary and these medicines would now be procured centrally. While taking into consideration large scale procurement of medicines through local purchase, the Public Accounts Committee in their 24th Report (15th Lok Sabha) had recommended steps to be taken by the Ministry to explore the

feasibility of doing away with the local purchases altogether so that exploitation of the system by certain vested interests is prevented and higher payment towards locally procured medicines checked. In response, the Ministry have submitted that given the need to make medicines available to beneficiaries without delay and taking note of existing prescription practices and newer medicines being introduced from time to time, it is not possible to entirely do away with local purchase, though efforts are being made to further reduce local purchase. In the interest of eradicating the malaise of freely resorting to local purchase of medicines resulting in disproportionate, avoidable and infructuous expenditure, the Committee strongly reiterate their earlier recommendation and emphasize that Ministry of Health and Family Welfare should ensure that all the CGHS Wellness Centres maintain their formularies and update them at regular intervals. Since there still is an opportunity to go for the cheaper branded drug with the same chemical composition. The Committee also emphasize the imperative need for regular inspections of the Wellness Centres as well as prompt action on the complaints/grievances received from CGHS beneficiaries on the matter. Punitive action may also be taken where laxity is detected in updating the formulary during inspections.

5. The Committee observe that the doctors continue to prescribe drugs outside the formulary despite the adverse recommendations of the Parliamentary Committee. As a result, the audit revealed that drugs valuing ₹ 1119 crore were purchased from outside the formulary during 2009-12. As regards the action taken against those doctors who are frequently prescribing expensive branded medicines instead of low cost equally effective drugs, the Committee have been informed that a prescription Audit was conducted in one of the Wellness Centres in the last week of August, 2014 and show cause notices were issued to two doctors deputed as Medical Specialists, for prescribing medicines out of CGHS formulary. While the case is under process, one of the doctors has resigned. Their deputation as Medical Specialist, was also withdrawn. It is surprising that

out of total 250 CGHS units operating in 23 cities, prescription Audit has been conducted in only one Wellness Centre (representing 0.4% of total units) and that too was undertaken only after the Audit Report came out and oral evidence of the representatives of the Ministry of Health and Family Welfare was taken by the Public Accounts Committee. The situation of prescribing drugs outside the formulary, could have been improved had the suo-motu inspection/Prescription Audit been done at regular interval by the Ministry of Health and Family Welfare. Sample selection and audit coverage should also be more extensive. In this connection, the Committee desire to be apprised of the periodicity and coverage of Prescription Audit. The Committee have also been informed by the Secretary, Ministry of Health and Family Welfare that as far as the Government doctors are concerned, the CGHS, Delhi has recently been computerized and the Ministry is able to identify as to which doctor has prescribed which medicine. The Committee would, therefore, desire that immediate steps be taken to computerize all the 250 CGHS Wellness Centres across the country. A Report indicating the details of total No. of Wellness Centres in the Country, No. of Centres computerized, yet to be computerized and by which date all the Centres would be computerized may be furnished to the Commiittee within two months of the presentation of this Report to Parliament. Further, in order to keep check on the prescription pattern of doctors, the Committee in their 24th Report (15th Lok Sabha) had recommended that the monitoring mechanism be strengthened and exemplary action taken against the errant doctors, who frequently prescribe medicines outside the formulary so that superfluous local purchase of medicines is avoided. However, while not accepting the ATN of the Ministry of Health and Family Welfare thereon, the Committee In their 84thReport (15th Lok Sabha) presented to Parliament on 30-04-2013 had further recommended to evolve a transparent and effective mechanism enabling the aggrieved patients to lodge their complaints against the errant doctors without fear or pressure so that more instances of malpractices are detected and large scale purchase of medicines outside the formulary is avolded. The Committee desire to know the number of such

cases detected in the Wellness Centres in the last 2 years following this recommendation. They desire that due explanation may be sought from those CGHS doctors who make prescriptions which are regularly at variance. It seems from the latest Audit observation on the subject that the recommendations of Public Accounts Committee were not properly addressed by the Ministry as prescribing expensive medicines by the doctors is continuing without any check. The Committee would, therefore, reiterate that stringent measures for evolving an effective and transparent mechanism are needed to keep an eye on the errant doctors.

6. The Committee find that the rates of large number of drugs were not finalized particularly during the years 2009-10 and 2010-11. Percentage of branded drugs of which rate had not been finalized is 30.56 % during the year 2009-10 and 32.74% during 2010-11. However, during the year 2011-12, it had reduced to 4.82 percent. The reasons, attributed by the Ministry for non-finalization of rates of various drugs, are items being de-registered by the Drug Controller, rates of drugs not being negotiable, firms having changed drug composition to bypass National Pharmaceuticals Pricing Authority (NPPA), firm not being the manufacturer of the quoted item etc. Further, with regard to non-finalization of the rates of Generic drugs, the Committee find that out of 818 Generic drugs in the formulary, the rates for only 218 drugs were approved. In this case, the contributory reasons are paucity of valid bidders in tender for Generic groups, a firm/company being deregistered subsequently, some companies stopping the manufacturing of drug of particular brands and meager requirement for some drugs for which companies are not interested in finalizing the rate contract. The Committee feel that the aforesaid reasons can be resolved by taking timely appropriate action at the Ministry's level. The Committee are surprised to note that while healthcare is under the domain of Ministry of Health and Family Welfare, making available essential medicines at affordable prices is under the purview of Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers. The Committee have been informed that the prices are fixed by

National Pharmaceuticals Pricing Authority (NPPA) in its meetings which inter-alia has an ex-officio Member from the Ministry of Health and Family Welfare. The Department of Pharmaceuticals also coordinates with Ministry of Health and Family Welfare for revision/updation of the National List of Essential Medicines (NLEM). Whenever required, technical input is also taken from Ministry of Health and Family Welfare. The Committee desire that Ministry of Health and Family Welfare and the Department of Pharmaceuticals should make earnest and concerted efforts to coordinate and meet at regular intervals to ensure speedy finalization of procurement rates of drugs so as to ensure timely delivery of drugs to Wellness Centres thereby reducing the avoidable expenditure on account of local purchase of medicines.

7. The Committee note that many drugs are available in both Generic as well as Branded versions. Generic drugs are substantially cheaper than the Branded versions. In September, 2010 the Minister of Health and Family Welfare, while approving the revised formulary of Branded drugs, had expressed serious concern on prescribing of Branded drugs by doctors instead of Generic versions and directed for complete shift towards Generic drugs, within one year both in prescriptions and supplies. In order to promote Generic drugs, the Ministry, had revised in May 2011 Generic drug formulary from 818 to 1128 drugs. Director (CGHS) also inter-alia issued instructions to analyze and take necessary steps for better utilization of Generic drugs. However, there has not been tangible progress in the procurement and distribution of Generic drugs. The Committee note that during 2009-2012, the percentage of Generic drugs procured in Delhi was only 2 to 5 percent and in Bhubaneswar it was around 5 to 7 percent during the same period. Further, in major cities like Ahmadabad, Kolkata, Chennai and in Mumbai, the graph of percentage of Generic drugs procured has drastically come down from nearly 50 percent during 2009-10 to below 10 percent in 2011-12. According to the Ministry of Health and Family Welfare, one of the main reasons for less procurement of Generic drugs by CGHS

was that rates were approved by MSO for only 25 percent of the Generic drug formulary and also many of the drugs listed in the Generic formulary were only for the hospital use and not required in the Wellness Centres. Test check also revealed that 59 drugs selected for Branded drug formulary were already listed in the Generic formulary. Further, a comparison of rates of 30 Branded drugs with the rates of Generic drugs in Janaushadhi scheme revealed that an amount of ₹ 11.81 crore could have been saved by CGHS Delhi during 2011-12, had Generic drugs been procured instead of Branded drugs. The Committee deprecate this apathy on the part of the concerned authorities towards ensuring financial discipline. With regard to corrective measures taken by the Ministry to augment the procurement of Generic drugs, a Committee under the chairmanship of DGHS has since been constituted to revise the Generic formulary of 1447 drugs. The Committee in its meeting held on 19.01.2015 has inter-alia decided as follows:

a) All the drugs, which are presently being procured through local purchase are to be included in the Generic list.

b) MSO should take up tendering process for finalization of rate contract of drugs. Priority in tendering is to be given to drugs which are presently being procured through local indent.

The Committee, however, deplore the fact that till 2015 no Committee was constituted for revision of Generic formulary of 1447 drugs. It seems that the Ministry has taken action only after the matter came under examination by the PAC. The Committee deplore the laxity on the part of the Ministry and desire the Ministry of Health and Family Welfare to continue with appropriate corrective action taken in coordination with CGHS Wellness Centres to effectively implement the long-term measures for complete shift towards the procurement and distribution of Generic drugs. The Committee would also like to be apprised of the findings of the Committee set up under DG (Health Services) and action taken thereon by the Ministry. Further, the current status regarding finalization of the rates of

proposed 1165 drugs for inclusion in Generic formulary along with the copy of instructions, if any, issued to doctors regarding necessity of completely shifting towards Generic medicines in their prescriptions may also be intimated to the Committee at the earliest.

