1	STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2019-20) SEVENTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

[Action Taken by the Government on the Observations / Recommendations contained in the Fifty Fourth Report of the Standing Committee on Chemicals and Fertilizers (Sixteenth Lok Sabha) on " Pricing of Drugs with Special Reference to Drugs (Prices Control) Order, 2013" (Department of Pharmaceuticals)]

सत्यमेव जयते

FIRST REPORT

LOK SABHA SECRETARIAT
NEW DELHI

DECEMBER, 2019 /AGRAHAYANA, 1941 (SAKA)

FIRST REPORT

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS
(2019-20)

(SEVENTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT PHARMACEUTICALS)

[Action Taken by the Government on the Observations / Recommendations contained in the Fifty Forth Report of the Standing Committee on Chemicals and Fertilizers (Sixteenth Lok Sabha) on "Pricing of Drugs with Special Reference to Drugs (Prices Control) Order, 2013" (Department of Pharmaceuticals)

Presented to Lok Sabha on 05 December 2019
Laid in Rajya Sabha on 05 December 2019

LOK SABHA SECRETARIAT
NEW DELHI

DECEMBER, 2019 /AGRAHAYANA, 1941 (SAKA)

COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2019-20)

Smt. Kanimozhi Karunanidhi - Chairperson

MEMBERS
LOK SABHA

2	Shri Maulana Badruddin Ajmal
3	Shri Ramakant Bhargava
4	Shri Prataprao Govindrao Patil Chikhalikar
5	Shri Rajeshbhai Naranbhai Chudasama,
6	Shri Ramesh Chandappa Jigajinagi
7	Shri Kripanath Mallah
8	Shri Satyadev Pachauri
9	Smt Aparupa Poddar
10	Shri Arun Kumar Sagar
11	Shri M. Selvaraj
12	Shri Pradeep Kumar Singh
13	Shri Uday Pratap Singh
14	Shri Nandigam Suresh
15	Shri Er. Bishweswar Tudu
16	Shri H. Vasanthakumar
17	Shri Prabhubhai Nagarbhai Vasava
18	Dr. Vishnu Prasad M.K.
19	Shri Deepak Baij
20	Dr. Manoj Rajoria
21	Vacant

RAJYA SABHA

22	Shri Ranjib Biswal
23	Shri G.C.Chandrashekhar
24	Dr. Anil Jain
25	Shri Ahmad Ashfaque Karim
26	Shri Amar Singh
27	Shri Vijay Pal Singh Tomar
28	Vacant
29	Vacant
30	Vacant
31	Vacant

SECRETARIAT

1.	Shri Manoj K. Arora	-	Officer on Special Duty
2.	Shri A.K. Srivastava	-	Director
3.	Shri C. Kalyanasundaram	-	Additional Director
4.	Ms Sonia Sankhla	-	Assistant Committee Officer

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2019-2020) having been authorised by the Committee to present the Report on their behalf, present this First Report (Seventeenth Lok Sabha) on Action Taken by the Government on the observations/ recommendations contained in the Fifty-Fourth Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2018-19) on the subject "Pricing of Drugs with Special Reference to Drugs (Prices Control) Order, 2013" pertaining to the Department of Pharmaceuticals.

2. The Fifty-Fourth Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers was presented to Lok Sabha on 13.02.2019. The Action Taken replies of Government to all observations / recommendations contained in the Report were received on 27.09.2019. The Standing Committee on Chemicals and Fertilizers (2018-2019) considered and adopted this Report at their sitting held on 13.11.2019.

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

4. For facility of reference and convenience, the Comments of the Committee have been printed in bold letters in the body of the Report - **Chapter-I.**

New Delhi;
25 November, 2019
04 Agrahayana, 1941 (Saka)

KANIMOZHI KARUNANIDHI
Chairperson
Standing Committee on
Chemicals and Fertilizers

REPORT

CHAPTER-I

This Report of the Standing Committee on Chemicals and Fertilizers deals with the action taken by the Government on the Observations/Recommendations contained in the **Fifty-Fourth Report** (16th Lok Sabha) of the Committee on the subject 'Pricing of Drugs with Special Reference to Drugs (Prices Control) Order,2013' was presented to Lok Sabha and Rajya Sabha on 13 February, 2019. In all, the Committee made 9 (nine) Observations / Recommendations in the Report.

2. Ministry of Chemicals & Fertilizers (Department of Chemicals and Petrochemicals) were requested to furnish replies to the Observations / Recommendations contained in the Fifty-Fourth Report within three months from the date of presentation of the Report, i.e. by 13 May,2019. The Action Taken Replies of the Government in respect of all the nine (09) Observations / Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) vide their OM No. 31026/07/2019-Pricing dated 27 September, 2019. These Replies have been categorized as follows:-

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

Sl. Nos. 4.1, 4.2, 4.4, 4.7 & 4.8 (Total =05)

These are included in Chapter II of the Report.

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

Sl. Nos. 4.3 and 4.6 (Total = 02)

These are included in Chapter-III of the Report

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

Sl. Nos. 4.5 and 4.9 (Total = 02)

These are included in Chapter IV of the Report.

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

Nil (Total=Nil)

These are included in Chapter V of the Report.

3. The Committee desire that the Action Taken Notes on the Observations / Recommendations contained in Chapter-I of this Report should be furnished expeditiously and not later than three months from the date of presentation of this Report.

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

Recommendation (Sl. No. 4.2)

5. The Committee in their 54th Report (16th Lok Sabha) had observed / recommended as under:-

"The Committee are not in agreement with the nomenclature of "National List of Essential Medicines". Every medicine/drug is essential to treat a particular disease/ailment. When a person is affected by any disease/ailment, particular medicine becomes essential to treat that disease/ailment and as such every medicine is essential from the context of treating the disease for which it is formulated. The Committee, therefore, feel that the present nomenclature of NLEM is not appropriate and recommend that the same may be reviewed and the present nomenclature may suitably be modified."

Reply of the Government

6. In reply to the aforementioned observations / recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

"The concept of essential medicines, first introduced by WHO in 1977, has now been adopted by many countries, non-governmental organizations and international non-profit supply agencies. The list is considered to include the most cost-effective medicines for a particular indication. It is developed in concordance with the standard treatment guidelines keeping in mind the healthcare needs of the majority of the population. Careful selection of a limited range of essential medicines results in a higher quality of care, better management of medicines and more cost-effective use of health resources. The list of essential medicines guides the hospital drug policies, procurement and supply of medicines in public sector, medicine cost reimbursement and medicine donations. It helps in monitoring the pricing of medicines. The list serves as a reference document for correct dosage form and strength for prescribing. Preference is given to single drug formulations as opposed to fixed dose combinations where appropriate. Hence use of National List of Essential Medicines (NLEM) is expected to improve prescribing practices as well as the health outcomes. The appropriate use of medicines selected in the NLEM promotes rational use of medicines. Such rational use of medicines, especially antimicrobial drugs, reduces development of drug resistance. The list also serves as a reference for assessing the healthcare access of the populace. Lastly, NLEM serves as a tool for public education and training of healthcare providers. The Hon'ble Committee is, therefore, requested that the present nomenclature, may continue to be used since it is internationally recognized.

