54	STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2018-19) SIXTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

"PRICING OF DRUGS WITH SPECIAL REFERENCE TO DRUGS (PRICES CONTROL) ORDER, 2013"

FIFTY-FOURTH REPORT

LOK SABHA SECRETARIAT
NEW DELHI

February, 2019/ Magha, 1940 (Saka)

CC&F.No.54

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(SIXTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

"PRICING OF DRUGS WITH SPECIAL REFERENCE TO DRUGS (PRICES CONTROL) ORDER, 2013"

Presented to Lok Sabha on 13 February 2019

Laid in Rajya Sabha on 13 February 2019

LOK SABHA SECRETARIAT
NEW DELHI
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COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2018-19)

Shri Anandrao Adsul - Chairperson

MEMBERS

LOK SABHA

2. Shri Sarfaraz Alam
3. George Baker
4. Shri B.N. Chandrappa
5. Shri Pankaj Chaudhary
6. Shri Sankar Prasad Datta
7. Dr. (Smt.) Ratna De (Nag)
8. Smt. Veena Devi
9. Shri R.Dhruvanarayana
10. Shri Innocent
11. Shri K. Ashok Kumar
12. Dr. (Prof.) Azmeera Seetaram Naik
13. Shri Chhedi Paswan
14. Smt. Kamla Devi Patle
15. Sushree Sadhvi Savitri Bai Phoole
16. Shri S. Rajendran
17. Dr. Kulamani Samal
18. Dr. Uma Saren
19. Dr. Krishna Pratap Singh
20. Smt. Rekha Arun Verma
21. Vacant

RAJYA SABHA

22. Shri Biswajit Daimary
23. Shri Prem Chand Gupta
24. Shri B.K. Hariprasad
25. Shri Ranvijay Singh Judev
26. Shri Sanjay Dattatraya Kakade
27. Elamaram Kareem
28. Dr. Sanjay Singh
29. Shri Vijay Pal Singh Tomar
30. Shri Abdul Wahab
31. Vacant

SECRETARIAT

1. Shri V.K. Tripathi - Joint Secretary
2. Shri C. Kalyanasundaram - Additional Director
3. Ms. Sonia Sankhla - Executive Assistant

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2018-19) having been authorized by the Committee to submit the Report on their behalf, present the Fifty-fourth Report (16th Lok Sabha) on the subject 'Pricing of Drugs with special reference to drugs (Prices Control) Order**,** 2013' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

The subject 'Pricing of Drugs with special reference to drugs (Prices Control) Order**,** 2013' has been selected by the Standing Committee on Chemicals and Fertilizers (2018-19) for examination and report. The Committee were briefed on the subject by the representatives of the Department of Pharmaceuticals on 24.05.2018 and their oral evidence was taken on the subject in the sitting held on 22.10.2018

The Report was considered and adopted by the Committee at their sitting held on 11-02-2019.

The Committee wish to express their thanks to the officers of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for furnishing necessary written replies, views and other material / information to the Committee for the examination of the subject.

The Committee also place on record their appreciation for the valuable assistance rendered to them by the officials of Lok Sabha Secretariat attached to the Committee.

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

New Delhi.

11 February, 2019
22 Magha, 1940 (Saka)

Chairperson
Standing Committee on
Chemicals and Fertilizers

REPORT

CHAPTER-I

INTRODUCTORY

The expenditure on medicines forms a major chunk of medical expenditure both in rural and urban areas of the country. As per the Publication titled "Health in India" - NSS 71st Round (January-June, 2014) brought out by the National Sample Survey Organization (NSSO), in 2014 at all India level as well as the state level the highest percentage of total expenditure is made towards medicines. At all India level, around 72% in rural sector and 68% in urban sector of the total medical expenditure was done for purchasing medicines. Hence, the affordability of medicines is a crucial element in availing medical treatment by all sections of the people particularly poor people in the country. Poor people including those below the poverty line may face immense difficulties to cope with the expenditure on medicines while treating a disease/ailment. The Committee, therefore, selected the subject "Pricing of drugs with special reference to Drug (Price Control) Order, 2013 for examination and report on priority basis. Succeeding parts of this Report deal with the various aspects of this subject.

ORIGIN AND DEVELOPMENT OF PRICE CONTROL REGIME IN INDIA

1.2 Price control over drugs was first introduced in the country with the promulgation of the Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963. These were promulgated under the Defense of India Act, and had the effect of freezing the prices of drugs as on 1st April 1963. The Price Control Order of 1963 was revisited in 1966, in the backdrop of the criticism that the prices of relevant raw materials were not similarly frozen. Selective increase in prices was allowed in 1966 with prior approval of the Government. In 1968, the new drugs and the drugs having pharmacopoeia name (generic name) were exempted from prior price approval.

1.3 Subsequently, the Drugs (Prices Control) Order 1970 was promulgated which had provision of mark-up applicable to essential and other formulations with overall profitability not exceeding 15 per cent on sales turnover. The Drugs (Prices Control) Order of 1966 and the Drugs (Prices Control) Order of 1970 were issued under the "Essential Commodities Act" 1955[“EC Act”] by declaring drugs to be essential commodities.