8. In the Committee's view, one reason for slow progress in the procurement of Generic drugs could be the alleged nexus between doctors and Pharmaceutical Companies which refrain the doctors from prescribing Generic drugs by luring them with foreign trips and costly gifts. The Ministry of Health and Family Welfare have apprised the Committee that two such cases have already come to the notice of CGHS. A complaint was received against the then Addl. Director, CGHS (Patna)for which the matter is under investigation by the CBI. The concerned Addl. Director has since been relieved of his charge. Another complaint has been received against the Addl. Director CGHS, Thiruvananthapuram and the matter is under examination. However, the reply is silent about the dates when such complaints were received, remedial action taken by the Ministry thereon and present status of both the cases. The Committee feel that much stricter punishment is required for doctors indulging in such unethical practices since Pharma companies continue to sponsor foreign trips of doctors and give them expensive gifts which ultimately gets added to the cost of drugs. The aforesaid two cases should also be vigorously pursued for conclusive and deterrent action. Further, the Committee are informed that from January, 2015, the Department of Pharmaceuticals has sent new guidelines to all the Pharmaceutical Companies advising them to follow the Uniform Code of Conduct to break the nexus between them and doctors. Initially, it is for voluntary compliance for a period of six months. After six months, the matter would be reviewed to see that this statutorily met for follow up. As the said period is over and the matter should be reviewed now, the Committee would await the outcome of these measures and emphasize the need for developing an effective monitoring mechanism for regular oversight of the appropriate compliance of these guidelines by the

Pharma Companies, failing which the drug manufacturing/distribution licences need to be cancelled for atleast five years. The Committee would like to be apprised of the outcome of the steps taken in this regard.

9. Medical Stores Deports (MSD), Delhi is the nodal office which procures drugs for all CGHS Wellness Centres in Delhi. The Committee note that MSD, instead of procuring the required drugs directly, had been procuring the same through Hospital Services Consultancy Corporation (HSCC). In terms of Rule 165 of General Financial Rules and Para 1.2.1 of Manual of Policies and Procedure of Employment of Consultants issued by Ministry of Finance, the consultants may be employed in the condition of absence of required expertise in house and when it is felt absolutely essential. Strangely enough, MSD, Delhi incurred an infructuous and avoidable expenditure of ₹ 13.52 crore as consultancy charges paid to the HSCC during 2002-03 to 2010-11. The Committee believe that this huge avoidable expenditure is absolutely in contravention of the General Financial Rules particularly when no expertise is required for such procurement. Moreover, this indirect procurement is all the more condemnable and incriminating, when the rates and concerned supplies of the drugs listed in the approved drug formulary are finalized by the Ministry. HSCC did not add value to the procurement process and simply acted as a conduit between the Ministry and supplier, resulting in windfall earning of ₹ 13.52 crore with no efforts and expertise on their part. The Ministry explained to the Committee that HSCC was engaged for Delhi only in 2003 under specific circumstances when MSO's functioning was being questioned. Besides this arrangement lasted till 2014 only after which MSO was re-assigned its responsibility of procuring medicines throughout the country. The Committee find this a typical instance of a double whammy where due to malfunctioning of MSO, another institution was brought in, which simply added no value to the procurement process, thus resulting in wasteful expenditure. The Committee hope that the Ministry have learnt valuable lessons from this episode.

10. The Committee note that in January, 2007 CGHS proposed to implement a pilot-project to streamline the procurement of drugs in CGHS. This project was supposed to eliminate delays in supply of drugs present in the prevailing central procurement system through HSCC in Delhi and through GMSDs in cities outside Delhi. However, the Committee note that contrary to the proposal, which envisaged procurement of both formulary and non-formulary drugs, the approved list under pilot project contained only non-formulary drugs. The Committee further find that MSD submitted (September 2010) that all the 622 drugs in the new drug formulary as approved by the Ministry may be included in the Pilot Project, which was meant to cut down delays in procurement through HSCC as well as to effect savings of commission of 2.5 percent being paid to HSCC. This proposal was, however, not approved by the Ministry. The Committee are concerned to note that in CGHS Chennai, Kolkata, Jaipur and Hyderabad even the drugs included in the Pilot Project were procured through local purchase at higher rates leading to an extra expenditure of ₹ 85.22 lakh. The Committee would like to know the specific reasons for not approving the MSD's proposal, which envisaged to cut down delays in procurement of 622 drugs and resultant avoidance of extra expenditure and also to effect saving in commission paid to HSCC.

11. The Committee are constrained to observe that no definite time frame has been fixed for regular revision of formulary lists though there is constant evolution of new drug formulations required to treat diseases. This is particularly significant in view of several new diseases being identified now. The Committee find that the Generic formulary was revised in 2008, then in 2011 and last revision of Generic formulary was done in June, 2013. Further, as regard the branded formulary the Committee find that it was last revised in 2010. Again, no mechanism exists in the Ministry for inspection of CGHS Wellness Centres so as to ensure that these Centres maintain their formularies and update them at regular intervals for identifying/purchasing essential drugs. However, Director General of Health Services during his

deposition before the Committee had admitted the need to do so every three months. That this was not done is deplorable. The Committee would like to know as to why regular inspections cannot be undertaken. They also recommend that the Ministry of Health and Family Welfare should also consider the setting up of a strong on-line surveillance system as well as a team of inspectors with emphasis on surprise inspections of the Wellness Centres.

12. The Committee notice that for procurement of life saving drugs in CGHS Delhi, Thiruvananthapuram, Allahabad and Kolkata, CGHS incurred avoidable extra expenditure of ₹ 6.26 crore on procuring high priced drug brands despite availability of low cost brands within the list itself. CGHS did not accord reasons for including several brands of the drug of the same composition in the list of life saving drugs which led to procurement of drugs in an arbitrary manner. In CGHS Hyderabad, the life saving drugs were purchased at rates higher than the authorized list resulting in avoidable extra expenditure of ₹ 20.22 lakh. Further, in June, 2009, the MSD Delhi initiated an open tendering process for procurement of Generic drugs. However, the tender documents could not be finalized due to issues relating to modification of clauses in the tender documents. Thus, the MSD failed to implement the proposal of procuring life saving drugs through open tender as of July, 2012. The Committee are informed that the reason attributed for delay in finalization of tender documents process of Generic life saving drugs, is poor response from the Pharmaceutical industry. However, as on 20.04.2015 tenders have been floated for more than 1200 drugs. This is something totally unacceptable to the Committee as the Ministry have not specified the conditions which actually dissuaded the pharmaceutical Industry to come forward as well as measures initiated by them, if any, to encourage the industry to participate on the tender. The Committee are concerned to note that if the test check of only four stations had brought out such huge avoidable expenditure, the quantum of loss could be huge if a check of all stations is conducted. The Committee also found

unconscionable delay in streamlining the procedure for purchase of life saving drugs. Currently, the life saving drugs are being procured on L1 (lowest) rate after inviting sealed enquiries. Further, to have rate contract of life saving drugs, tender for which was stated to be yet-not-issued, a list of 268 drugs has been finalized after invitation of Expression of Interest (EOI). The list has been approved by a Clinical Expert Committee and forwarded to the competent authority for approval for initiating E-tender through MSO. The Committee desire to be apprised of the status thereof. They take a serious view of arbitrary manner of procurement of life saving drugs which resulted in avoidable extra expenditure of ₹ 6.26 crore and recommend that the matter should be examined for fixing responsibility for financial impropriety. The Committee desire to be apprised of the action taken in this regard within two months of presentation of this report.

13. The drugs procured by MSD are subject to mandatory test in laboratories before supply to CGHS. The Committee are sad to learn that in CGHS Kolkata, drugs were issued to the patients before receipt of test reports, which were later reported as sub-standard by GMSD. In CGHS Mumbai medicines worth ₹ 28.45 lakh received from GTMSD during 2009-12 were declared sub-standard. Out of these, medicines worth ₹ 15.66 lakh stood already issued to patients. Further, in CGHS Hyderabad drugs worth ₹ 21.39 lakh procured from GMSD did not have prescribed shelf life and the shortfalls in shelf life were in the range of one to three months. In Chandigarh drugs valuing ₹ 13.53 lakh expired between April 2009 and November 2011 implying that the requirement of drugs was not assessed properly. Undoubtedly, such instances highlight the absence of a fool-proof mechanism for quality assurance which exposes the patients to the life threatening hazards of sub-standard medicines. However, the Committee have been informed that the medicines procured through MSO have inbuilt quality assurance mechanism. In-house laboratory test Reports are provided by the manufacturers. Has it been so, the cases cited in the audit expose a serious lapse/carelessness on the part of medicine handling

personnel in CGHS. The Committee, therefore, desire the Ministry to probe as to how inspite of having inbuilt quality mechanism, sub-standard drugs were issued to patients by CGHS Kolkata and Mumbai. The Committee also desire to be apprised of the punitive action taken against the officers/staff responsible for issuing sub-standard drugs to patients. The Committee are also given to understand that no lab testing is done on drugs purchased through local chemists since drugs are procured through local chemists on day-to-day basis and issued to beneficiaries on the next working day. In such cases, Drug Controller of India keeps lifting random samples for drug testing. However, periodicity of lifting random samples has not been mentioned by the Ministry. Although several measures are stated to have been initiated by the Ministry to ensure proper quality assurance of drugs procured both centrally and locally, the Committee impress upon the Ministry to carry out periodical inspections of manufacturers as well as the local chemists and exemplary action taken against them so that any possibility of supply of sub-standard medicines to the patients is eliminated.

14. Further, the Committee are extremely concerned that medicines, whose shelf life has expired, are found to be still available in the stores of several Wellness Centers and are being provided to the patients too. As administering expired drugs to the patients exposes them to severe health hazards and even, death, the Committee urge upon the Ministry to get the stores of WCs inspected/checked regularly and fix responsibility to take stringent action against the errant/delinquent officials/WC staff. Periodical inspections of the stores of Wellness Centres are vital with a view to prevent the stockpiling of medicines and replacing the expired stock with the fresh one.