Further, the Standing National Committee on Medicines (SNCM) agrees with the spirit and sentiments expressed by the Hon'ble Parliament Standing Committee that every medicine is essential to treat particular disease/ailment. The example include:-

* Medicines used for conditions such as Gaucher disease (enzyme replacement therapy), myasthenia gravis (pyridostigmine) etc. However, these conditions are rare in nature and will be required in very few patients in the country.

* Several fixed dose combinations that are available in the country and are very openly prescribed, such as combination of several vitamins, analgesics, anti-hypertensives etc. More than one analgesic or antihypertensive medicine may be required for some patients but not for the majority.

The essential medicines list is the list of the drugs which caters to the majority of the population of a country. It is prepared in a country specific manner, depending on the disease prevalence in that region, and helps prepare policies of the country.

NLEM, 2015 was prepared considering the public health problems in India and adhering to the basic problems of efficacy, safety, cost-effectiveness. This essential list included the medicines which should be useful in majority of the population and depends on the prevalence data of various diseases in the country. It is expected that such medicines will be available in good quality at all times at an affordable price. This list is not exhaustive but is limited to serve the above-said purpose. It could be called as a best-fit list.

In India, the NLEM was prepared initially in 1996 and later revised in 2003, 2011 and 2015. NLEM, 2015 was prepared after several nationwide consultations with experts in different subjects, NGOs and other stakeholders. The potential uses of NLEM include but are not limited to procurement by Government agencies, price fixing by National Pharmaceutical Pricing Authority, prescribing by doctors, economizing and optimizing the health care resources.

The NLEM in no way undermines the importance of any drug which may be useful/life saving for limited number of patients. There is a separate list of life saving drugs by Ministry of

Health & Family Welfare (M/o H&FW) and a separate policy for drugs for rare diseases is being drafted."

Comments of the Committee

7. In regard to the Committees' recommendation to review the present nomenclature of National List of essential Medicines so as to include more and more medicines, the Committee note the reply given by the Ministry that the National List of Essential Medicines in no way undermines the importance of any drug which may be useful/ life saving for limited number of patients and that there is a separate list of life saving drugs by the Ministry of Health &Family Welfare. Further, a separate

policy for drugs for rare diseases is being drafted. While accepting the reply of the government in this regard the Committee recommends that this policy for drugs for rare diseases may be drafted expeditiously and adopted in a time bound manner.

Recommendation (Sl. No.4.5)

8. The Committee in their 54th Report (16th Lok Sabha) had observed / recommended as under:-

"The Committee note that the Ministry of Health and Family welfare has constituted a Standing National committee on Medicines to review and revise the National List of essential Medicines (NLEM). There are 23 Members in the Committee representing various Health and family welfare sectors. One representative is from the Department of Pharmaceuticals but there is no representation for NPPA in the committee. Even though a representative from NPPA will be a special invitee for the meetings of the Committee, permanent representation has not been given to NPPA. NPPA is entrusted with the responsibility of fixation and revision of prices of scheduled formulations under drugs (Prices control) order and also responsible for monitoring and enforcing drug prices in the country. The Committee, therefore, recommend that permanent representation should be given to NPPA in the Core Committee."

Reply of the Government

9. In reply to the aforementioned observations / recommendation of the Committee, the Department of Pharmaceuticals has stated as under :-

" A Standing National Committee on Medicines and other Health Care Products (SNCM&HCP) has already been constituted by the Ministry of Health & Family Welfare to review and revise the NLEM. It is submitted that as per Order dated 03/07/2018 (Annexure - I), a representative of NPPA has been made a special invitee. The Member Secretary (NPPA) and Director, NPPA are attending the meetings of the aforesaid committee as special invitees. "

Comments of the Committee

10. Since the representative of the National Pharmaceuticals Pricing Authority (NPPA) is only a special invitee in the Standing National Committee on Medicines which is empowered to review and revise the National List of Essential Medicines (NLEM), the Committee specifically recommended that permanent representation should be given to NPPA in the Committee. In this regard, the reply given by the Ministry that the Standing National Committee on Medicines and other Health Care

Products has already been constituted and that a representative of the NPPA has been made a special invitee is not acceptable to the Committee. Since NPPA is entrusted with the responsibility of fixing prices of drugs, monitoring and enforcement of prices for the entire country, the Committee reiterate the earlier recommendation that permanent representation should be given to NPPA in the Standing National Committee on Medicines.

Recommendation (Sl. No. 4.7)

11. The Committee in their 54th Report (16th Lok Sabha) had observed / recommended as under:-

"The Committee are satisfied to note that the total number of scheduled formulations have increased from 530 under NLEM 2011 to 851 under NLEM 2015. It is also heartening to note that ceiling prices of 370 scheduled formulations under NLEM 2011 which witnessed 0 to 30% decrease with respect to maximum price has increased to 670 formulations under NLEM 2015. However, the number of scheduled formulations which witnessed 35-40 percentage and above 40 percentage reduction with respect to maximum price have reduced from 34 to 24 and 126 to 59 under NLEMs 2011 and 2015, respectively. The clarification provided by the Department in this regard that the reduction in these cases are limited while refixing the ceiling price of the common formulations under NLEMs 2011 and 2015 is not satisfactory. The Committee recommend that the Government should take all necessary steps to bring more number of formulations under these two categories so that overall prices of drugs in the country are affordable to people particularly to poor people."

Reply of the Government

12. In reply to the aforementioned observations / recommendation of the Committee, the Department of Pharmaceuticals has stated as under :-

" The Ministry of Health & Family Welfare (M/o H&FW) notifies the National List of Essential Medicines. As per the NPPP, 2012, all the medicines specified in the National List of Essential Medicines are included in the First Schedule of DPCO, 2013 and brought under price control. Under the DPCO, 2013, prices of drugs are fixed on 'Market based pricing' methodology which is in accordance with the NPPP, 2012. Since the prices of drugs are fixed on 'Market based pricing', the number of formulations witnessing reduction by a particular percentage cannot be controlled or determined by the Government."

Comments of the Committee

13. The Committee note the reply given by the Ministry that there is no provision in the Drug Prices Control Order, 2013 regarding cancellation of license of

manufacturers or retailers who indulges in overcharging. There is also no provision under the Drugs & Cosmetics Act, 1940 & Rules, 1945 regarding cancellation of licenses of the manufacturers who do not deposit the demanded amount within the prescribed time limit given by NPPA. While understanding the constraint being faced by the Government in this regard, the Committee recommend that relevant provisions of DPCO, 2013 and Drugs & Cosmetics Act 1940 and its Rules should be revisited by the Ministry and necessary action should be taken for the amendment of these Orders/Acts/Rules so as to make these provisions more stringent and effective.