1.4 Cost based pricing came into effect with the notification of Drugs (Prices Control) Order of 1979. This was the underlying principle of the Drugs (Prices Control) Order, 1987 and the Drugs (Prices Control) Order, 1995 [DPCO, 1995]. The DPCO, 1995 implemented the Drug Policy of 1994. The Drug Policy of 1994 was introduced in the context of the liberalization of economy and financial reforms of 1991. The principle for price control broadly adopted in this policy represented a radical departure from the earlier policies. As per the criteria of 1994 policy, a list of

74 bulk drugs was identified. These drugs, as well as formulations based on these drugs, were brought under the price control regime.

1.5 The National List of Essential Medicines 2003 ["NLEM-2003"] was finalized by the Ministry of Health & Family Welfare. A Task Force set up under the Chairmanship of Principal Advisor, Planning Commission, Dr. Pronab Sen submitted its recommendations in 2005 on various aspects of drug pricing and other aspects related to the pharmaceutical sector.

1.6 Meanwhile, the Ministry of Health and Family Welfare notified the National List of Essential Medicines, 2011 ["NLEM-2011"]. NLEM,2011 consisted of 377 medicines and 948 formulations. The National Pharmaceutical Pricing Policy ["NPPP-2012"] was thereafter notified on 07.12.2012.

1. 7 The objective of National Pharmaceutical Pricing Policy (NPPP)-2012 is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines i.e. *essential medicines* at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well being for all. Subsequently the Government notified the Drugs (Prices Control) Order, 2013 ["**DPCO, 2013**"] on 15.05.2013. The NLEM-2011 has been adopted as the First Schedule of the Drugs (Prices Control) Order 2013.

1.8 In pursuance of the Policy, the Drugs (Prices Control) Order, 2013 (DPCO, 2013) has been implemented. The essential medicines included in Shedule-1 of DPCO are subject to price ceilings and thus available at reasonable prices. The medicines which are not included in Schedule -1 are not subject to price ceilings and through this measure sufficient opportunity has been provided to Pharma industry for innovation and competition. The preferred objectives of NPPP 2012 have been achieved to a considerable extent.

NATIONAL PHARMACEUTICAL PRICING POLICY (NPPP), 2012

1.9 As per the information furnished by the Ministry, the three key principles of the National Pharmaceutical Pricing Policy(NPPP)-2012 are as below:

(i) Essentiality of Drugs: The regulation of prices of drugs is on the basis of essentiality of drugs as per the medicines under NLEM-2011. The NLEM 2011 has been as the First Schedule of DPCO 2013. Formulations listed in the National List of Essential Medicines (NLEM) are under price control.

(ii) Control of Formulations prices only: The prices of formulations only are to be regulated and not the prices of the Bulk Drugs and the resulting formulations as adopted in the Drug Policy 1994.

iii) Market Based Pricing: The ceiling prices of medicines is fixed on Market Based Pricing (MBP) methodology. In this regard the Committee were informed further during evidence that the ceiling price is calculated based on

‘market based data’ wherein 'Average Price to Retailer’ is considered for pricing. MRP is arrived at by adding Local Taxes to Ceiling Price. Brands selling above Ceiling Price have to bring down to Ceiling Price and the brands selling below Ceiling Price having to retain the same price.

IMPORTANT FEATURES OF NPPP-2012

1.10 As per the information provided by the Department, the following are the features of NPPP, 2012:-

(i) Methodology of Price Fixation: The ceiling prices of scheduled medicines, is worked out, adopting the Simple Average Price of all the brands having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of the total market turnover of that medicine, and then by adding a notional 16 % retailer's margin to the average arrived at, for working out the ceiling price.

ii) Span of Control: The Span of Price Control is as per the dosages and strengths of formulations as listed in Schedule I of DPCO 2013.

iii) Revision of Prices: The ceiling prices of scheduled medicines will be allowed an annual increase as per the Wholesale Price Index [“WPI”] as notified by the Department of Industrial Policy & Promotion.

iv) Non-scheduled formulations: In order to keep a check on overall drug prices, of prices of all the drugs, even the non-scheduled will be done on regular basis. Non-scheduled medicines are allowed a price increase of 10% per annum.

(v) Availability of NLEM-2011 and to prevent shifting the manufacturers out of Price Control: If a manufacturer of a scheduled formulation with dosages and strengths as specified in the First Schedule launches a new drug by combining the scheduled formulation with either a scheduled or a non-scheduled formulation or by changing the strength and dosages of the scheduled formulation, such manufacturers are required to seek prior price approval from the Government before launching the new drug.

(vi) No separate price for Imported Drugs: The Ceiling Prices determined for scheduled formulations shall be applicable to those which are domestically produced and imported. Under DPCO, 1995, the prices of imported scheduled medicines were being fixed on the basis of landed cost declared by the importer.

(vii) Exemptions: To promote innovation and R&D, exemption from price control is given to formulations developed through indigenous R&D etc.

DRUGS (PRICES CONTROL) ORDER (DPCO) -2013

1.11 The Drugs Price Control Order, 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. However, in addition to price fixation, provisions have been made in DPCO, 2013 to ensure that there is reduction in the ceiling price with respect to the price of highest priced brand (of the essential medicine) having at least one percent market share, proper and effective control and regulation in price movement of scheduled as well as non-scheduled medicines and availability of the essential medicines. Some of such provisions are as below:

(i) To ensure reduction in ceiling price in cases where there is absence of competition, the percentage reduction of the highest priced formulation of other strengths and dosages of the same formulation, or another scheduled formulation in the same sub-therapeutic group or the another scheduled formulation of the same therapeutic group are taken into account (Paragraph 6(1) of DPCO, 2013).