15. The Committee believe that the existence of any amount of adulterated/spurious drugs is fraught with hazards to the health of patients and all efforts are required to be made to curb the tendency to produce and market such drugs. The Committee note that the percentage of drugs

samples declared spurious/adulterated during the years 2009-10 to 2014-15 (upto September, 2014) has been 0.29, 0.19, 0.27, 0.11, 0.16 and 0.06 respectively. While the trend seems to be coming down, the very existence of adulterated/spurious drugs, to whatsoever extent, is a crime against humanity. The Ministry are stated to have taken various steps like announcing Whistle Blower Scheme, issuing guidelines for taking action on cases of sub-standard drugs, strengthening of drugs testing laboratories, good manufacturing practices, introduction of good laboratory practices, strengthening of drug regulatory system, amendments in Drugs and Cosmetics Act etc. Further, in pursuance of the recommendation contained in their earlier Report, the Committee is happy to note various initiatives taken like creation of additional Posts for Central Drugs Standard Control Organisation (CDSCO), launching of the National Pharmaco Vigilance Programme, issuance of detailed Guidelines and statutory Directions etc. were also undertaken by the Ministry to counter the menace of spurious drugs. Since spurious/adulterate drugs have serious ramifications on the life and health of the beneficiaries, the Committee emphasize the need for periodical reviews to strengthen the existing remedial measures and continuous vigilance to curb and eradicate the existence of even negligible extent of adulterated/spurious drugs. The Committee also emphasize that the manufacture, supply and sale of spurious/adulterated drugs are dealt with most stringent penalties in order to eradicate this malaise.

16. To, sum up, the Committee find that there have been several deficiencies in the management of Pharmaceutical procurement procedure for procurement of allopathic drugs for CGHS. The Committee find that 71 percent of the drugs procured consisted of drugs outside the formulary despite the fact that prices of drugs in the formulary are comparatively lower. CGHS resorted to procurement of higher priced branded drugs despite availability of low cost brands. Branded drugs continue to be preferred over Generic drugs despite adverse comments from the Parliamentary Committees. This has caused significant additional financial

burden on the exchequer. High incidence of local purchase of drugs and irregularities has been reported in such procurements. Prescription pattern of the Doctors is leading to high incidence of local purchase of drugs. Despite there being a code of ethics in the Indian Medical Council Rules introduced in December 2009 forbidding doctors from accepting any gift, hospitality, trips to foreign and domestic destinations etc. from healthcare industry, there is no let-up in this evil practice. The delays in procurement and non-availability of formulary drugs at CGHS Wellness Centres led to procurement of these drugs by CGHS Centres from local chemists at higher rate. Life saving drugs were purchased at rates higher than the authorized list. Drugs were issued to the patients before receipt of test reports, which were later reported as sub-standard by GMSD. Such instances highlight the absence of a robust mechanism for procurement of Allopathic drugs in the CGHS which exposes the patients to health hazards and causes significant financial burden on the exchequer. The Committee are further constrained to observe that the money value involved in the cases highlighted by the Audit Constitute only a small percentage of actual procurement. However, the monetary impact of such irregular practice would be much higher if the entire procurement system is audited. The Committee, therefore, urge the Ministry of Health and Family Welfare to plug the loopholes and take timely corrective action as suggested by them in the preceding Paragraphs and recommend that the Ministry should strengthen their internal control system to check irregularities in procurement process and ensure procurement of good quality medicines at affordable prices in accordance with the canons of financial propriety. The Committee also recommend that the particulars of the CGHS Wellness Centres performing well and those lagging behind may be furnished to the Committee and also placed in the Public domain periodically. The Ministry should also conduct a study of the best health care systems and models in different countries both developed and developing countries and try to emulate them in order to ensure supply and availability of quality medicines at affordable prices in the Country.

NEW DELHI;
12th August, 2015
21 Shravana, 1937 (*Saka*)

PROF. K.V. THOMAS
Chairperson,
Public Accounts Committee

Annex-I

(Referred to in paragraph no. 1.2.6)

Comparison of rates of branded drugs in formulary and low cost options available in market for the year 2011-12

(Amount in ₹)

Drug composition		Higher cost brand listed in Branded formulary				Example of lower cost brand available in market					
Sl. No.	Drug Composition	Number of lower cost brands available in market	Brand procured in formulary	Name of Manufacturer	Procurement Rate after discount	lower cost Brand available in market	Name of manufacturer	MRP Rate	Difference in rate of Branded and Generic drug	Quantity of medicines procured in 2011-12	Avoidable extra expenditure
1.	Gliclazide-60 mg	22	Diamicron XR (60 mg)	Serdia Pharmaceuticals (India) Ltd	7	Claz OD (60 mg)	Franco Indian Remedies	4.9	2.1	1566278	3289183.80
2.	Glimepiride-2 mg	141	Amaryl (2 mg)	AVENTIS PHARMA LTD.	8.3	Azulix (2 mg)	Delta (Torrent Pharmaceuticals Ltd.)	5.3	3	2503830	7511490
3.	Nicorandil-10 mg	16	Nikoran (10 mg)	Torrent Pharmaceuticals Ltd	8.78	Duorandil (10 mg)	Medreich Saimirra Ltd	5.9	2.88	381890	1099843.2
4.	Telmisartan-40 mg + Hydrochlorothiazide-12.5 mg	42	Arbitel-H (40+12.5)	Micro Labs Ltd	5.51	Telmikind H (40+12.5)	Mankind Pharmaceuticals Pvt. Ltd.	3.25	2.26	1255760	2838017.6
5.	Fexofenadine -120 mg	81	Allegra FC (120 mg)	Aventis Pharma Limited	6.22	Histafree (120 mg)	Mankind Pharmaceuticals Pvt. Ltd.	4.75	1.47	1668980	2453400.6

[1]Source www.medguideindia.com

6.	Levocetirizine-5 mg Montelukast-10 mg	87	MONTAIR LC	CIPLA LIMITED.,	8.7	Lazine M (5+10)	Genx (Hetero Healthcare Ltd)	5.9	2.8	1295410	3627148
7.	CETRIZINE 10MG	336	CETZINE	GLAXOSMITHKLINE LTD	2.44	Bealert (10 mg)	Genx Healthcare	1.2	1.24	4179000	5181960
8.	Gliclazide-60 mg	21	DIANORM OD 60	MICRO LABS LIMITED	4.42	Nuzide (60 mg)	Intas Pharmaceuticals Ltd.	2.7	1.72	384370	661116.4
9.	Amlodipine-5 mg Hydrochlorothiazide-12.5 mg	3	AMLONG-H	MICRO LABS LIMITED	2.6	Amlokind-H (5+12.5)	Mankind Pharmaceuticals Pvt. Ltd.	1.25	1.35	680100	918135
10.	Ramipril-10 mg	32	CARDACB 10	AVENTIS PHARMA LTD.	9.98	Proace (10 mg)	Alembic Chemical Works Co Ltd	6.35	3.63	391320	1420491.6
11.	Ramipril-5 mg	105	CARDACB 5	AVENTIS PHARMA LTD.	7.7	Namipril (5 mg)	Nicholas Piramal India Ltd.	5.8	3.9	2047630	3890497
12.	Atenolol-50 mg	113	ATEN 50	CADILA HEALTHCARE LTD.	1.94	Atekind (50 mg)	Mankind Pharmaceuticals Pvt. Ltd.	1.08	0.86	973874	837531.64
13.	Atenolol-50 mg Indapamide-2.5 mg	3	ATEN D	CADILA HEALTHCARE LTD.	2.45	Atekind-D (50+2.5)	Mankind Pharmaceuticals Pvt. Ltd.	1.14	1.31	135944	178086.64
14.	Atenolol-25 mg	71	ATEN 25	CADILA HEALTHCARE LTD.	1.26	Lotenol (25 mg)	Lupin Laboratories Ltd.	0.7	0.56	545328	305383.68
15.	Mecobalamin-500 mcg	85	METHYCOBAL TABLET	WOCKHARDT LIMITED.	4.19	Nurokind (500 mcg)	Mankind Pharmaceuticals Pvt. Ltd.	1.99	2.2	7074930	15564846

16.	Aspirin-75 mg	23	ECOSPRIN-75	USV LIMITED.	0.21	CvSprin (75 mg)	Cadila Pharmaceuticals Ltd.	0.19	0.02	4889244	97784.88
17.	Pantoprazole Sodium Sesquihydrate -20 mg Domperidone -10 mg	134	PAN - D	ALKEM LABORATORIES LTD.	5.34	Pantadom Tab (20+10)	Mankind Pharmaceuticals Pvt. Ltd.	3	2.34	4958040	11601813.6
18.	Pantoprazole Sodium Sesquihydrate -40 mg	724	PAN 40	ALKEM LABORATORIES LTD.	4.54	Pantakind (40 mg)	Mankind Pharmaceuticals Pvt. Ltd.	1.75	2.79	4433140	12368460.6
19.	Metformin-500 mg.	154	GLYCIP HAGE SR	FRANCO INDIAN PHARMACEUTICALS LTD.	1.22	Glumet EXT (500 mg)	Cipla Limited	0.65	0.57	5210940	2970235.8
20.	Amlodipine-5 mg	164	AMLON G-5	MICRO LABS LIMITED.	2.5	Amlosyl (5 mg)	Nicholas Piramal India Ltd.	1.33	1.17	4121220	4821827.4
21.	Pantoprazole Sodium Sesquihydrate -40 mg	1010	PANTOCID	SUN PHARMACEUTICALS INDUSTRIES LIMITED.	4.82	Nupenta (40 mg)	Macleods Pharmaceuticals Pvt Ltd	2.15	2.67	4072248	10872902.16
					Total						**92510155.60**

Annex-II

(Referred to in paragraph no. 1.6.7)

Expenditure on procurement of drugs in CGHS Delhi

(₹ in crore)

	2009-10	2010-11	2011-12	Total	Percent
A. Drugs listed in the Formulary (through HSCC)					
i) Branded	11.73	56.03	125.53@	193.29	18.54
ii) Generic	0.33	0.84	0.83	2.00	0.19
iii) Local purchase Branded (MSD)	0.38	0.49	0.48	1.35	0.13
Total (A)	12.44	57.36	126.84	196.64	18.87
B. Drugs outside the Formulary					
i) Life saving drugs	75.32	102.21	104.11	281.64	27.02
ii) Pilot project	77.16	110.83	0*	187.99	18.04
iii) Insulin direct	7.63	8.43	10.22	26.28	2.52
iv) Local Purchase (Wellness Centre)	155.60	108.45	85.76	349.81	33.56
Total (B)	315.71	329.92	200.09	845.71	81.13
Grand Total (A+B)	328.15	387.28	326.93	1042.36	100.00