Recommendation (Sl. No.4.9)

14. The Committee in their 54th Report (16th Lok Sabha) had observed / recommended as under:-

> "The Committee are constrained to note that presently National Pharmaceutical Pricing Authority (NPPA) has only a part-time member apart from the chairperson. NPPA is entrusted with the responsibility of enforcing the Drugs (Prices control) order and to monitor availability of drugs in the country, identify shortages and to take remedial steps thereon. In the absence of even a full time member and a strong management team, the Committee are skeptical that the authority will be able to carry out its functions effectively. The Committee are of the view that the current composition of the authority needs to be expanded to include more full time expert members so that the administrative efficiency of the organization is enhanced to fulfill the mandate of NPPA. Thus, the Committee strongly recommend that the Composition of NPPA may be reviewed and more full time members may be appointed. "

Reply of the Government

15. In reply to the aforementioned observations / recommendation of the Committee, the Department of Pharmaceuticals has stated as under :-

" The issue of restructuring of the NPPA was examined and it has been decided to strengthen the NPPA at lower levels in order to enable it to fulfill its mandate. Accordingly, NPPA has been asked to prepare a proposal for strengthening the NPPA at lower levels."

Comments of the Committee

16. The Committee are constrained to note that the reply furnished by the Ministry has not addressed the main recommendation of the Committee on review of

composition of NPPA and appointment of more full time members. This recommendation was made by the Committee based on the submission made by the Secretary that three or four full time members are necessary to strengthen NPPA. However, the Ministry has decided to strengthen NPPA only at lower level. Presently, apart from Chairman, NPPA has only a Member Secretary and three other part time Members. Since current composition of the authority needs to be expanded to include more full time expert members so that the administrative efficiency of the organization is enhanced to fulfill the mandate of NPPA, the Committee reiterate the earlier recommendation that the composition of NPPA should be reviewed and more full time Members may be appointed alongwith the strengthening of NPPA at lower levels.

CHAPTER – II

OBSERVATIONS / RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

Recommendation (Sl. No. 4.1)

The observations / recommendations of the Committee are as under :-

"The Committee note that about 70% of medical expenditure in our country is incumbent on medicines and as such affordability of medicines is a crucial element in availing medical treatment by all sections of the people in the country particularly poor people. The Committee, therefore, selected and examined the subject 'Pricing of drugs with special reference to Drug (Price control) order, 2013 on priority basis. DPCO, 2013 was notified on 15.05.2013 under the essential commodities Act and is based on the broad guidelines of the National pharmaceuticals pricing policy, 2012 which aimed at bringing a regulatory framework for pricing of drugs so as to ensure availability of required medicines at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals and shared economic well being for all. The Government has dawn a National List of Essential Medicines (NLEM), 2015 as first schedule of DPCO, 2013 which was notified on 10 March, 2016. As per NLEM, the essential medicines are those that satisfy the priority health care needs of the population. The list is made with consideration to disease prevalence, efficacy, safety and comparative cost-effectiveness of the medicines. All efforts should be made by the Union Government in coordination with State Governments to provide medicines to poor people at a price affordable to them."

Reply of the Government

2.2 The Action Taken Reply of the Department of Pharmaceuticals is as under :-

" The National Pharmaceutical Pricing Authority (NPPA) has notified ceiling prices of 857 formulations contained in schedule - I of the Drugs (Prices Control) Order, 2013 (DPCO) to make these formulations affordable. In addition, prices of Cardiac stents, Knee Implants and 106 Anti-diabetic and Cardiovascular medicines were notified under paragraph 19 of the DPCO. The fixation of ceiling prices/MRP has resulted in a total annual saving of Rs. 11,463 crores to the public. Further, recently the NPPA has put a cap on Trade margin of select anti-cancer medicines under 'Trade Margin Rationalization Approach' by invoking paragraph 19 of the DPCO. This would result in approximate yearly saving of Rs. 983 crore for the patients.

Further, the Department of Pharmaceuticals (DoP) is running a scheme namely "Pradhan Mantri Bhartiya Janaushadhi Pariyojana" (PMBJP) for providing affordable medicines to the public. Under this scheme, the target of opening 5000 PMBJP Kendras by the end of the financial year 2018-19 has already been achieved on 05.02.2019. However, the target now is to cover all the districts of the country by the end of current financial year.

India is among countries with the highest out of pocket expenses on health care. As per analysis of NSSO 2014 data, it is estimated that nearly 70% of Out of Pocket (OP)

expenditure on health is on account of OP care of which expenditure on drugs constitutes more than 67% of out of pocket expenditure.

Provision of free drugs in public health facilities can, therefore, bring enormous relief to people if essential drugs are provided free to all patients visiting public health facilities since the cost to Government for procuring generic drugs in bulk is drastically lower than the price paid for a branded drug by an individual consumer. Thus, it does not really cost the government very much if essential drugs are provided free to all patients visiting public health facilities, but it brings huge savings to the patients.

Pursuant to the Union budget announcement in 2014, Operational Guidelines along with Model Request For Proposal (RFPs) for implementing the National Health Mission (NHM) Free Drug Service Initiative were developed and shared with the States on 2nd July, 2015. To nudge State towards adoption of policy to provide free essential generic drugs in public health facilities, upto 5% additional funding (over and above the normal allocation of the state) under the NHM was introduced as an incentive. Advocacy by the Ministry of Health and Family Welfare under the National Health Mission was done with all the States for provision of free essential drugs in all public health facilities under this initiative. Accordingly, all the States/UTs have reported to have notified policy to provide free drugs in public health facilities.

Support under the NHM is provided not only for drugs but also for various components necessary for effective implementation of Free Drug Service Initiative viz. strengthening/setting up robust systems of procurement, quality assurance, IT backed supply chain management systems like Drugs and Vaccines Distribution Management Systems (DVDMS) developed by CDAC, warehousing, prescription audit, grievance redressal, Information, Education and Communication (IEC), training, dissemination of Standard Treatment Guidelines, etc. The DVDMS provides real-time status of drugs and vaccines in different health facilities to help in better planning, execution and control on demand and supply at all the levels thereby avoiding stock outs and wastages. A few states are also implementing the same through their State enabled IT System.

Based on the National List of Essential Medicines, the indicative number of drugs / formulations to be provided at facilities have been provided in the guidelines (District Hospitals - 544, Community Health Centres – 455, Primary Health Centres -285 and Sub-centres – 57). However States have the flexibility to add more. Hence the Essential Drugs List (EDL) of States vary from State to State.

The operational Guidelines issued in 2015 provide for procurement of generic drugs, prescription of drugs by generic names, training and orientation of Doctors on rational drug use and prescription by generic names and also for putting in place a system of prescription audit to monitor prescription by generic names as well as rational prescription of drugs."