(ii) Continuation of price control if a scheduled formulation is re-launched by another manufacturer (Paragraph 12(2) of DPCO, 2013).

(iii) The manufacturers selling scheduled formulations below the ceiling price are to maintain the sub-ceiling price (Paragraph 13(2) of DPCO, 2013).

(iv) The manufacturers proposing to produce a combination/new strength/ new dosage form of the medicines included in the First Schedule, need to take price approval before selling it (Paragraph 15 of DPCO 2013).

(v) Further, the manufacturers have to take permission of the Government before discontinuing the manufacture of essential medicines (Paragraph 21 of DPCO, 2013).

(vi) The ceiling price of an essential medicine would be reviewed in case of change in market structure of the medicine (Paragraph 18(ii) and 18(iii) of DPCO, 2013).

(viii) The Government can fix the ceiling price of any medicine even the non-scheduled one in case of certain extra ordinary situations or in public interest (Paragraph 19 of DPCO, 2013).

(ix) The ceiling price, so notified by the Government has to be implemented within 45 days of the notification for all the medicines available in the market (Paragraph 13(1) of DPCO, 2013).

(x) Schedule I of the DPCO, 2013 consists of NLEM-2011 and it covers 27 therapeutic categories and includes the medicines for HIV, cancer, diabetes, Heart Diseases amongst others. There were 628 formulations covering 348 medicines.

(xi) Schedule I of the DPCO 2013 was revised on 10.3.2016 based on National List of Essential Medicines 2015, and it covers 30 therapeutic categories and includes the medicines for HIV, cancer, diabetes, Heart Diseases, ENT amongst others. There were 948 formulations covering 376 medicines. Coronary Stents were added later on 22.12.2016 making total of medicines to 377 and number of therapeutic categories to 31.

MARKET BASED PRIZING MECHANISM

1.12 In regard to market based pricing, the Committee pointed out during oral evidence of the representatives of Department of Pharmaceuticals that cost of medicines should be fixed as done in the case of other commodities because medicines are essential needs of common man and that there is lot of difference in the prices of big and small drug manufacturing companies. In this regard, the Secretary, Department of Pharmaceuticals made the following submission:-

> "Sir, for those things, somebody will need to study what is the right profit margin. We did not have any drug innovation for the last 20 years because we are not investing enough. One innovation will cost, at least, a billion dollar of investment. There are 99 failures and then you got one success. Now, if I do not add the cost of the failures on the drug, then it will become difficult for me to do innovation. Nobody will experiment. If I put the drug price only at the cost-based or because I am not taking the cost of the failures in the experiments, it will be difficult for me to put the price of the drugs on the cost-based basis. Cost base presume that I am only calculating the cost of inputs which have gone into production of that drug but what about the failure in the production of the drug where I had put the money? There are complications in that and, I assure, that we will work out. We will try and see its feasibility. If it is feasible, we will do it. But, as of now, the Government of India, in its wisdom, in 2013, decided that we should move away from cost-based to the market-base. Sir, for those things, somebody will need to study what is the right profit margin. We did not have any drug innovation for the last 20 years because we are not investing enough. One innovation will cost, at least, a billion dollar of investment. There are 99 failures and then you got one success. Now, if I do not add the cost of the failures on the drug, then it will become difficult for me to do innovation. Nobody will experiment. If I put the drug price only at the cost-based or because I am not taking the cost of the failures in the experiments, it will be difficult for me to put the price of the drugs on the cost-based basis. Cost base presume that I am only calculating the cost of inputs which have gone into production of that drug but what about the failure in the production of the drug where I had put the money? There are complications in that and, I assure, that we will work out. We will try and see its feasibility. If it is feasible, we will do it. But, as of now, the Government of India, in its wisdom, in 2013, decided that we should move away from cost-based to the market-base."

1.13 During the course of the evidence, the Secretary further clarified regarding Government's decision to go for market based price fixation as under:-

> "it is now market-based. It was cost-based under DPCO, 1995 till 2013. Our experience in the cost-based calculation of price of the medicines was not very conducive to continue with it. One of the reasons was as follows. It is because the same drug may be manufactured by 200 companies. We take

the cost of each company differently. A company which is an exporting company consisting of scientists, having its own lab, and a big establishment will have a different cost whereas a small scale industry which is producing the same drug will have a different cost. The second reason was, we cannot audit the cost as such. Whatever the company gives that this is its cost, we have to accept it. That was leading to an inspectorial raj that I enter into their premise, start looking into their audit books and say that they imported this drug at this cost and not at that cost and this is only the conversion rate, etc. This was giving rise to a lot of problems in actual cost-based price fixing and that too was not very (representative) because not every company will divulge the cost.

As he had explained, these were not transparent costs, not known to the public that this is the right cost. In the market-based data, there is, at least, transparency. What we do is, we take every such formulation which is in the market, having more than one per cent market share, take their prices to the retail, which is a known price and average it out. There are plus and minus on both sides. The cost-based system may be ideal and that is something which is giving a true reflection. But it is very difficult to arrive at a cost-based pricing. So, the Government, in its wisdom at that point of time, decided that we would go for more transparency and less intrusive inspector *raj* and, therefore, we will go by the market data available instead of going to each factor and asking as to what their cost-based pricing is. That is the clarification."