*included in the formulary during 2011-12

@ includes ₹ 97.98 crore for pilot project

Annex-I

(Referred to in paragraph no. 7.2.6)

Comparison of rates of branded drugs in formulary and low cost options available in market for the year 2011-12

(Amount in ₹)

Drug composition			Highest cost brand listed in branded formulary			Example of lower cost brand available in market					
Sl. No.	Drug Composition	Number of lower cost brands available in market	Brand procured in formulary	Name of Manufacturer	Procurement Rate after discount	lower cost Brand available in market	Name of manufacturer	MRP Rate	Difference in rate of Branded and Generic drug	Quantity of medicines procured in 2011-12	Avoidable extra expenditure
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2.	Glimepiride-2 mg	141	Amaryl (2 mg)	AVENTIS PHARMA LTD.	8.3	Azulix (2 mg)	Delta (Torrent Pharmaceuticals Ltd.)	5.3	3	2503830	7511490
3.	Nicorandil-10 mg	16	Nikoran (10 mg)	Torrent Pharmaceuticals Ltd	8.78	Duorandil (10 mg)	Medreich Saimirra Ltd	5.9	2.88	381890	1099843.2
4.	Telmisartan-40 mg + Hydrochlorothiazide-12.5 mg	42	Arbitel-H (40+12.5)	Micro Labs Ltd	5.51	Telmikind H (40+12.5)	Mankind Pharmaceuticals Pvt. Ltd.	3.25	2.26	1255760	2838017.6
5.	Fexofenadine -120 mg	81	Allegra FC (120 mg)	Aventis Pharma Limited	6.22	Histafree (120 mg)	Mankind Pharmaceuticals Pvt. Ltd.	4.75	1.47	1668980	2452400.6

[1]Source www.medguideindia.com

6.	Levocetirizine-5 mg Montelukast-10 mg	87	MONTAIR LC	CIPLA LIMITED.,	8.7	Lazine M (5+10)	Genx (Hetero Healthcare Ltd)	5.9	2.8	1295410	3627148
7.	CETRIZINE 10MG	336	CETZINE	GLAXOSMITHKLINE LTD	2.44	Bealert (10 mg)	Genx Healthcare	1.2	1.24	4179000	5181960
8.	Gliclazide-60 mg	21	DIANORM OD 60	MICRO LABS LIMITED	4.42	Nuzide (60 mg)	Intas Pharmaceuticals Ltd.	2.7	1.72	384370	661116.4
9.	Amlodipine-5 mg Hydrochlorothiazide-12.5 mg	3	AMLONG-H	MICRO LABS LIMITED	2.6	Amlokind-H (5+12.5)	Mankind Pharmaceuticals Pvt. Ltd.	1.25	1.35	680100	918135
10.	Ramipril-10 mg	32	CARDACB 10	AVENTIS PHARMA LTD.	9.98	Proace (10 mg)	Alembic Chemical Works Co Ltd	6.35	3.63	391320	1420491.6
11.	Ramipril-5 mg	105	CARDACB 5	AVENTIS PHARMA LTD.	7.7	Natmipril (5 mg)	Nicholas Piramal India Ltd.	5.8	1.9	2047630	3890497
12.	Atenolol-50 mg	113	ATEN 50	CADILA HEALTHCARE LTD.	1.94	Atekind (50 mg)	Mankind Pharmaceuticals Pvt. Ltd.	1.08	0.86	973874	837531.64
13.	Atenolol-50 mg Indapamide-2.5 mg	3	ATEN D	CADILA HEALTHCARE LTD.	2.45	Atekind-D (50+2.5)	Mankind Pharmaceuticals Pvt. Ltd.	1.14	1.31	135944	178086.64
14.	Atenolol-25 mg	71	ATEN 25	CADILA HEALTHCARE LTD.	1.26	Latenol (25 mg)	Lupin Laboratories Ltd.	0.7	0.56	545328	305383.68
15.	Mecobalamin-500 mcg	85	METHYCOBAL TABLET.	WOCKHARDT LIMITED.	4.19	Nurokind (500 mcg)	Mankind Pharmaceuticals Pvt. Ltd.	1.99	2.2	7074930	15564846

16.	Aspirin-75 mg	23	ECOSPRIN-75	USV LIMITED.	0.21	CvSprin (75 mg)	Cadila Pharmaceuticals Ltd.	0.19	0.02	4889244	97784.88
17.	Pantoprazole Sodium Sesquihydrate -20 mg Domperidone -10 mg	134	PAN - D	ALKEM LABORATORIES LTD.	5.34	Pantadom Tab (20+10)	Mankind Pharmaceuticals Pvt. Ltd.	3	2.34	4958040	11601813.6
18.	Pantoprazole Sodium Sesquihydrate -40 mg	724	PAN 40	ALKEM LABORATORIES LTD.	4.54	Pantakind (40 mg)	Mankind Pharmaceuticals Pvt. Ltd.	1.75	2.79	4433140	12368460.6
19.	Metformin-500 mg.	154	GLYCIPHAGE SR	FRANCO INDIAN PHARMACEUTICALS LTD.	1.22	Glumet BXT (500 mg)	Cipla Limited	0.65	0.57	5210940	2970235.8
20.	Amlodipine-5 mg	164	AMLONG-5	MICRO LABS LIMITED.	2.5	Amlosyl (5 mg)	Nicholas Piramal India Ltd.	1.33	1.17	4121220	4821827.4
21.	Pantoprazole Sodium Sesquihydrate -40 mg	1010	PANTOCID	SUN PHARMACEUTICALS INDUSTRIES LIMITED.	4.82	Nupenta (40 mg)	Macleods Pharmaceuticals Pvt Ltd	2.15	2.67	4072248	10872902.16
						Total					92510155.60

Annex-II

(Referred to in paragraph no. 16.7)

Expenditure on procurement of drugs in CGHS Delhi

(₹ in crore)

	2009-10	2010-11	2011-12	Total	Percent
A. Drugs listed in the Formulary (through HSCC)					
i) Branded	11.73	56.03	125.53@	193.29	18.54
ii) Generic	0.33	0.84	0.83	2.00	0.19
iii) Local purchase (Branded (MSD))	0.38	0.49	0.48	1.35	0.13
Total (A)	12.44	57.36	126.84	196.64	18.87
B. Drugs outside the Formulary					
i) Life saving drugs	75.32	102.21	104.11	281.64	27.02
ii) Pilot project	77.16	110.83	0*	187.99	18.04
iii) Insulin-direct	7.63	8.43	10.22	26.28	2.52
iv) Local Purchase (Wellness Centre)	155.60	108.45	85.76	349.81	33.56
Total (B)	315.71	329.92	200.09	845.71	81.13
Grand Total (A+B)	328.15	387.28	326.93	1042.36	100.00

*included in the formulary during 2011-12

@ includes ₹ 97.98 crore for pilot project

Annex-III

(Referred to in paragraph no. 55)

List of drugs which are common in Branded and Generic drug formulary

Sl. No.	Drug in Branded Formulary			Same drug composition in Generic Formulary	
	VMS Number	Name of Brand	Name of manufacturer	VMS Number	
1.	P03097	ALLEGRA 120MG	AVENTIS PHARMA LTD.	G03007	Fexofenadine 120mg Tablet
2.	P03098	ALLEGRA 180MG	AVENTIS PHARMA LTD.	G03008	Fexofenadine 180mg Tablet
3.	P03100	CETZINE	GLAXOSMITHKLINE LTD	G03009	Cetrizine 10mg Tablet
4.	P09082	BETALOC 25MG	ASTRA ZENECA PHARMA INDIA LTD	G12006	Metoprolol Tartrate 25 mg Tablets
5.	P09083	BETALOC 50MG	ASTRA ZENECA PHARMA INDIA LTD	G12007	Metoprolol Tartrate 50 mg Tablets
6.	P09080	BETACAP TR 40	SUN PHARMACEUTICALS INDUS TRIES LIMITED	G12010	Propranolol Hydrochloride Propranolol Hydrochloride 40 mg Tablets
7.	P09107	DILZEM-30	TORRENT PHARMACEUTICALS LTD.	G12019	Diltiazem Hydrochloride30 mg Tablets
8.	P09150	NEBISTAR-SA	LUPIN LABORATORIES LTD	G12034	Amlodipine 2.5 mg Tablets
9.	P09062	AMLOPRESS- 5	CIPLA LIMITED	G12035	Amlodipine 5 mg Tablets
10.	P09063	AMLOVAS-5	MACLEODS PHARMACEUTICALS LIMITED.		
11.	P09057	AMLONG-10	MICRO LABS LIMITED.	G12036	Amlodipine 10 mg Tablets
12.	P09071	ATEN 50	CADILA HEALTHCARE LTD	G12037	Atenolol 50 mg Tablets
13.	P09081	BETACARD -50	TORRENT PHARMACEUTICALS LTD.		
14.	P09067	ARKAMINE	UNICHEM LABORATOREIS LTD.	G12041	Clonidine Hydrochloride 100 mcg Tablets
15.	P09116	ENVAS 2.5	CADILA PHARMACEUTICALS LTD.	G12043	Enalapril Maleate 2.5 mg Tablets
16.	P09117	ENVAS 5	CADILA PHARMACEUTICALS LTD.	G12044	Enalapril Maleate 5 mg Tablets
17.	P09115	ENVAS 10	CADILA PHARMACEUTICALS LTD.	G12045	Enalapril Maleate 10 mg Tablets