[Ministry of Chemicals & Fertilizers (Department Of Pharmaceuticals)

O.M. No. 31026/07/2019-Pricing dated 27/09/2019]

Recommendation (Sl. No. 4.2)

The observations / recommendations of the Committee are as under :-

"The Committee are not in agreement with the nomenclature of “National List of Essential Medicines”. Every medicine/drug is essential to treat a particular disease/ailment. When a person is affected by any disease/ailment, particular medicine becomes essential to treat that disease/ailment and as such every medicine is essential from the context of treating the disease for which it is formulated. The Committee, therefore, feel that the present nomenclature of NLEM is not appropriate and recommend that the same may be reviewed and the present nomenclature may suitably be modified."

Reply of the Government

3.2 In reply to the aforementioned observations / recommendation of the Committee, the Department of Pharmaceuticals has stated as under :-

"The concept of essential medicines, first introduced by WHO in 1977, has now been adopted by many countries, non-governmental organizations and international non-profit supply agencies. The list is considered to include the most cost-effective medicines for a particular indication. It is developed in concordance with the standard treatment guidelines keeping in mind the healthcare needs of the majority of the population. Careful selection of a limited range of essential medicines results in a higher quality of care, better management of medicines and more cost-effective use of health resources. The list of essential medicines guides the hospital drug policies, procurement and supply of medicines in public sector, medicine cost reimbursement and medicine donations. It helps in monitoring the pricing of medicines. The list serves as a reference document for correct dosage form and strength for prescribing. Preference is given to single drug formulations as opposed to fixed dose combinations where appropriate. Hence use of National List of Essential Medicines (NLEM) is expected to improve prescribing practices as well as the health outcomes. The appropriate use of medicines selected in the NLEM promotes rational use of medicines. Such rational use of medicines, especially antimicrobial drugs, reduces development of drug resistance. The list also serves as a reference for assessing the healthcare access of the populace. Lastly, NLEM serves as a tool for public education and training of healthcare providers. The Hon’ble Committee is, therefore, requested that the present nomenclature, may continue to be used since it is internationally recognized.

Further, the Standing National Committee on Medicines (SNCM) agrees with the spirit and sentiments expressed by the Hon’ble Parliament Standing Committee that every medicine is essential to treat particular disease/ailment. The example include:-

* Medicines used for conditions such as Gaucher disease (enzyme replacement therapy), myasthenia gravis (pyridostigmine) etc. However, these conditions are rare in nature and will be required in very few patients in the country.

* Several fixed dose combinations that are available in the country and are very openly prescribed, such as combination of several vitamins, analgesics, anti-hypertensives etc. More than one analgesic or antihypertensive medicine may be required for some patients but not for the majority.

The essential medicines list is the list of the drugs which caters to the majority of the population of a country. It is prepared in a country specific manner, depending on the disease prevalence in that region, and helps prepare policies of the country.

NLEM, 2015 was prepared considering the public health problems in India and adhering to the basic problems of efficacy, safety, cost-effectiveness. This essential list included the medicines which should be useful in majority of the population and depends on the prevalence data of various diseases in the country. It is expected that such medicines will be available in good quality at all times at an affordable price. This list is not exhaustive but is limited to serve the above-said purpose. It could be called as a best-fit list.

In India, the NLEM was prepared initially in 1996 and later revised in 2003, 2011 and 2015. NLEM, 2015 was prepared after several nationwide consultations with experts in different subjects, NGOs and other stakeholders. The potential uses of NLEM include but are not limited to procurement by Government agencies, price fixing by National Pharmaceutical Pricing Authority, prescribing by doctors, economizing and optimizing the health care resources.

The NLEM in no way undermines the importance of any drug which may be useful/life saving for limited number of patients. There is a separate list of life saving drugs by Ministry of

Health & Family Welfare (M/o H&FW) and a separate policy for drugs for rare diseases is being drafted."

Comments of the Committee

(Please see Para No.7 of Chapter- I of the Report)

Recommendation (Sl. No. 4.4)

2.3 The observations / recommendations of the Committee are as under :-

"The Committee are concerned to note the lot of difference between the prices of Jan Aushadhi and branded medicines. In this regard, the Committee note that the cost of branded medicines are more due to inclusion of promotional cost in them. Number of Jan Aushadhi stores is less in the country. Moreover, awareness among people about Jan Aushadhi medicines is also not quite high. Most of the doctors prescribe branded medicines and the people incur lot of expenditure on buying them and most of the times such expenditure is beyond their buying capacity. In this regard, the Committee recommend the following steps:-

(a) The government should take necessary steps to ensure that branded medicines are not heavily priced and their pricing should not be more than certain ceiling to be fixed by NPPA viz-a-viz Jan Aushadhi medicines.

(b) More number of Jan Aaushadhi stores should be opened in all districts in country particularly near railway stations, bus terminals, Government hospitals, etc.

(c) Awareness among people about PMBJP scheme, cheaper prices of Jan Aushadhi medicines and their proven quality should be created.

(d) Doctors should be advised to prescribe Jan aushadhi/generic medicines which are cheaper than branded medicines."

Reply of the Government

2.4 The Action Taken Reply of the Department of Pharmaceuticals is as under :-

(a) As per paragraph 14(1) of DPCO, 2013, no manufacturer shall sell the scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government. The NPPA regularly monitors the prices of medicines sold by retail pharmacists by way of purchase of formulation samples and on the basis of references received from State Drug Controllers and general public. Further, in respect of the Non-scheduled formulations, the companies are allowed to increase the price of drugs not more than 10% in the past twelve months. The cases of violation of notified ceiling prices are taken up for recovery from the defaulting pharmaceutical companies.

Recently, the NPPA has put a cap on Trade margin of select anti-cancer medicines under 'Trade Margin Rationalization Approach' by invoking paragraph 19 of DPCO as a Pilot for 'Proof of Concept' which may entail the possibilities of mid-course correction and further up-scaling by inclusion of more medicines, based on experience. The data submitted by manufacturers in this regard has shown reduction in more than 90% of MRPs of brands.

(b) As on 24/07/2019, 5463 Pradhan Mantri Bhartiya Janaushadhi Kendras are opened in the country. PMBJP has covered 680 districts out of 723 districts of the country and remaining 43 are being covered on priority. The target is to cover all 723 districts of the country by 31st March, 2020. It has also been planned to open 1200 new PMBJP Kendras by 31st March, 2020. As on 24.07.2019, 843 PMBJP Kendras are functional in Government premises in 29 States/UTs, out of which 801 PMBJP Kendras are functional in Government Hospitals in 27 States/UTs of the country. In the current financial year, as on 24/07/2019, 26 PMBJP Kendras have been opened in government premises.

The target of opening 5000 PMBJP Kendra by the end of the financial year 2018-19 was achieved on 05.02.2019. However, the target in this year is to cover all the districts of the country. Letters have been written to the Collectors of the respective uncovered districts for expeditious opening of PMBJP Kendras in those districts.