1.14 The Committee also brought to the attention of the representatives of the Department that there is wide difference between the prices of Jan Aushadi and the branded medicines. The Secretary, Department of Pharmaceuticals clarified as below:-

"Jan Aushadhi is related to generic medicine. Drug is the same. When a brand name is given to paracetamol, it becomes (Crocin) Then, there is a whole lot of medical representatives by the company which is manufacturing crocin. So, crocin's rate will become a little higher because overhead cost of all the medical representatives is there. When crocin is sold as paracetamol, it is not promoted by anything. In fact, we should call it as promoted drug and unpromoted drug. These unpromoted drugs have therefore a lower cost because there is no promotional cost in that. There is no branding of that. There is no medical representative. There is nobody going to the doctor and saying that you please recommend crocin."

1.15 During the course of examination of the subject, the Committee asked about the factors that determine essentiality of drugs and inclusion of drug formulations/medicines under National List of Essential Medicines. The Department in their written replies stated as under:-

"As per Report of the Core-Committee for Revision of National List of Essential Medicines 2015, the criteria for inclusion of a medicine in NLEM are as follows:

- The medicine should be approved/licensed in India.
- The medicine should be useful in disease which is a public health problem in India.
- The medicine should have proven efficacy and safety profile based on valid scientific evidence.
- The medicine should be cost effective.
- The medicine should be aligned with the current treatment guidelines for the disease.
- The medicine should be stable under the storage conditions in India.
- When more than one medicine are available from the same therapeutic class, preferably one prototype/ medically best suited medicine of that class to be included after due deliberation and careful evaluation of their relative safety, efficacy, cost-effectiveness.
- Price of total treatment to be considered and not the unit price of a medicine.
- Fixed Dose Combinations (FDCs) are generally not included unless the combination has unequivocally proven advantage over individual ingredients administered separately, in terms of increasing efficacy, reducing adverse effects and/or improving compliance.
- The listing of medicine in NLEM is based according to the level of health care, i.e. Primary (P), Secondary (S) and Tertiary (T) because the treatment facilities, training, experience and availability of health care personnel differ at these levels.
- The criteria for deletion of a medicine from NLEM is as follows:
- The medicine has been banned in India.
- There are reports of concerns on the safety profile of a medicine.
- A medicine with better efficacy or favorable safety profiles and better cost-effectiveness is now available.
- The disease burden for which a medicine is indicated is no longer a national health concern in India.
- In case of antimicrobials, if the resistance pattern has rendered a medicine ineffective in Indian context.

As per Report of the Core-Committee for Revision of National List of Essential Medicines 2015, “Every medicine may be necessary or even critical for specific disease conditions for which it is indicated. But in the context of NLEM, a medicine may be essential considering the population at large. Hence, a medicine which is critical for a specific condition may not be listed in the list of essential medicines if the disease condition for which it is indicated has low prevalence or is rare. This does not mean that if a particular medicine is not included in the list of essential medicines, it is not necessary. In no way, exclusion of such medicines from the list undermines their importance in therapeutics and need of their availability at an affordable cost." It has further been stated by the Ministry that the NLEM 2015 has been prepared adhering to the basic principles of Efficacy, Safety, Cost-Effectiveness; consideration of diseases as public health problems in India. The list could be called as a Best-Fit List.

1.16 Regarding the composition of the Core Committee for Revision of National List of Essential Medicines constituted by the Ministry of Health and Family Welfare (MOHFW) and status of representation of Department of Pharmaceuticals/NPPA in this Core Committee to enhance coordination, the Department in their written reply

stated that as per the Office Order no. X.11035/923/2017-DRS, dated 03.07.2018, the Ministry of Health and Family Welfare has constituted a Standing National Committee on Medicines (SNCM) to review and revise the National List of Essential Medicines (NLEM) by way of addition and deletion in the existing NLEM in the context of contemporary knowledge of use of therapeutic products in health & hygiene of general public. The Composition of the committee is as follows:

1.	Secretary, DHR and DG, ICMR	Chairman
2.	Prof. Y.K. Gupta, Former Prof & Head Department of Pharmacology, AIIMS, New Delhi	Vice-Chairman
3.	A representative of director General of Health Services (DGHS), Ministry of Health and Family Welfare	Member
4.	A representative of Department of Pharmaceuticals, Ministry of Chemical & Fertilizers	Member
5.	A representative of National Vector Borne Diseases Control Programme, Ministry of Health & Family Welfare	Member
6.	Director, National Institute of Biologicals (NIB) NOIDA (U.P), Ministry of Health & Family Welfare	Member
7.	Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare Ghaziabad	Member
8.	Additional Director General (Stores, Directorate General Health Services, Ministry of Health and Family Welfare	Member
9.	Director, National Institute of Malaria Research, Ministry of Health and Family Welfare	Member
10.	Director, National Institute of Pharmaceuticals Education and Research (NIPER), Guwahati	Member
11.	Director-General, Employees State Insurance Corporation, Ministry of Labour or his nominee	Member
12.	Representative from Ministry of AYUSH	Member
13.	Director, Central Government Health Scheme (CGHS), Ministry of Health & Family Welfare	Member
14.	Representative of Department of Consumer Affairs	Member
15.	Five Experts as nominated by the Chair	Member
16.	Drugs Controller General (India), Ministry of Health and Family Welfare, or his representative	Member
17.	Principal Secretary, Health, Tamil Nadu	Member
18.	Principal Secretary, Health, Uttar Pradesh	Member

The representative of Department of Pharmaceuticals is a member of the Core Committee. A representative from NPPA will be special invitee."