18.	P09097	COVANCE- 25	RANBAXY LABORATORIES LTD	G12047	Losartan Potassium 25 mg Tablets
19.	P09135	LOSAR -25	UNICHEM LABORATOREIS LTD.		
20.	P09166	REPACE 25MG	SUN PHARMACEUTICALS INDUSTRIES LIMITED.	G12048	Losartan Potassium 50 mg Tablets
21.	P09098	COVANCE- 50	RANBAXY LABORATORIES LTD		
22.	P09166	REPACE 50 MG	SUN PHARMACEUTICALS INDUSTRIES LIMITED.		
23.	P09190	TOZAAR- 50	TORRENT PHARMACEUTICALS LTD.		
24.	P09136	LOSAR -50	UNICHEM LABORATOREIS LTD.		
25.	P09113	ECOSPRIN-75	USV LIMITED	G12065	Acetyl Salicylic Acid 75 mg Tablets
26.	P09132	LOPRIN DS	UNICHEM LABORATOREIS LTD.	G12077	Aspirin 150mg Tablet
27.	P09103	DEPLATT	TORRENT PHARMACEUTICALS LTD.	G12078	Clopidogrel 75mg Tablet
28.	P09096	CLOPIGREL	USV LIMITED.		
29.	P09161	RAMISTAR 2.5	LUPIN LABORATORIES LTD	G12080	Ramipril 2.5mg Tablet
30.	P09124	HOPACE-2.5	MICRO LABS LIMITED.		
31.	P09089	CARDACE 5	AVENTIS PHARMA LTD.	G12081	Ramipril 5mg Tablet
32.	P09162	RAMISTAR 5	LUPIN LABORATORIES LTD		
33.	P09123	HOPACE- 5	MICRO LABS LIMITED.		
34.	P09133	LORVAS	TORRENT PHARMACEUTICALS LTD.	G12082	Indapamide 2.5mg Tablet
35.	P09186	TIDE-10	TORRENT PHARMACEUTICALS LTD.	G16013	Torsemide 10mg Tablet
36.	P13015	OCID 20	CADILA HEALTHCARE LTD	G17004	Omeprazole 20 mg Capsules
37.	P13016	OMEZ	DR REDDYS LABS LTD		
38.	P13026	RANTAC 150	JB CHEMICALS & PHARMACEUTIALS LTD.	G17006	Ranitidine Hydrochloride 150 mg Tablets
39.	P13017	PAN - D	ALKEM LABORATORIES LTD.	G17033	Pantoprazole 40mg Tablet

40.	P13023	PANTODAC TABLET	CADILA HEALTHCARE LTD.		
41.	P13022	PANTOCID	SUN PHARMACEUTICALS INDUSTRIES LIMITED.		
42.	P04037	DAONIL	AVENTIS PHARMA LTD	G18017	Glibenclamide 5 mg Tablets
43.	P04036	CETAPIN XR 500MG	AVENTIS PHARMA LTD.	G18020	Metformin 500 mg Tablets
44.	P04059	GLYCIRHAGE SR	FRANCO INDIAN PHARMACEUTICALS LTD.		
45.	P27001	THYRONORM 100MCG	ABBOTT INDIA LTD.	G18030	Thyroxin Sodium 100mcg tablets
46.	P04046	ELTROXIN 100 MCG	GLAXOSMITHKLINE LTD		
47.	P27004	THYROX-100	MACLEODS PHARMACEUTICALS LIMITED.		
48.	P04033	AMARYL 1MG	AVENTIS PHARMA LTD.	G18041	Glimepride 1mg Tablet
49.	P04034	AMARYL 2MG	AVENTIS PHARMA LTD.	G18042	Glimepride 2mg Tablet
50.	P04052	GLIZID 80	PANACEA BIOTEC	G18044	Gliclazide 80mg Tablet
51.	P04040	DIAMICRON	SERDIA PHARMACEUTICALS (I) PVT. LTD.		
52.	P04054	GLUCOBAY 50	BAYER INDIA LTD.	G18047	Acarbose 50mg Tablet
53.	P04038	DIABOSE-50	MICRO LABS LIMITED.		
54.	P08015	TRYPTOMER 25MG	WOCKHARDT LIMITED.	G24012	Amitriptyline Hydrochloride 25 mg Tablets
55.	P08007	ANXIT-0.25	MICRO LABS LIMITED.	G24017	Alprazolam 0.25 mg Tablets
56.	P08013	TRIKA 0/25	UNICHEM LABORATOREIS LTD.		
57.	P08006	ALPRAX-0-25	TORRENT PHARMACEUTICALS LTD.		
58.	P08005	ALPRAX -0.5	TORRENT PHARMACEUTICALS LTD.	G24018	Alprazolam 0.5 mg Tablet
59.	P03104	MONTAIR LC	CIPLA LIMITED	G25031	Montelukast 10mg Tablet

Annex-IV

(Referred to in paragraph no.55)

Comparison of rates of drugs listed in both Generic formulary and Branded formulary/Pilot Project

Sl. No	Name of brand in branded formulary/Pilot project	Name of generic medicine	Branded Rate per tablet in formulary/ pilot project (in ₹)	Generic Rate per tablet (Janaushadhi scheme rates)[2] (in ₹)	Difference of rate (in ₹)	Quantity procured in pilot project	Avoidable extra expenditure (in ₹)
YEAR 2011-12							
1.	VOVERAN SR 100	Diclofenac Sodium IP 100 mg. SR	3.38	0.34	3.04	1508550	4585992
2.	NIMULID 100	Nimesulide IP 100 mg.	2.48	0.27	2.21	748900	1655069
3.	PAN-40	Pentaprazole 40mg Tabs	4.54	1.03	3.51	4433140	15560321
4.	PANTODAC		4.35		3.32	480460	1595127
5.	PANTOCID		4.8		3.77	4072248	15352375
6.	OMEZ	Omeprazole IP 20 mg.	3.53	0.69	2.84	1027955	2919392.2
7.	OCID 20		3.54		2.85	2094810	5970208.5
8.	CETZINE	Tab. Citirazine 10mg	2.44	0.28	2.16	4179000	9026640
9.	DOXIFLO 400	Doxofyllin 400 mg	3.02	1.47	1.55	2326318	3605792.9
10.	MAZETOL SR 200	Carbamazepin 200mg tabs	1.02	0.92	0.1	332730	33273
11.	BETACARD -50	Atenolol 50 mg Tabs	1.96	0.5	1.46	266494	389081.24
12.	ENVAS 5	Enalapril 5mg Tabs	1.92	0.66	1.26	851430	1072802
13.	ALPRAX -0.5	Alprazolam .5mg Tabs	1.67	0.3	1.37	686235	940141.95
14.	ANXIT-0.25	Alprazolam .25mg Tabs	1.19	0.26	0.93	556110	517182.3

[2] In the absence of procurement rates of all generic drugs, rates of Janaushadhi scheme of Ministry of Chemeical and Fertilisers were adopted.

15.	ALPRAX-0-25		1.01		0.75	1868025	1401019
16.	TRIKA 0.25		0.81		0.55	235120	129316
17.	LISTRIL-5	Lisinopril 5mg	3.94	0.88	3.06	228046	697821
18.	COVANCE-50	Losartan Potassium 50mg Tablets	4.72	0.94	3.78	569760	2153692.8
19.	REPACE 50		4.09		3.15	820910	2585867
20.	TOZAAR- 50		4.26		3.32	317710	1054797
21.	LOSAR -50		3.72		3.72	1139220	4237898
22.	DACNIL	Glibenclamide 5 mg Tabs	0.67	0.27	0.4	149750	59900
23.	CETAPIN XR 500MG	Metformin Hydrochloride 500mg Tabs	1.74	0.6	1.14	1475682	1682277
24.	GLYCIPHAGE SR		1.22		0.62	5210940	3230783
25.	GLUFORMIN XL 500		1.39		0.79	2027060	1601377.4
26.	GLUFORMIN XL 1000	Metformin Hydrochloride 1000 mg Tab	2.15	0.77	1.38	1491790	2058670
27.	AMARYL 2MG	GLIMEPIRIDE 2mg Tab	8.31	1.18	7.13	2503830	17852308
28.	GLIMER 2MG		7.62		6.44	1207690	7777524
29.	AMARYL 1MG	GLIMEPIRIDE 1mg Tab	4.49	0.79	3.7	1657360	6132232
30.	GLIMER 1MG		3.93		3.14	698490	2193259
				Total			**118072139.29**

Annex V

(Referred to in paragraph no. 60)

Delay in procurement of drugs through HSCC

Month of intimation of requirement to HSCC	Period during which supply received	Delay in receipt of supply after intimation	Period during which medicines delivered in wellness centre	Delay in receipt at wellness centre after intimation	Remarks
2011-12					
January 12	March to May 12	2 to 5 months	March to July,12	2 to 7 months	1st installment
March 12	May to August 12	2 to 5 months	May to September 12	2 to 7 months	2nd installment
2010-11					
June 10	June to November 10	1 to 6 months	July, 10 to January 11	1 to 8 months	1st installment
January 11	February, 11 to June 11	1 to 6 months	February, 11 to September 11	1 to 9 months	2nd installment

Annex- VI

(Referred to in paragraph no. 69.)