Moreover, applications are invited for opening the Kendras from Government bodies like Railways/ State Transport Departments/ Urban local bodies/ Panchayati Raj Institutions/ Post Offices/ Defence establishments/ PSUs, etc. In the State of Maharashtra, the Bureau of Pharma PSUs of India (BPPI) (the implementing agency of PMBJP) has signed a MoU with Maharashtra State Road Transport Corporation (MSRTC) for opening 530 PMBJP Kendras, across the bus stands of Maharashtra State.

(c) The Bureau of Pharma PSUs of India (BPPI) (implementing agency of PMBJP) ran various media and publicity campaigns to educate the general public about the affordability and quality of generic medicines highlighting the huge difference in the prices of PMBJP medicines and branded medicines. The details of the publicity campaign are as under:-

Social Media: Educating the general public through Social Media platforms like facebook, twitter, linkedin, pinterest, Instagram, whatsapp, Youtube, etc. by making posts everyday on the difference of the prices in branded and generic, quality of generic medicines, advantages and salient features of Pradhan Mantri Bhartiya Janaushadhi Pariyojana.

Digital Media: BPPI has initiated cinema advertisements by running video ads in cinema halls during the popular movies. We have also made audio advertisement at ST Bus Stands through public address system, in various States, across the country.

Out-of-home (OOH) Media: Mass awareness campaign have been made on the salient features of PMBJP through outdoor media publicity which includes Bus Queue Shelter branding, Bus branding, Hoardings and LCD Screens, across the country. We have also made advertisement in Delhi-NCR metro through display panels.

Print Media: Newspaper advertisements were made on salient features and advantages of PMBJP to educate the general public for taking benefits of the pariyojana.

In addition to the above, BPPI have conducted various seminars, workshops, public meetings, participated in exhibitions and also made exhibition stall on PMBJP in different Mela's, Yatra's to make aware general public about PMBJP through our field officials. During these events, pamphlets, booklets, brochures, etc. on PMBJP are distributed by BPPI to spread the awareness amongst the people.

(d) Clause 1.5 (Use of Generic names of drugs) of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prescribes "Every physician should prescribe drugs with generic names legibly and preferably in capital letters and ensure that there is a rational prescription and use of drugs". The Medical Council of India vide its letter dated 21.04.2017 addressed to all Medical Colleges/Hospitals/Director, Medical Education/Health Secretary of all States/State Medical Councils/Director, Health Services directed the registered medical practitioners to comply with the provisions of above mentioned Regulations. Further, Clause 6.8 (Code of Conduct for doctors in their relationship with pharmaceutical and allied health sector industry) of the said regulations prohibits doctors from taking gifts, travel facilities, hospitality and cash or monetary grants from pharmaceutical and allied health sector industry. Violation of these norms prescribes severe punishment as laid down in the said regulations."

[Ministry of Chemicals & Fertilizers (Department Of Pharmaceuticals)
O.M. No. 31026/07/2019-Pricing dated 27/09/2019]

Recommendation (Sl. No. 4.7)

4.3 The observations / recommendations of the Committee are as under :-

"The Committee note that on the issue of violation of Drug Price Control Order (DPCO),2013 with respect to overcharging, the National Pharmaceuticals Pricing Authority issued Demand Notices but the actual amount recovered in 2013-14, 2014-15, 2015-16, 2017-18 and 2018-19 is Rs 40.08 crores, Rs.90.17 crores, Rs. 12.32 crores, Rs. 148.42 crores and Rs. 17.43 crores respectively which is too meager in comparison to the amount due to be recovered which was Rs. 406.83 crores, Rs. 581.10 crores, Rs.931.63 crores, Rs.704.12 crores and Rs. 194.81 crores respectively during the period except in 2016-17 when out of Rs. 333.97 crores, Rs. 302.08 crores were recovered. The Committee firmly feels that unless DPCO rules are made stringent and effectively implemented, the unfair market practices by pharma companies may continue to hamper the availability of affordable medicines to the people. Since overcharging of drugs/medicines is a violation of consumers right to basic healthcare, the Committee strongly recommend that if the manufacturer do not deposit the demanded amount within the prescribed time limit given by NPPA, cancellation of licenses of such companies to manufacture that medicine/drug may be considered. Similar action may also be taken on retailers who indulge in overcharging of drugs/medical devices."

Reply of the Government

4.4 The Action Taken Reply of the Department of Pharmaceuticals is as under :-

"As per the prevalent practice in the NPPA, the cases where the demanded amount is not deposited by the manufacturers are referred to concerned District Collectors for recovery of the overcharged amount as arrears of land revenue under Section-3 of the Essential Commodities Act, 1955. However, there is no such provision in the DPCO, 2013 regarding cancellation of license of such defaulting manufacturers or the retailers.

There is no provision under the Drugs & Cosmetics Act, 1940 & Rules, 1945 regarding cancellation of licenses of the manufacturers who do not deposit the demanded amount within the prescribed time limit given by NPPA. Thus, presently it is not permitted under the prevalent law."

Comments of the Committee
(Please see Para No.13 of Chapter- I of the Report)

Recommendation (Sl. No.4.8)

2.5 The observations / recommendations of the Committee are as under :-

"The Committee are concerned to note the sale of spurious and non-standard quality drugs/medicines in the country. Drug samples are annually tested by the State Drugs Controller in States as well as Zonal and Sub-Zonal Offices of Central Drug Standards Control Organization. However, the Committee are discomfit to note that the number of samples tested is very less, such that 74586, 76721 and 82599 samples were tested by State Drug Controller during 2015-16, 2016-17 and 2017-18 respectively. During the same period 2897, 5207 and 7088 samples were tested by Central Drug Standards Control

Organization. Considering the size of the country and the huge quantum of medicines being distributed and sold in the country, this sample size is not adequate to measure the actual problem of spurious and nonstandard quality drugs in the country. The Committee also note that the punishment for the spurious drugs under the amendments made in Drugs and Cosmetics Act 1940 which came into force since 10th August, 2009 are stringent and 22 States have set up designated Special Courts for the purpose. However, the Committee is dismayed to note that the decision is pending in most of cases such that in the year 2015-16 out of 289 prosecutions launched against manufacture, sale and distribution of spurious/adulterated drugs only 2 cases have been decided. Similarly in 2016-17 out of 186 cases of prosecutions against manufacture, sale and distribution of spurious/adulterated drugs only 17 cases were decided and in 2017-18 out of 131 prosecution cases only 16 cases were decided. The Committee, therefore, strongly recommend that the Government should take adequate measures to considerably increase the number of samples of drugs to be tested so as to instill fear in those who indulges in sale/distribution of spurious/non-standard quality drugs. There is also urgent need for time bound decision on the prosecutions launched against manufacture, sale and distribution of spurious/non-standard quality. The Committee in this regard recommend that more Special Designated Courts may be opened in all the States/UTs and those courts may also impressed upon the need for timely disposal of cases."