1.17 To a query of the Committee, whether the National Pharmaceutical Pricing Policy has taken into account the income levels and purchasing power of people belonging to BPL families in preparing NLEM, the Department in their written reply stated as under:-

"The NLEM is prepared by the Core Committee for Revision of National List of Essential Medicines constituted by the Ministry of Health and Family Welfare. The income levels and purchasing power of people belonging to BPL families is not a relevant factor in preparing NLEM as diseases make no distinction between BPL & non BPL families."

1.18 In response to the Committee query during oral evidence of the Department held on 22.10.2018, regarding non-usage of BPL as a relevant factor in preparing NLEM the Secretary Department of Pharmaceuticals stated as under:

"…the National List of Essential Medicines (NLEM), is prepared by a technical committee which is looking into only the technical aspects of the medicine. Affordability is not their issue. When they prepare the National List of Essential Medicines, they only prepare the essentiality from the point of view of the disease burden of the region. Therefore, the sentence reads, which I agree, should have been framed better that the poverty or the income level is not considered while finalising the NLEM…."

1.19 The Committee also asked the Department to comment on the paradox, that on one hand the mandate of NPPP 2012 is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines i.e. essential medicines at reasonable prices, on the other hand the income levels of BPL families is not a relevant factor in preparing NLEM by MOHFW as well as current pricing method under DPCO, 2013 by NPPA, the Department in their written note stated as under:

"As per National List of Essential Medicines (NLEM), 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. Such medicines are intended to be available in adequate amounts, in appropriate dosage forms and strengths with assured quality. They should be available in such a way that an individual or community can afford."

1.20 Further, during the oral evidence of the representatives of the Department by the Committee on 24.05.2018, the Chairperson of the Committee made the following observation on the essentiality of medicines:-

"My objection is on the word 'essentiality'. Each and every medicine is essential. It may be a small tablet or anything else. It is because I am having pain, I am purchasing a pain killer or tablet. It is essential for me. If I am a cancer patient, then I have to buy these costly medicines. That is why, each and every medicine is essential. There should not be any bifurcation between essential and non-essential. You cannot say that it is non-essential. All these medicines should be put under the definition of essential."

1.21 In response, the Secretary, Department of Pharmaceuticals gave the following reply during the course of oral evidence:-

"Sir, I absolutely agree with what you said about essentiality. If I am suffering from something, that drug is essential for me. But this essentiality does not mean individual patient-wise. The Health Department studies the disease burden of a country like kala-azar is a disease burden in India. Polio was a disease burden in India. Malaria is a disease burden in India. There is an expert committee which studies what is the normal disease burden of this country. Based on that, they decide that these medicines, not from individual point of view it is essential, no, but from the country's point of view it is essential. It is because these are major ailments which a country goes through, therefore, we must have these medicines and from that point of view essentiality was defined by the Health Ministry. They made that list. As I said, most of the ailments are covered by this but there would be some ailments for which there would be some orphan drugs in the sense that there is a very specific psychological disease with which everybody does not suffer but for him that medicine will be very essential but that medicine is not listed here because may be only some few thousand people suffer from that disease. So, the Health Department brings that list of essentialities. While I agree with you that every medicine is essential and that is why in the DPCO, we put a clause 19, that based on the individual condition, emergency and the requirement, we can bring any medicine into a price control order. The 106 medicines which we showed were brought in the price control like that. Those 106 medicines were not in the list of essential medicines. But in 2014, there was a price cap on those 106 medicines. So, we are trying to handle your concerns which is our concern also through para 19 of DPCO."

1. 22 The Committee also asked about the next revision of NLEM proposed to be undertaken and new drugs/medicines that are proposed to be added in the list, the Department in their written note stated as under:

"Department of Health and Family Welfare has constituted a Standing National Committee on Medicines (SNCM) for the revision of National list of Essential Medicines (NLEM) vide Order No X.11035/923/2017-DRS dated 3rd July 2018. The number of drugs/medicines to be included in the NLEM will be decided by the Committee only."

1.23 The Committee thereafter asked, whether the current Market Based Pricing methodology adopted for fixing of prices of NLEM drugs/medicines has been able to ensure fair price with quality drugs/medicines to consumers, the Department in their written note stated in affirmative that the current Market base policy has been successful in ensuring fair price with quality drugs/medicines to the consumer. The reduction in the prices under DPCO 2013 as follows:-

Statement showing reduction in ceiling prices of scheduled formulations with respect to maximum price		
% reduction with respect to Maximum Price	No. of scheduled formulations (NLEM 2011)	No. of scheduled formulations (NLEM 2015)
0<= 5%	80	234
5<=10%	50	134
10<=15%	57	98

15<=20%	43	98
20<=25%	65	93
25<=30%	49	65
30<=35%	26	46
35<=40%	34	24
Above 40%	126	59
Total formulations	530	851

1.24 In view of the above data, as per current market based pricing methodology, 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 percentage and 126 to 59 respectively under NLEM 2011 and 2015. Thus the Committee asked about the reasons for decrease in number of scheduled formulations under these two categories and the steps that are proposed thereon. In this regard, the Department in their written reply stated as under:

> "National Pharmaceutical Pricing Authority (NPPA) fixed the ceiling price of 851 scheduled formulations under National List of Essential Medicines (NLEM), 2015, out of which majority of formulations are common formulations under NLEM, 2011 and NLEM 2015, where the price was already fixed under NLEM, 2011. Therefore, while re-fixing the ceiling price of these common formulations the reduction in these cases are limited which has affected overall reduction under NLEM 2015."