Comparison of rates of different brands of same drug in the list of Life Saving drugs of CGHS

(Amount in ₹)

Generic name of drug	High cost brand in list	Low cost brand in list	Name of manufacturer	Price of high cost brand in the list	Price of low cost brand in the list	Difference in price	Quantity procured of high cost brand in 2011-12	Extra expenditure incurred
ANASTRAZOL	ARIMIDEX 1MG		ASTRA ZENCA	373.94		331.26	56588	18745381.3
		ALTRAZ 1MG	ELKEM		42.68			
Doxorubicin HCL Liposomal	CAELYX 20MG		JHONSON & JHONSON	39541.6		32716.6	156	5103789.6
		NUDOXA 20	ZYDUS		6825			
Exemestane 25MG	AROMACIN 25MG		PFIZER	230.16		197.91	10410	2060243.1
		X-TANE 25MG	NATCO		32.25			
Fulbexterant 250	FASLODEX 250		ASTRA ZENCA	20458.2		7708.2	156	1202479.2
		FULVENAT 250MG	NATCO		12750			
Ibandornic Acid 50 MG	BONDRONATE 50MG		ROCHE	400.05		359.1	4228	1518274.8
		BANDRONE 50MG	NATCO		40.95			
Ibandornic Acid 6 MG	BONDRONATE 6MG		ROCHE	8749.65		6678.15	97	647780.55
		BANDRONE 6MG	NATCO		2071.5			

irinotecan 100 MG	CAMPTO 100		PFIZER	14976		14776.5	136	2009604
		NEXIRON 100	ZYDUS		199.5			
Letrozole 2.5 MG	FEMARA 2.5		NOVARTIS	171.15		143.85	16805	2417399.25
		LETROZ 2.5MG (TAB.)	ALKEM		27.3			
MycophenolateMofetil 500	MYCOFIT 500 (TAB.)		INTAS BIO FHARMA	80.955		24.955	9520	237571.6
		MOFILET 500MG	GENNOVA		56			
MycophenolateMofetil S 360	MYCOFIT S360 (TAB.)		INTAS BIO FHARMA	71.085		15.085	20180	304415.3
		MOFILET S360MG	GENNOVA		56			
Oxaalipatin 100 MG	DACOTIN 100MG		DR. REDDYS	8070.27		3439.77	363	1248636.51
		OXIDECH 100	RANBAXY		4630.5			
Oxaalipatin 50 MG	DACOTIN 50MG		DR. REDDYS	4024.64		1871.16	248	464047.68
		OXIDECH 50	RANBAXY		2153.48			
Paclitaxel 100 100 MG	TAXOL 100		BRISTOL-MAYER-SQUIBB	4918.03		1617.74	242	391493.08
		MITOTAX 100	DR. REDDYS		3300.29			
Paclitaxel 100 30 MG	TAXOL 30		BRISTOL-MAYER-SQUIBB	2039.1		634.33	223	141455.59
		MITOTAX 30	DR. REDDYS		1404.77			
Albumin Bound Paclitaxel	ABRAXANE 100 (VIAL)		BIOCHEM	14608.7		5320.26	576	3064469.76
		ALBUPAX 100 (VIAL)	NATCO		9288.44			
Bortezomib 3.5 MG	VELCADE 3.5 MG		JHONSON & JHONSON	49987.27		36757.27	81	2977338.87
		BORTENAT 3.5	NATCO		13230			

		MG						
Carboplatin 150 MG	PARA PLATIN 150		BRISTOL-MAYER-SQUIBB	2030	770	352		271040
		BIOCARB 150	BIOCHEM		1260			
Docetaxel 80 MG	TAXOTERE 80		SANOFI-AVENTIS	13569.23	6300	479		3017700
		DOCBNAT 80	NATCO		7269.23			
Epirubicin HCL 50 MG	FARMORUBICIN 50		PFIZER	2646.84	1001.16	223		223258.68
		RUBIZEN 50	RANBAXY		1645.68			
Erythropoitein 4000 I.U.	EPREX 4000		JHONSON & JHONSON	1365	756	13214		9989784
		NEORECORMON 4000	ROCHE		609			
Erythropoitein 40000 I.U.	EPREX 40000		JHONSON & JHONSON	10584	2835	1089		3087315
		EPOFER 40000	ROCHE		7749			
Total								59123478*

* In addition similar cases worth ₹ 9.50 lakh and ₹ 25.42 lakh were noticed in Kerala and Kolkata

ANNEXURE – VII

(Referred to in paragraph no. 7.9.)

Number of samples tested and enforcement actions taken by State Drugs Controller during last six years

Year	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	No. of prosecution launched for manufacturing, sale and distribution of spurious/ adulterated drugs	No. of cases (as mentioned in the earlier column) decided	No. of persons arrested
2009-10	39248	1942	117	138	6	147
2010-11	49682	2372	95	147	9	72
2011-12	48082	2186	137	212	16	141
2012-13	58537	2362	70	214	6	110
2013-14	72712	3028	118	237	44	86
2014-15	38,655	1823	25	65	7	45

Number of samples tested and enforcement actions taken by State Drugs Controller during 2010-11

S.No.	States	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	No. of prosecution launched for manufacturing, sale and distribution of spurious/ adulterated drugs	No. of cases (as mentioned in the earlier column) decided	No. of persons arrested
1	Andhra Pradesh	4052	52	1	1	Nil	Nil
2	Arunachal Pradesh	2	Nil	Nil	Nil	Nil	Nil
3	Assam	764	63	4	1	Nil	Nil
4	Bihar	2336	58	8	39	Nil	24
5	Goa	642	26	Nil	1	Nil	Nil
6	Gujarat	5037	217	6	17	0	Nil
7	Haryana	2348	67	1	4	Nil	Nil
8	Himachal Pradesh	1125	17	Nil	Nil	Nil	Nil
9	Jammu & Kashmir	1480	27	4	3	Nil	Nil
10	Karnataka	3740	136	5	2	Nil	4
11	Kerala	2485	128	Nil	36	Nil	Nil
12	Madhya Pradesh	1936	82	Nil	Nil	Nil	Nil
13	Maharashtra	6404	449	31	3	Nil	2
14	Manipur	Nil	Nil	Nil	Nil	Nil	Nil
15	Meghalaya	159	1	Nil	1	Nil	Nil
16	Mizoram	80	3	Nil	Nil	Nil	Nil
17	Nagaland	63	0	Nil	Nil	Nil	Nil
18	Orissa	3160	111	Nil	2	Nil	Nil
19	Punjab	2864	60	Nil	Nil	Nil	Nil
20	Rajasthan	2315	163	9	4	Nil	2
21	Sikkim	24	4	Nil	Nil	Nil	Nil
22	Tamilnadu	3632	284	3	6	Nil	38
23	Tripura	518	10	Nil	Nil	Nil	Nil
24	Uttar Pradesh	1247	179	38	38	2	1
25	West Bengal	912	30	Nil	Nil	Nil	Nil
26	Pondicherry	Nil	0	Nil	Nil	Nil	Nil
27	Andaman & Nicobar	11	3	Nil	Nil	Nil	Nil
28	Chandigarh	33	3	Nil	Nil	Nil	Nil
29	Delhi	651	24	Nil	1	Nil	1
30	Dadra & Nagar Haveli	10	Nil	1	1	Nil	Nil
31	Daman & Diu	49	1	Nil	Nil	Nil	Nil
32	Lakshadweep	Nil	0	Nil	Nil	Nil	Nil
33	Chattisgarh	182	63	Nil	Nil	Nil	Nil
34	Jharkhand	195	16	Nil	7	Nil	Nil
35	Uttaranchal	102	1	Nil	Nil	1	Nil
	Total	49682	2372	95	167	9	72

Annexure - B

Number of samples tested and enforcement actions taken by State Drugs Controller during 2011-12

S.No.	States	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	No. of prosecution launched for manufacturing, sale and distribution of spurious/ adulterated drugs	No. of cases (as mentioned in the earlier column) decided	No. of persons arrested
1	Andhra Pradesh	4758	22	2	Nil	Nil	Nil
2	Arunachal Pradesh	95	2	Nil	Nil	Nil	Nil
3	Assam	315	25	Nil	Nil	Nil	Nil
4	Bihar	711	8	Nil	24	Nil	32
5	Goa	765	25	Nil	Nil	Nil	Nil
6	Gujarat	2874	186	64	6	Nil	Nil
7	Haryana	1669	32	12	3	Nil	2
8	Himachal Pradesh	1470	32	0	1	6	0
9	Jammu & Kashmir	1940	133	5	1	Nil	Nil
10	Karnataka	5268	159	2	3	Nil	Nil
11	Kerala	3904	202	Nil	Nil	Nil	Nil
12	Madhya Pradesh	2617	104	Nil	Nil	Nil	Nil
13	Maharashtra	6928	521	19	7	6	Nil
14	Manipur	Nil	Nil	Nil	Nil	Nil	Nil
15	Meghalaya	68	Nil	Nil	Nil	Nil	Nil
16	Mizoram	71	Nil	Nil	Nil	Nil	Nil
17	Nagaland	12	Nil	Nil	Nil	Nil	Nil
18	Orissa	2910	54	Nil	Nil	Nil	Nil
19	Punjab	3031	41	1	2	2	Nil
20	Rajasthan	1605	128	Nil	13	Nil	Nil
21	Sikkim	26	1	Nil	Nil	Nil	Nil
22	Tamilnadu	4110	298	4	4	Nil	Nil
23	Tripura	185	8	4	Nil	Nil	Nil
24	Uttar Pradesh	1328	152	11	136	2	91
25	West Bengal	687	18	3	5	Nil	5
26	Pondicherry	48	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar Island	Nil	Nil	Nil	Nil	Nil	Nil
28	Chandigarh	79	6	Nil	Nil	Nil	Nil
29	Delhi	283	13	9	5	Nil	11
30	Dadra & Nagar Haveli	Nil	Nil	Nil	Nil	Nil	Nil
31	Daman & Diu	89	1	Nil	Nil	Nil	Nil
32	Lakshadweep	Nil	Nil	Nil	Nil	Nil	Nil
33	Chattisgarh	36	9	Nil	Nil	Nil	Nil
34	Jharkhand	20	3	Nil	1	Nil	Nil
35	Uttaranchal	180	3	1	Nil	Nil	Nil
	Total	48082	2186	137	241	16	141

Number of samples tested and enforcement actions taken by State Drugs Controller during 2012-2013