Reply of the Government

2.6 The Action Taken Reply of the Department of Pharmaceuticals is as under :-

"Measures taken to increase the number of samples tested:

Ministry of Health &. Family Welfare and Central Drugs Standard Control Organization (CDSCO) have taken various regulatory measures from time to time to strengthen the Drug Regulatory System including the testing of samples to ensure the quality of drugs in the country.

Details are as under:

(i) State Drugs Controllers and CDSCO have been sensitized from time to time through Drugs Consultative Committee (DCC) meetings regarding issues related to the quality of drugs in the country.
(ii) The number of sanctioned posts in CDSCO has been increased from 111 in 2008 to 510 in 2018.
(iii) Testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened to expedite testing- of drug samples in the country.
(iv) To expedite the procedure of test and analysis by the laboratories, G.S.R. 103(E) dated 17.02.2017 was published providing that the results of test or analysis shall be furnished by the Government Analysts within a period of sixty days from the receipt of sample. It has also been provided that where it is not possible to test or analyse the sample within the specified period, the Government Analyst shall seek extension of time from the Government giving specific reasons for delay in such testing or analysis.
(v) As a result, year-wise number of samples tested in the country has gradually increased and the same may be observed from the following:-

Data on the number-of samples tested during the last five years:

(A) Testing by State/UT Drugs Control Authorities:-

Year	2013-14	2014-15	2015-16	2016-17	2017-18
No. of drugs samples tested	58537	72712	74586	76721	82599

(B) Testing by CDSCO:

Year	2013-14	2014-15	2015-16	2016-17	2017-18
No. of drugs samples tested	4110	3605	2897	5207	7088

(vi) Further, the Government has approved a proposal for strengthening the drug regulatory system in the country, both at the level of Central and the State Governments at a total expenditure of Rs. 1750 crores. Out of this, Rs. 900 crore is for strengthening the central drug regulatory structures and Rs.850 crore is for strengthening the drug regulatory system in the States. During the years 2016-17 and 2017-18, Rs. 128.39 crore was released under the Central component whereas Rs. 87.90 crore was allocated during 2018-19 under this component. Under the State component, Rs. 81.36 crore was released during 2016-17 and 2017-18 whereas Rs. 206 crore was allocated during 2018-19 under this component.

(vii) The Government has approved setting up of 08 Mini Drug Testing Laboratories at major ports and airports in the country to monitor the standards of imported and exported drugs and reduce the time spent on quality assessment. The 8 Mini Drug Testing Laboratories are situated at the following locations:-

1. Hyderabad (Airport)	2. Mumbai (Airport)
3. Bangalore (Airport)	4. Nhava Sheva (Sea Port)
5. Ahmedabad (Airport)	6. Kolkata (Sea Port)
7. Delhi (Airport)	8. Chennai (Sea Port)

Necessary accommodation for all Mini Labs except at Kolkata Sea Port has been arranged.

The aforesaid measures will increase the number of samples of drugs to be, tested so as to instill fear in those who indulge in sale/distribution of spurious/'not of standard quality (NSQ) drugs.

Measures for time bound decision on prosecutions and setting up of more Special Designated Courts:

As already stated, Ministry of Health & Family Welfare and Central Drugs Standard Control organization (CDSCO) have taken various regulatory measures from time to time to strengthen the Drug Regulatory System including time bound decision on prosecution launched against the manufacture, sale and distribution of spurious/NSQ drugs to maintain the quality of drugs in the country.

As regards setting up of more Special Designated Courts, it may be mentioned that State/UT Governments have been requested to be proactive in this regard to set up more Special Designated Courts to ensure time bound disposal of the cases of prosecution launched against the manufacture, sale and distribution of spurious/NSQ drugs so as to maintain the quality of drugs in the country."

[Ministry of Chemicals & Fertilizers (Department Of Pharmaceuticals)

O.M. No. 31026/07/2019-Pricing dated 27/09/2019]

CHAPTER – III

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

Recommendation (Sl. No. 4.3)

3.3 The observations / recommendations of the Committee are as under :-

"The Committee note that the Department has adopted market based pricing system for drugs in the country even though it has accepted that cost- based system may be ideal and that may give a true reflection of drug prices. However, the Government has adopted market based system as it is very difficult to arrive at a cost-based pricing due to non-divulgence of actual cost by every company. The government decided to go for market based pricing to bring in more transparency, less intrusive inspector raj and to encourage innovation and research in the field. In this regard, the Committee are of the firm view that it is the responsibility of the Government to protect the interests of common man through actual and affordable prices for drugs in the country. The Committee, therefore, recommend that an expert Committee should be constituted to study the impact of market based and cost based pricing systems on drug prices in the country and to take appropriate steps on the basis of the recommendations of that Committee."

Reply of the Government

3.4 "Under National Pharmaceutical Pricing Policy-2012 (NPPP-2012), the regulation of prices of drugs is on the basis of regulating the prices of formulations through Market Based Pricing. This was different from the earlier principle of regulating the prices through Cost Based Pricing under the Drug Policy, 1994; wherein ceiling prices of drugs are fixed through a cost **+** margin method using cost data provided by individual drug manufacturers. Under Market Based Pricing, the ceiling price is first determined by working out simple average of Price to Retailer (PTR) in respect of all branded and generic versions of all formulations, which are having a market share of 1 % and above and then adding a notional retailer margin of 16%.

3.5 The reasons for the shift in the methodology for price fixation from cost based to market based was clearly spelt out in NPPP-2012 as mentioned below:-

(i) Under Cost Based Pricing, the prices of drugs had to be calculated afresh every year which require a complex variety of data. For this, the manufacturers were required to provide their pricing data in an extremely detailed manner which was intrusive and hence highly resisted by the individual manufacturers resulting in possible manipulation and time delay of provision of the base costing data. This also made it difficult for Department of Pharmaceuticals to properly check the data provided by individual manufacturers in a timely and adequate manner. Secondly, the data was also subject to variations in terms of production cost depending on technologies used for production. Also the government had no control on the cost of production of medicines by different companies.

(ii) Under Market Based Pricing, the ceiling price is fixed on the basis of market data for Price to Retailers (PTR) which is easily available. The Price to Retailer data of

pharmaceutical companies which have more than 1 % market-share in the sales of that formulation is picked up from the Pharmatrac database. It is this data which is taken for calculating the average PTR and finally the ceiling price. The calculation sheets are uploaded on the website of the National Pharmaceutical Pricing Authority (NPPA). The process of ceiling price fixation under this methodology is thus crystal clear and transparent and is available in public domain.

(iii) The Indian economy is largely market-driven and, particularly in the area of pricing of manufactured products, prices are determined by market conditions and market forces. Determination of prices, based on Cost Based Pricing, particularly where the input prices themselves were not subjected to any form of price control and were determined in the open market by market forces, was found to be subjective and anomalous. It was observed that, this would, in medium and the long term, lead to severe distortions, particularly in the product-mix and investment patterns in the industry and there was a serious possibility of production moving out of controlled drugs into non-controlled drugs. This would have led to serious implications for the availability of National List of Essential Medicines (NLEM) medicines in the future and for the growth and structure of the Pharmaceutical Industry as a whole. Further, the resultant implications on the growth and innovation would have impacted the industry's ability to invest in Research and Development (R&D) for enhancing the capabilities to capture the overseas markets.