1.25 The Committee were informed that NITI Aayog has proposed a new drug pricing index for pharmaceuticals. In this regard, when the Committee sought its difference from the current pricing mechanism under DPCO, 2013, the Department in their written note stated as under:

> "NITI Aayog in their report on NLEM and DPCO has recommended that the average price to first point of sale (where first point of sale could be Stockist/Wholesaler/ Distributor/ Hospital) should be considered for calculating ceiling prices of the drugs/ devices, instead of the presently followed system based on average price to the retailer. Niti Aayog suggested that overall WPI may be replaced with the WPI for Pharmaceutical Products. The same was not accepted by the Department. In this regard, representations were received from Pharma Industry to keep the prices in pharma industry aligned with overall price movements in the economy. Overall WPI is higher than WPI for Pharmaceutical Products. Overall WPI includes multiple factors of the market which are not taken into consideration while calculating WPI pharma. Accordingly, the Department has proposed to retain the overall WPI."

1.26 In view of the above written note by the Department, the Committee further asked the Department the reasons for non acceptance of the WPI for Pharmaceutical Products as the basis for calculating ceiling prices for drugs/devices

and also regarding the proposals to reconsider this matter so as to lower the prices of drug/medicines. The Department in their written note stated as under:

> "The department has not accepted the WPI for pharmaceutical products as the basis for circulating annual revisions in ceiling prices for drugs because overall WPI is a more relevant for this annual exercise. Movements in prices of inputs such as labour cost, transportation cost etc. are not captured by WPI for pharmaceutical products."

1.27 Regarding the criteria and standard procedure for regulating the non-scheduled medicines prices which is fixed in view of extra ordinary situations or public interest, the Department in their written note stated as under:

> "As per provision of the para 19 of the DPCO 2013, the Government may, in case of extra-ordinary circumstances, if it considers necessary so to do in public interest, fix the ceiling price or retail price of any Drug (scheduled as well as non-scheduled drugs) for such period, as it may deem fit and where the ceiling price or retail price of the drug is already fixed and notified, the Government may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index for that year. There is no specific criteria defined for the invoking para 19 of the DPCO 2013 and the government decision under this provision is considered on the basis of the merit of the case."

1.28 Further on the issue of the margins which are allowed to a wholesaler and distributers for drugs and medicines under DPCO 2013, the Department in their written note stated that the Ceiling price or retail price of medicines is fixed by adding sixteen percent margin to retailer on the average price to retailer. There are no margins, other than this prescribed in the DPCO.

1.29 The Committee also asked about the details regarding notification of annual increase in ceiling prices of scheduled medicine allowed/notified under DPCO,2013, the Department in their written note stated as under:

> "As per para 16(1) of the DPCO 2013, The Government shall revise the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for preceding calendar year on or before 1st April of every year and notify the same on the 1st day of April every year.
> As per para 16 (2) of the DPCO 2013, The manufacturers may increase the maximum retail price (MRP) of scheduled formulations once in a year, in the month of April, on the basis of the wholesale price index with respect to previous calendar year and no prior approval of the Government in this regard shall be required."

CHAPTER-II

ROLE OF NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

2.1 The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers was formed by the Govt. of India vide Resolution published in the Gazette of India No. 159 dated 29.08.97. The functions of NPPA, inter-alia include fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines.

2.2 In view of the above, the Committee asked about the mandate and the role of National Pharmaceutical Pricing Authority (NPPA) in regulating prices of scheduled and non-scheduled drugs/medicines, the Department in their written note gave the following as mandate of the National Pharmaceutical Pricing Authority (NPPA):

> "(1) To implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.
> (2) To deal with all legal matters arising out of the decisions of the Authority.
> (3) To monitor the availability of drugs, identify shortages, if any, and to take remedial steps;
> (4) To collect/maintain data on production, exports and imports, market share of individual companies, profitability of companies etc. for bulk drugs and formulations;
> (5) To undertake and/or sponsor relevant studies in respect of pricing of drugs/pharmaceuticals;
> (6) To recruit/appoint the officers and other staff members of the Authority, as per rules and procedures laid down by the Government;
> (7) To render advice to the Central Government on changes/revisions in the drug policy;
> (8) To render assistance to the Central Government in the parliamentary matters relating to the drug pricing."

2.3 On being asked about the coordination mechanism between Indian Pharmacopoeia Commission and Drugs Controller General of India which fall under the Ministry of Health and Family Welfare with the Department of Pharmaceuticals / NPPA in the decision making / monitoring process relating to maintenance of quality standards, safety and rational use of medicines in the country, the Department in their written note stated as under:-

> "Department of Pharmaceuticals is a member of Governing Body and the General Body of Indian Pharmacopoeia Commission. Department of Pharmaceuticals is represented by a Joint Secretary to this Body. The regulatory control over the import, manufacture, distribution and sale of drugs, cosmetics and notified medical devices in the country, is under the provisions of the Drugs and Cosmetics Act, 1940 & Drugs and Cosmetics Rules, 1945 and Medical Devices Rules, 2017.