S.No.	States	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	No. of prosecution launched for manufacturing, sale and distribution of spurious/ adulterated drugs	No. of cases (as mentioned in the earlier column) decided	No. of persons arrested
1	Andhra Pradesh	6327	78	19	29	49	
2	Arunachal Pradesh	103	6	Nil	Nil	Nil	Nil
3	Assam	665	50	Nil	Nil	Nil	Nil
4	Bihar	Data awaited					
5	Goa	637	36	Nil	Nil	Nil	Nil
6	Gujarat	6907	551	4	1	1	Nil
7	Haryana	3713	52	25	1	Nil	Nil
8	Himachal Pradesh	1318	27	Nil	1	Nil	Nil
9	Jammu & Kashmir	2410	86	3	3	-	-
10	Karnataka	6336	229	2	2	Nil	3
11	Kerala	4569	189	Nil	Nil	Nil	Nil
12	Madhya Pradesh	2049	74	Nil	Nil	Nil	-
13	Maharashtra	7538	360	3	Nil	Nil	26
14	Manipur	Nil	Nil	Nil	Nil	Nil	Nil
15	Meghalaya	1	4	Nil	Initiated	Nil	Nil
16	Mizoram	64	Nil	Nil	Nil	Nil	Nil
17	Nagaland	84	4	-	Nil	Nil	-
18	Orissa	4005	37	1	Instructed to file prosecution in spurious drugs cases	Nil	Nil
19	Punjab	3087	37	Nil	Nil	Nil	-
20	Rajasthan	1625	81	15	36	Nil	2
21	Sikkim	47	Nil	Nil	Nil	Nil	Nil
22	Tamil Nadu	3906	210	4	9	1	Nil
23	Tripura	236	Nil	Nil	Nil	Nil	Nil
24	Uttar Pradesh	1016	161	3	156	Nil	76
25	West Bengal	1186	35	Nil	2	Nil	3
26	Pondicherry	Nil	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar Island	1	Nil	Nil	Nil	Nil	Nil
28	Chandigarh	109	8	Nil	Nil	Nil	Nil
29	Delhi	475	19	Nil	Nil	Nil	Nil
30	Dadra & Nagar Havell	Nil	Nil	Nil	Nil	Nil	Nil
31	Daman & Diu	58	Nil	Nil	Nil	Nil	Nil
32	Lakshadweep	Nil	Nil	Nil	Nil	Nil	Nil
33	Chattisgarh	15	4	Nil	Nil	Nil	Nil
34	Jharkhand	38	11	Nil	Nil	Nil	Nil
35	Uttaranchal	212	13	Nil	1	Nil	Nil
	Total	58537	2362	70	274	6	110

S.No.	States	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	No. of prosecution launched for manufacturing, sale and distribution of spurious/	No. of cases (as mentioned in the earlier column) decided	No. of persons arrested	Appr ox. value of drug seized	No. of Raids Conducte d	Action taken w.r.t no. of raids conducted
1	Andhra Pradesh	7343	61	12	12	Under trial	Not given	134.6 8	1645 shops	SO issued -950 Cancellations-300 Warnings-112
2	Arunachal Pradesh	183	6	Nil	NA	NA	NA	NA	NA	NA
3.	Assam	1097	39	Nil	Nil	Nil	Nil	Nil	Nil	Nil
4	Bihar	1139	52	4	1	Nil	Nil	####	884	explanation given 60 suspended -27
5	Goa	590	34	Nil	Nil	Nil	Nil	Nil	Nil	Nil
6	Gujarat	9713	567	32	Nil	Nil	1	Nil	13	Under investigation
7	Haryana	2494	52	3	3	Nil	1	Appr x. 2Lak h	6839	Drug License suspended -078 Drug Lice. Cancelled-139 Coun case lnuned -27 FIR yet registered -9
	Himachal Pradesh	751	28	1	1(seizure in 2011)	Nil	Nil	NA	Nil	NA
9	Jammu & Kashmir	4550	153	6 (03-spurious, 03-Adultrated)	6 (03-spurious, 03- Adultrated)	sub-judice	Nil	####	Nil	Nil
10	Karnataka	9366	292	4	1	Nil	Nil	Nil	Nil	Nil
11	Kerala	4557	152	Nil	Nil	Nil	Nil	Nil	Nil	NA
12	Madhya Pradesh	1370	75	Nil	Nil	Nil	Nil	Nil	Nil	Nil
13	Maharashtra	6097	466	19	11	Nil	5	37.85 lakhs	17	7
14	Manipur	7	Nil	Nil	Nil	Nil	Nil	Nil	Nil	NA
15	Meghalaya	31	1	Nil	Initiated	Nil	Nil	Nil	Nil	Nil
16	Mizoram	115	Nil	Nil	Nil	Nil	6	12 lakhs	6	prosecuted the arrested persons and the seized drugs were destroyed
17	Nagaland	266	4	Nil	Nil	Nil	Nil	Nil	Nil	Nil
18	Orissa	4226	74	2	1	Nil	Nil	####	1475	Raids conducted and steps taken
19	Punjab	3449	106	3	1	42	Nil	####	1210	About 620 drug license suspended and 12 drug license were cancelled
20	Rajasthan	1516	38	7	7	2	1	####	1915	147
21	Sikkim	109	Nil	Nil	Nil	Nil	NA	Nil	Nil	Nil
22	Tamilnadu	8356	314	6	4	Nil	Nil	####	154	72 sanction orders have been issued for launching prosecutions before the concerned court
23	Tripura	798	35	2	1	Nil	Nil	Nil	Nil	NA
24	Uttar	2068	336	5	120	Not	68	####	1188	51 FIR lodge
25	West Bengal	894	22	Nil	Nil	Nil	3	####	10	3
26	Pondicherry	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar	3. results are awaited	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
28	Chandigarh	100	3	None	None	None	None	None	4	Found Satisfactory
29	Delhi	166	17	5	Nil	Nil	Nil	NA	NA	NA

30	Dadra & Nagar	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
31	Daman & Diu	33	Nil	Nil	Nil	NA	Nil	Nil	Nil	NA
32	Lakshadw	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
33	Chattisgar	520	11	Nil	Nil	Nil	Nil	Nil	Nil	Nil
34	Jhorkhand	402	59	Nil	63	Nil	1	Nil	4	2
35	Uttarakhand	405	31	7	2	Nil	Nil	Not Yet calculated	7	License suspended 3 and canceled 1
Total		72712	3028	118	237	44	86	424.67 lacs	14567	

Number of samples tested and enforcement actions taken by State Drugs Controller during April 2014- September 2014

S.No	States	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	No. of prosecution launched for manufacturing, sale and distribution of spurious/ adulterated drugs	No. of cases (as mentioned in the earlier column) decided	No. of persons arrested	Approx. value of drug seized	No. of Raids Conducted	Action taken w.r.t no. of raids conducted
1	Andhra Pradesh	846	62	NIL	Nil	Nil	Nil	8,15,035	263	Warnings issued-3(Not issued/ 599 SCN's issued-63
2	Arunachal Pradesh	87	6	Nil	Nil	Nil	Nil	Does not arise.	Does not arise	Does not arise
3	Assam	506	33	Nil	Nil	Nil	Nil	Nil	Nil	Nil
4	Bihar	682	11	Nil	Nil	Nil	Nil	Nil	198	158
5	Goa	205	05 Not of Standard Quality	Nil	01 Not of Standard Quality	Nil	Nil	Nil	Regular Inspections are carried out to detect Not of standard Quality/ Spurious/ Adulterated Drugs	Does not arise
6	Gujarat	5456	282	2	Nil	Nil	Nil	Nil	1	Under investigation
7	Haryana	1216	21	2	1	Nil	Nil	Nil	4599	28- License Cancelled 127- License Suspended 12- Court case launched 01- warning issued 118- under investigation where Show cause notice issued 01- FIRs Registered
	Himachal Pradesh	481	18	Nil	Nil	NA	Nil	Nil	Nil	Nil
9	Jammu & Kashmir	3072	28	Nil	Nil	Nil	Nil	18,18,487.	Nil	Nil
10	Karnataka	3776	131	....	....	....	....	....	....	....
11	Kerala	2235	61	Nil	Nil	Nil	Nil	Nil	Nil	Nil
12	Madhya Pradesh	828	14	Nil	Nil	Nil	Nil	Nil	Nil	Nil
13	Maharashtra	1824	191	10	04 (Prosecution order issued in all 10 cases		7	76527	6	2-Prosecution launched 1-Pending 3-Pending for investigation
14	Manipur	5	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
15	Meghalaya	11	Nil	Nil	Does not arise	Nil	Nil	Nil	Nil	Nil
16	Mizoram	46	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
17	Nagaland	30	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
18	Orissa	1991	44	NORR-TZ 8. No. 78 detected during 2013-14	04 nos of seizure have been made during 2013-14 and 02 nos of seizure have been made during 2014-15	Nil	Nil	Rs. 97,240	389 (Upto Sept.)	(i) S.C.N. under rule 66 (1) are being issued against the I/R submitted by the D.I. after conducting raid. (ii) Steps have been taken for drug recall of N.S.Q. drugs under intimation to concerned D.C./F.D.A. for further action at their end and to send their action taken report along with investigation report for finalisation of further action against manufacturers with due recommendation of the screening committe of the State so constituted in compliance to
19	Punjab	1268	33	Nil	Nil	Nil	Nil	1398274/-	2313	Under Process
20	Rajasthan	1127	28	3	3	1	4	2929097	315	27