(iv) Under Cost Based Pricing, as the controlled prices of formulations based on a particular API were determined on a 'lowest common denominator' basis, they tended to be clustered within a narrow band. This allows virtually no space for a new entrant to come in at an uncovered price point. As a result, production activity and competition in the product segment tended to stagnate. In the Market Based Pricing, since there is a wider price-band, in comparison to the cost based method, it was held that there would be ample space for manufacturers;

domestic, foreign or new entrant, to position themselves in an appropriate price band below the ceiling price and thereby also retain competition in the market.

(v) The price determined on the basis of normative cost under the earlier cost based pricing methodology was unable to account for the heterogeneity in the Indian pharmaceutical industry, as it did not distinguish between companies that invested in state-of-the art world class plants and those which were not so, even though, it did recognize costs associated with special features having therapeutic value. Further, Cost Based Pricing did not recognize costs incurred in innovation in drug delivery or in R&D in New Chemical Entities thereby it was discouraging innovation and efficiency in Pharmaceutical Industry.

(vi) The market based formula, which arrives at a moderated price based on simple average methodology, allows availability of medicine at different price points, which, to some extent limits inter-brand price differences. Further, prices of imported medicines etc. are also considered in the same basket, such that there is no differential treatment of foreign or domestically produced formulations.

(vii) In case of scheduled formulations, the notified ceiling price is subject to annual revision which is notified by National Pharmaceutical Pricing Authority (NPPA), and

which would be effective from the first day of April every year, based on the annual Wholesale Price Index [WPI] notified by the Department of Industrial Policy and Promotion with respect to the previous calendar year. The revision may mean increase or decrease depending on whether the WPI is positive or negative. This keeps the prices under control and also ensures availability. In fact, the ceiling price of the scheduled formulations was revised with effect from 1st April 2014, applying the WPI of 6.32%; again with effect from 1st April 2015, applying the WPI of 3.849%, again from 1st April 2016 applying the WPI of (-) 2.711% and again from 1st April 2017 applying 1.972%. Protection from cost escalation is already dealt in the price revision formula as revised prices are indexed to WPI. Accounting for general inflation, can, to a large extent, provide adequate buffer for contingencies such as rise in input costs, increase in the cost of active pharmaceutical ingredients etc. Under Market based Policy, the DPCO 2013 provides for reduction in ceiling price of scheduled formulations on revision of NLEM (Schedule I) or five years whichever is earlier, which was not available under cost based system. Thus by adjusting for inflation, Market Based Pricing accounts for variability in the economy as against the argument that Market Based Pricing takes on components which are based on variable factors.

(viii) Under Cost Based approach, the criteria of selecting medicines for price control were market share and monopoly. However, this criterion had shifted to essentiality as stipulated by the NPPP-2012. The essential medicines are essentially the medicines used by majority of the Indian population for majority of the diseases. By shifting to the market based pricing policy, NPPP-2012 had tried striking a balance between affordability and availability of essential medicines.

3.6 That under Para 19 of the Drugs (Prices Control) Order, 2013, Government can, in case of extraordinary circumstances, if it considers necessary so to do in public interest, fix the ceiling price or retail price of any drug for such period as it may deemed fit. The Government has used this provision for fixing the ceiling price of essential medicines which are used for treatment of Diabetic and Cardio Vascular diseases. Recently, the government has also used this power for fixing the ceiling price of Coronary Stents, Knee Implants and Anti-Cancer Drugs. These are significant steps taken by the Government to bring down out of pocket expenditure for healthcare expenses in the country.

3.7 That under the present Market based Policy, the ceiling price fixation has resulted in the estimated saving to general public as follows:-

Category	Savings Estimated(Rs. in crore)
NLEM 2011	2,422
NLEM 2015	2,644
NLEM 2015- Coronary Stents	4,450
Para 19 - Knee Implants	1,500
Para 19 - Cardio and Anti Diabetic drugs	350
Para 19 – Anti-Cancer Drugs	980
Grand TOTAL	**12,443**

Hence the contention that price control based on market driven factors would be unreasonable, irrational or disadvantageous to the consumer is not supported by above mentioned facts and figures.

3.8. That market-based pricing is definitely a superior formula for fixing the ceiling price of drugs. Unlike cost-based method, it is based on a reliable and authentic data set available on regular intervals, hence accuracy and validity is maintained in the process. Also the entire procedure of ceiling price fixation is available in the public domain which accounts for transparency and accountability of the process. Further, under Market Based Pricing, the interests of both consumers and producers/suppliers are protected by keeping a wider price band in comparison to cost based method. The ceiling price fixed is subjected to annual revision on the basis of Wholesale Price Index (WPI), thereby maintaining price stability and ensuring un-interrupted supply of essential medicines. The new ceiling price fixation has also resulted in enormous amount of savings to the general public in terms of reduction in out-of-pocket health expenditure. Further, the main argument against Market-Based Pricing that the prices thus fixed are above the prices fixed under Cost-Based Pricing, is denied as the prices fixed under the two methodologies are almost similar. Thus the ceiling price fixation based on Market- Based Pricing fits well with the objective of NPPP-2012 of ensuring sustained availability of essential medicines at reasonable prices while providing sufficient opportunity for innovation and competition to support the growth of the pharmaceutical industry, thereby meeting the goals of employment and shared economic well-being for all."

[Ministry of Chemicals & Fertilizers (Department Of Pharmaceuticals)

O.M. No. 31026/07/2019-Pricing dated 27/09/2019]

Recommendation (Sl. No. 4.6)

3.9 The observations / recommendations of the Committee are as under :-

"The Committee are satisfied to note that the total number of scheduled formulations have increased from 530 under NLEM 2011 to 851 under NLEM 2015. It is also heartening to note that ceiling prices of 370 scheduled formulations under NLEM 2011 which witnessed 0 to 30% decrease with respect to maximum price has increased to 670 formulations under NLEM 2015. However, the number of scheduled formulations which witnessed 35-40 percentage and above 40 percentage reduction with respect to maximum price have reduced from 34 to 24 and 126 to 59 under NLEMs 2011 and 2015, respectively. The clarification provided by the Department in this regard that the reduction in these cases are limited while refixing the ceiling price of the common formulations under NLEMs 2011 and 2015 is not satisfactory. The Committee recommend that the Government should take all necessary steps to bring more number of formulations under these two categories so that overall prices of drugs in the country are affordable to people particularly to poor people."