The manufacture, sale and distribution of drugs in the country is primarily regulated by the State Drug Control Authorities appointed by the State Governments while control over drugs imported into the country and those introduced for the first time is exercised by the Central Government through Central Drugs Standard Control Organization (CDSCO) headed by the DCGI.
Under Chapter II and Section 5 of Drugs & Cosmetics Act 1940, Drugs Technical Advisory Board (DTAB) advises the Central Government and the State Governments on technical matters arising out of the administration of this Act and carries out the other functions assigned to it by this Act.
Under Chapter II and Section 7 of Drugs & Cosmetics Act, 1940, Drugs Consultative Committee (DCC) advises the Central Government, the State Governments and the Drugs Technical Advisory Board on any other matter tending to secure uniformity throughout India in the administration of this Act.
The drugs imported or manufactured for sale, distribution etc. are required to comply with the standards specified in the Second Schedule to the Drugs and Cosmetics Act. According to it, drugs included in the Indian Pharmacopoeia (IP), [a book of standards for drugs published by Indian Pharmacopeia Commission (IPC)], should comply with the standards specified therein. Drugs not included in IP but which are included in official pharmacopoeia of any other country, should comply with the standards specified in such Pharmacopoeia. In case of proprietary medicines (not included in any official Pharmacopoeia), the standards should be asper the formula displayed in the prescribed manner on the label of the container and such other standards as may be prescribed. There is interaction/coordination taking place between MoH&FW/CDSCO/IPC and DOP/NPPA on various polices initiatives relating to quality/ availability/affordability rational use of drugs etc."

2.4 Further the Committee asked to illustrate with an example, the complete cycle of price variation starting from manufacturer, wholesalers, retailer till consumer in the price fixation mechanism devised by NPPA under DPCO, 2013, the Department in their written reply stated that NPPA fixes the ceiling prices which are applicable throughout the country. However, individual companies can fix the MRP less than the ceiling price. All the companies may not be present throughout the country and on the basis of regional presence of the companies, the prices may vary. For example, in case of Metformin 500mg tablet, the ceiling price has been fixed as Rs. 14.10 per 10 tablets. Company A, which is operating in a particular region, may have MRP of Rs. 11 for 10 tablets whereas Company B may be having MRP of Rs. 14 for 10 tablets in another region.

2.5 While furnishing details regarding profit-margin in terms of percentage available for producers of scheduled medicines at prices fixed by NPPA on the basis of input/ output cost analysis along with comments regarding desirability of stipulating maximum profit margin to be allowed to a manufacturer on particular scheduled medicine, the Department in their written note stated as under:

"NPPA fixed the ceiling price based on average 'Price to retailer' plus sixteen percent, though there is no restriction in the trade margin. On the analysis of the data provided by the AIOCD AWACS, it is noticed that in most of the cases, the trade margin of distributor and retailer is 28% of the MRP."

2.6 The Committee also asked about the details of periodic survey conducted by NPPA of prices of drugs sold in the country with particular reference to percentage of NLEM covered drugs/medicines in the market, the Department in their written note stated that NPPA is collecting market price data from the agency named All India Organization of Chemists & Druggists & Advanced Working, Action and Correction System (AIOCD AWACS). The Annual Turnover for the last five years based on the figures reported in the AIOCD's AWACS is as follows:

	Year ending 31.3.2014	Year ending 31.3.2015	Year ending 31.3.2016	Year ending 31.3.2017	Year ending 31.3.2018
Scheduled	16,507	18,068	20,320	19,864	19,767
Non-Scheduled	63,477	72,501	82,294	93,064	99,618
TOTAL	79,983	90,570	1,02,614	1,12,929	1,19,386

Percentage

Scheduled	21%	20%	20%	18%	17%
Non-Scheduled	79%	80%	80%	82%	83%

Source: AICOS AWACS Pharmatrac Report of March 2018.
*the classification of Scheduled /Non – Scheduled medicines is as per present status.

2.7 In view of the above, the Committee asked the Department to furnish reasons for not conducting periodic survey on prices of drugs by NPPA, the Department in their written note stated as under:

> "NPPA has made agreement with the All India Organization of Chemists & Druggists & Advanced Working, Action and Correction System (AIOCD AWACS) who makes the collection of the data of the prices of the medicines, who collect the information from the majority of the distributors across the country. The information is provided on monthly basis. On the basis of analysis of the information submitted by the AIOCS AWACS, NPPA is monitoring the prices of the medicines and issue notices for violation of the prices of medicines and therefore objective of the survey is being fulfilled."

Growth of Pharma Industry during last 5 years has been as under:

Year	Annual Turnover (In Rs. Crores)	Percentage Increase
2013-14	128044	-
2014-15	165202	29.01%
2015-16	185388	12.21%
2016-17	219755	18.53%
2017-18	226423	3.03%

2.8 When the Committee asked about the reasons for reduction in percentage growth of the pharmaceuticals industry from 29% in 2014-15 to only 3% in 2017-18 and steps that are being taken to reverse this trend, the Department in their written note stated as under:

> "From the above table, it may be noted that the annual turnover of the pharma industry has increased continuously. However, the growth rate of annual turnover has reduced in the current year but there is no definite pattern of decline in the percentage increase of Annual Turnover of pharma sector as such. Annual turnover of an industry depends on multiple factors such as exports, production etc.