21	Sikkim	30	1	Nil	Nil	Nil	Nil	Nil	Nil	Nil
22	Tamilnadu	5065	176	Nil	Nil	NA	Nil	Nil	72 raids have been conducted during the said period against the sales premises.	239 sanction orders have been issued for launching prosecutions before the concerned court.
23	Tripura	372	17	Nil	Nil	Nil	Nil	0	Nil	Nil
24	Uttar Pradesh	5579	652	6	47	0	34	20,03,785	602	30 FIR were lodged and 34 persons were arrested
25	West Bengal	349	11	1	Nil	Nil	Nil	N/A	5	pending
26	Pondicherry	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar	Nil(4 samples have been sent for testing to CDL Kolkata)	Test report awaited from CDL Kolkata	Test report awaited from CDL Kolkata	Nil	Nil	Nil	Nil	Nil	Nil
28	Chandigarh	62	2	None	None	None	None	None	None	N/A
29	Delhi	21	Nil	1	Nil	Nil	No	19000	1	FIR Launched
30	Dadra & Nagar Haveli	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
31	Daman & Diu	35	Nil	Nil	NA	NA	Nil	Nil	Nil	NA
32	Lakshadweep	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
33	Chattisgarh	217	6	Nil	Nil	Nil	Nil	Nil	Nil	Nil
34	Jharkhand	155	17	Nil	2	6	Nil	1.4 lac	60:00	FIR & Susp.
35	Uttarakhand	138	8	....	....	....	....	....	3	....
36	Telangana	1938	21	Nil	Nil	Nil	Nil	94,20,600(in the month of April	Nil	Nil
Total		38,655	1823	25	65	7	45	18818045	8966	

MINUTES OF THE NINETEENTH SITTING OF THE PUBLIC ACCOUNTS COMMITTEE (2014-15) HELD ON 9TH APRIL, 2015.

The Committee sat on Thursday the 9th April 2015 from 1430 hrs. to 1700 hrs. in Committee Room 'D', Parliament House Annexe, New Delhi.

PRESENT

Prof. K. V. Thomas - Chairperson

MEMBERS

LOK SABHA

2. Shri S.S. Ahluwalia
3. Shri Nishikant Dubey
4. Shri Gajanan Kirtikar
5. Shri Bhartruhari Mahtab
6. Shri Dushyant Singh
7. Shri Janardan Singh Sigriwal
8. Shri Shiv Kumar Udasi
9. Dr. Kirit Somaiya
10. Shri Anurag Thakur

RAJYA SABHA

11. Shri Bhubaneswar Kalita
12. Shri Shantaram Naik

LOK SABHA SECRETARIAT

1. Shri A. K. Singh - Joint Secretary
2. Smt. Anita B. Panda - Director
3. Shri T. Jaya Kumar - Additional Director
4. Shri S.L. Singh - Under Secretary
5. Smt. Anju Kukreja - Under Secretary

REPRESENTATIVES OF THE OFFICE OF THE COMPTROLLER AND AUDITOR GENERAL OF INDIA

1.	Shri A.K. Singh	-	Dy. CAG(RC)
2.	Smt. Shubha Kumar	-	Director General (RC)
3.	Shri Satish Loomba	-	Director General
4.	Shri L.S. Singh	-	Principal Director (PAC)

REPRESENTATIVES OF THE MINISTRY OF HEALTH AND FAMILY WELFARE

1.	Shri B.P. Sharma	-	Secretary
2.	Dr. Jagdish Prasad	-	D.G.H.S
3.	Shri N.S. Kang	-	AS&DG (CGHS)

REPRESENTATIVES OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

1.	Dr. V.K. Subburaj	-	Secretary
2.	Shri Kalyan Nag	-	Adviser (Cost), NPPA

REPRESENTATIVE OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF CHEMICALS AND PETROCHEMICALS)

1.	Shri Surjit K. Chaudhary	-	Secretary

2. At the outset, the Chairperson welcomed the Members and the representatives of the Office of the C&AG of India to the Sitting of the Committee. The Chairperson then apprised the Members that during the Sitting, the Committee would take further oral evidence of the representatives of the Ministry of Health and Family Welfare and Ministry of Chemicals and Fertilizers (Departments of Pharmaceuticals and Chemicals and Petrochemicals) on the subject "Procurement of Allopathic drugs in CGHS" based on Para No. 6.3 of the C&AG Report No. 19 of 2013 in the first instance. Thereafter, the Committee would consider three draft Reports for adoption.

3. XXX The officers of the C&AG of India then briefed XXX the Committee on the issues XXX relating to the subject "Procurement of Allopathic drugs in CGHS". Thereafter, the representatives of the Ministry of Health and Family Welfare and Ministry of Chemicals and Fertilizers (Departments of Pharmaceuticals and Chemicals and Petrochemicals) were called in. The Chairperson during his introductory remarks highlighted the following significant lapses in procurement of drugs required for CGHS:

(i) The Committee constituted by the Ministry for preparation/revision of existing drug formulary for branded drugs opted for commonly prescribed brands of drugs instead of

identifying commonly prescribed drug composition. The methodology adopted by the Committee was predominantly based on the prescription of specific brands by the doctors.

(ii) Even the discounted price of the selected brands had been much higher than the MRP of other low cost brands, available in the market.

(iii) Despite firm and wise directions of the Government, the Ministry could not finalise the procurement rates of most of the drugs listed in the generic formulary.

(iv) The comparison of the rates of 30 branded drugs with the rates of generic drugs in "Janaushidhi Scheme" revealed that an amount of ₹ 11.81 crore could have been saved by CGHS, Delhi during 2011-12, had generic drugs been procured instead of branded drugs.

(v) The delays in procurement and non-availability for formulary drugs at CGHS Centres led to procurement of these drugs by CGHS Centres from local chemists at higher rates, leading to extra expenditure of ₹ 3.05 crore.

(vi) MSD procured these drugs through HSCC, instead of procuring them directly. As a result, consultancy charges of 4.5% had been paid to HSCC upto October 2008 and at the rate of 2.5% thereafter. In this process, MSD, Delhi incurred an avoidable expenditure of ₹ 13.52 crore during the period from 2002-03 to 2010-11.

(vii) Despite directions of the Ministry of Finance, issued at the instance of the PAC, a number of ATNs have not been submitted.

(viii) The Pharmaceutical Advisory Forum had not been meeting regularly.

(ix) Details of steps taken by the Department to ensure availability of essential medicines at reasonable price were sought too.

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4. The Chairperson also expressed displeasure of the Committee on the fact that though there is a clear prohibition for doctors accepting any gift, hospitality, trips to foreign and domestic destinations from health care industry, this evil practice has been continuing and the pharma companies continue to sponsor foreign trips to doctors and appease them with high value gifts as quid pro quo. He, therefore, desired that this unhealthy state of

affairs should be brought to the notice of the Government in Ministry of Health and Family Welfare and also Cabinet Secretary for taking effective and appropriate action against those responsible for lowering the image of the institution as well as the Government. Before commencing the examination, the Chairperson made it clear that the deliberations of the Committee were confidential and were not to be divulged to any outsider until the Report on the subject was presented to the Parliament. The Committee then proceeded with the examination of the subject.

5. The Members sought clarifications on various issues which inter-alia included shortcomings in present system of procurement, flooding of inferior quality Chinese medicines in the market, distribution and inventory management of drugs and measures taken by the Government to remove the same, excessive procurement of drugs through local purchases, prescribing drugs outside the formulary, steps taken by the Ministry to refrain the doctors from frequently prescribing expensive branded medicines instead of low cost yet equally effective drugs, non-updation of formulary list, non-inclusion of 397 generic drugs in the present formulary, reasons for giving procurement of drugs for CGHS Delhi to MSO from HSCC. The Members also sought clarifications about the spurious drugs prevalent in the Indian market and the steps taken by the Government to identify and stop those drugs. Thereafter, Members desired to know about the role of Department of Pharmaceuticals in fixing rate on drugs, total production capacity of drugs in India and steps taken by the Government to improve the same, measures initiated for making our country self dependent in regard to production of drugs, role of National Pharmaceutical Pricing Authority and Pharmaceutical Advisory Committee etc. The representatives of the Ministry of Health and Family Welfare and Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals and Chemicals and Petrochemicals) clarified that being a global leader, India export drugs to 220 countries. They apprised the Committee that 80 per cent of the raw material for the drugs was imported from China and after production India export drugs to foreign countries, especially to the entire Africa. They further replied that since January, 2015 the Ministry of Health and Family Welfare introduced a uniform Civil Code which forbids the doctors from accepting costly gifts, foreign trips etc. They assured that the information sought by the Committee would be furnished to them expeditiously.

6. Before concluding, the Chairperson thanked the representatives of both the Ministries and also asked them to furnish the requisite information that was sought by the Members within 10 days. The Chairperson also thanked the representatives of the Office of the

C&AG of India for providing valuable assistance to the Committee in the examination of the subject.

The witnesses then withdrew.

A copy of the verbatim proceedings of the Sitting was kept on record.

7. The Committee then took up the following draft Reports one by one for consideration:

(i) Draft Report on the subject **"Ultra Mega Power Projects under Special Purpose Vehicles"** based on C&AG Report No. 6 of 2012-13.

(ii) Draft Report on the subject **"Jawaharlal Nehru National Urban Renewal Mission"** based on C&AG Report No. 15 of 2012-13; and

(iii) Draft Report on the subject **"Excesses Over Voted Grants and Charged Appropriations (2012-13)** based on Para 3.4 and 3.5 of C&AG Report No. 1 of 2014.

8. Giving an overview of the issues contained in the draft Reports and comments of the Committee thereupon, the Chairperson solicited the views/suggestions of the Members. After some discussions, the Committee adopted the two draft Reports mentioned at Sl. Nos. (ii) and (iii) without any modifications. As regards the draft Report mentioned at Sl. No. (i), some Members suggested certain modifications and authorized the Chairperson to incorporate them suitably in the Report.

9. The Committee then authorized the Chairperson to finalize the Reports in the light of the factual verifications, if any, made by Audit and present them to Parliament on a convenient date.

The Committee, then, adjourned.