Reply of the Government

"The Ministry of Health & Family Welfare (M/o H&FW) notifies the National List of Essential Medicines. As per the NPPP, 2012, all the medicines specified in the National List of Essential Medicines are included in the First Schedule of DPCO, 2013 and brought under

price control. Under the DPCO, 2013, prices of drugs are fixed on 'Market based pricing' methodology which is in accordance with the NPPP, 2012. Since the prices of drugs are fixed on 'Market based pricing', the number of formulations witnessing reduction by a particular percentage cannot be controlled or determined by the Government. "

[Ministry of Chemicals & Fertilizers (Department Of Pharmaceuticals)

O.M. No. 31026/07/2019-Pricing dated 27/09/2019]

CHAPTER – IV

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

Recommendation (Sl. No.4.5)

The observations / recommendations of the Committee are as under :-

"The Committee note that the Ministry of Health and Family welfare has constituted a Standing National committee on Medicines to review and revise the National List of essential Medicines (NLEM). There are 23 Members in the Committee representing various Health and family welfare sectors. One representative is from the Department of Pharmaceuticals but there is no representation for NPPA in the committee. Even though a representative from NPPA will be a special invitee for the meetings of the Committee, permanent representation has not been given to NPPA. NPPA is entrusted with the responsibility of fixation and revision of prices of scheduled formulations under drugs (Prices control) order and also responsible for monitoring and enforcing drug prices in the country. The Committee, therefore, recommend that permanent representation should be given to NPPA in the Core Committee."

Reply of the Government

4.2 The Action Taken Reply of the Department of Pharmaceuticals is as under :-

"A Standing National Committee on Medicines and other Health Care Products (SNCM&HCP) has already been constituted by the Ministry of Health & Family Welfare to review and revise the NLEM. It is submitted that as per Order dated 03/07/2018 (Annexure - I), a representative of NPPA has been made a special invitee. The Member Secretary (NPPA) and Director, NPPA are attending the meetings of the aforesaid committee as special invitees."

Comments of the Committee

(Please see Para No.10 of Chapter- I of the Report)

Recommendation (Sl. No. 4.9)

4.5 The observations / recommendations of the Committee are as under :-

"The Committee are constrained to note that presently National Pharmaceutical Pricing Authority (NPPA) has only a part-time member apart from the chairperson. NPPA is entrusted with the responsibility of enforcing the Drugs (Prices control) order and to monitor availability of drugs in the country, identify shortages and to take remedial steps thereon. In the absence of even a full time member and a strong management team, the Committee are skeptical that the authority will be able to carry out its functions effectively. The Committee are of the view that the current composition of the authority needs to be expanded to include more full time expert members so that the administrative efficiency of the organization is

enhanced to fulfill the mandate of NPPA. Thus, the Committee strongly recommend that the Composition of NPPA may be reviewed and more full time members may be appointed."

Reply of the Government

4.6 The Action Taken Reply of the Department of Pharmaceuticals is as under :-

"The issue of restructuring of the NPPA was examined and it has been decided to strengthen the NPPA at lower levels in order to enable it to fulfill its mandate. Accordingly, NPPA has been asked to prepare a proposal for strengthening the NPPA at lower levels."

Comments of the Committee

(Please see Para No.16 of Chapter- I of the Report)

CHAPTER – V

OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT ARE STILL AWAITED

-NIL-

New Delhi;
25 November, 2019
04 Agrahayana 1941 (Saka)

Kanimozhi Karunanidhi
Chairperson
Standing Committee on
Chemicals and Fertilizers

MINUTES OF THE FIFTH SITTING OF THE
STANDING COMMITTEE ON CHEMICALS & FERTILIZERS

(2019-20)

The Committee sat on Wednesday, 13th November, 2019 from 1500 hrs. to 1700 hrs. in Committee Room no. 2, Block A, Extension to Parliament House Annexe Building, New Delhi.

PRESENT

Smt. Kanimozhi Karunanidhi- Chairperson

MEMBERS

LOK SABHA

2 Shri Satyadev Pachauri

3 Shri Arun Kumar Sagar

4 Shri Prabhubhai Nagarbhai Vasava

5 Dr. Manoj Rajoria

RAJYA SABHA

6 Shri G.C. Chandrashekhar

7 Dr. Anil Jain

8 Shri Ahmad Ashfaque Karim

9 Shri Vijay Pal Singh Tomar

SECRETARIAT

1. Shri Manoj Kumar Arora - Officer on Special Duty(LSS)
2. Shri A. K. Srivastava - Director
3. Shri C. Kalyanasundaram - Additional Director

LIST OF WITNESSES

I. MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF FERTILIZERS)

1	Shri Chhabilendra Roul	Secretary (Fert.)
2	Shri Dharam Pal	Addl. Secretary
3	Shri Partha Sarthi Sen Sharma	Joint Secretary
4	Shri Vinay Kumar Pandey	Director (P&K)
5	Shri Parbhas Kumar	Director (UPP)
6	Sh. B. Venkatesh	Director (CE)

2. At the outset, Hon'ble Chairperson welcomed the members of the Committee and representatives of the Ministry of Chemicals & Fertilizers (Department of Fertilizers) and other officials. Chairperson also introduced Dr. Manoj Rajoria, the newly nominated Member to the Committee.

3. After the witnesses introduced themselves, Secretary, Department of Fertilizers made a power point presentation to the Committee regarding 'System of Fertilizer Subsidy' of the Department of Fertilizers.

4. XXXXX XXXX XXXX XXXX XXXX

5. XXXXX XXXX XXXX XXXX XXXX

6. XXXXX XXXX XXXX XXXX XXXX

7. XXXXX XXXX XXXX XXXX XXXX

8. A copy of the verbatim record of the proceedings of the sitting has been kept.

9. The Committee thereafter took up for consideration and adoption the draft Action Taken Report on subject 'Pricing of Drugs with Special Reference to Drugs (Prices Control) Order, 2013 (Department of Pharmaceuticals). After deliberations, the Committee adopted the draft report unanimously without any changes/amendments. The Committee also authorised the Chairperson to finalize and present the report to the Parliament.

The Committee then adjourned.

Appendix – II
(*Vide* Para-3 of Introduction to Report)

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE FORTY-SIXTH REPORT (SIXTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS ON THE SUBJECT 'PROMOTION AND CO-ORDINATION OF BASIC-APPLIED RESEARCH IN AREAS RELATED TO PHARMACEUTICAL SECTOR' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACUETICALS)

I	Total No. of Recommendations	9
II	Observations / Recommendations which have been accepted by the Government: (*Vide* Recommendation Nos. 4.1, 4.2, 4.4, 4.7 & 4.8)	5
	Percentage of Total	55.6%
III	Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply:- (*Vide* Recommendation No. 4.3 and 4.6)	2
	Percentage of Total	22.2%
IV	Observations / Recommendations in respect of which reply of the Government have not been accepted by the Committee and which require reiteration:- (*Vide* Recommendation No. 4.5 and 4.9)	2
	Percentage of Total	22.2%
V	Observations / Recommendations in respect of which final replies of the Government are still awaited: (Nil)	0
	Percentage of Total	100%