2.9 With regard to steps taken by the Ministry, for the growth of Pharmaceutical industry, the Committee were informed that National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012) was notified with the objective to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – "essential medicines" at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of pharma industry thereby meeting the goals of employment and shared economic well-being for all. Also, the policies formulated by Government from time to time are made to give fillip to indigenous manufacturing. In this direction, the Government vide its notification dated 28th January, 2016 has withdrawn exemption of customs duty of certain categories of Bulk Drugs/APIs. Further, the Department of Pharmaceuticals has prepared an umbrella scheme namely 'Scheme for Development of Pharmaceutical Industry' with the objective to increase the efficiency and competitiveness of domestic pharmaceutical industry so as to enable them to play a lead role in the global market and to ensure accessibility, availability and affordability of quality pharmaceuticals of mass consumption. The umbrella scheme has the following sub-schemes:-

(i) Assistance to Bulk Drug Industry for Common Facility Centre;
(ii) Assistance to Medical Device Industry for Common Facility Centre;
(iii) Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS);
(iv) Assistance for Cluster Development; and
(v) Pharmaceutical Promotion Development Scheme (PPDS)"

2.10 The Committee also asked about the mechanism for monitoring of prices of all the non schedule drug formulations under DPCO 2013 and comment upon the effectiveness of the system, the Department in their written note stated as under:

> "NPPA is effectively monitoring the prices of scheduled as well as non-scheduled medicines under DPCO, 2013 so that these formulations are available to public at the ceiling prices notified and any increase in price is limited to the provisions of DPCO 2013. It takes action against companies found overcharging the consumers based on the references received from the State Drugs Controllers / individuals, samples purchased from the open market and reports from market based data and complaints received through the grievance redressal websites: 'Pharma Jan Samadhan' and 'Centralized Public Grievance Redressal and Monitoring System (CPGRAMS)'. The monitoring of increase in the price of formulations beyond the permissible limit is also done on the basis of market data submitted by AIOCD (Pharmatrac Data) and individual complaints."

2.11 The Committee were further informed that NPPA issue notices for overcharging as and when price violation cases come to notice based on the reports received from State Drug Controllers or based on samples purchased from market or complaints received from NGOs / individuals or based on PharmaTrac data. Action for recovery of the overcharged amount is taken as per the provisions of DPCO, 1995 and DPCO, 2013. The cases are also referred to District Collector for recovery of the overcharged amount as arrears of land revenue under Section-3 of Essential Commodities Act, 1955.

2.12 When the Department was about the agencies/authorities at national level, state level and district level that are responsible for enforcement of DPCO, 2013 and state-wise details of complaints received from consumers and complaints for violation of DPCO, 2013 for last Five years as well as complaints that have been resolved/settled, the Department in their written reply stated that NPPA is empowered for the implementation of DPCO 2013. However, NPPA is taking assistance of the State Drug Controllers at state level who provide information regarding price violation and also assist in recovery of the overcharged amount. State Drug Controller has Drug Controller officer at District level.

2.13 Further regarding the punishment for violating the DPCO, 2013 and steps taken by the government/NPPA on issue of overcharging by a manufacturer/retailer, the Department informed the Committee that the manufacturer violating the provision of DPCO 2013 is liable to deposit overcharged amount along with the Interest. In respect of new drug launched without the price approval, the penalty, is imposed as per guidelines. In case overcharging is not deposited the cases are referred to the District Collector concerned for recovery.

2.14 In regard to strengthening of NPPA the Secretary, Department of Pharmaceuticals made the following submission to the Committee during the oral evidence on 24.05.2018:

> " We will need your support because we do want to strengthen NPPA. NPPA has one full-time Member which is half-time now. But, in regular course, there is one full-time Member and one full time Member Secretary. This is not good enough. So, I want at least three-four full-time Members. Drug Controller is a Member there, but he is a part-time Member. Economic Advisor from DEA is a Member, but he is a part-time Member. I am not casting anything, but a part-time Member cannot do justice to this work in the manner which a full-time Member can do. So, I want the establishment to be strengthened with more full-time experts and Members. As administrators, we do not know the full play of the pharmaceutical industry."

CHAPTER- III

THE OTHER RELATED MATTERS

3.1 On the issue of pharmaceutical companies going to court of law in the past and the action taken by the NPPA on violation of DPCO,2013 order, the Committee asked the Department regarding the remedial measures taken in this regard so as to contain the problem of litigation as well as need for amendment in the existing rule to do away the problem of litigation, the Department in their written note stated as under:

> **"**Yes, since the inception of the price control, the pharmaceutical companies have been approaching the courts of law in relation to the issues mainly of overcharging and pricing etc. arising out of difference of interpretation of DPCO by the company and the government. There is a provision of review of order of NPPA by the government in the DPCO, 2013. The scope of litigation remains as there is always a possibility for a different interpretation suiting the company. An amendment is made when it is felt that making it will reduce the unnecessary litigation."

3.2 Regarding the steps that are being taken to reduce the number of litigations in this regard, the Department in their written note stated as under:

> "Before moving to the Court, the companies are free to come into the review under para 31 of DPCO, 2013 against the price notification of NPPA. Department provides review hearing to the companies and decide the matter as per provisions of DPCO, 2013. Further, in order to reduce the number of litigations, NPPA also provide an opportunity to the pharmaceutical companies for personal hearing and pass reasoned speaking orders."

3.3 Further, on details regarding cases of violation of DPCO, 2013 reported/ noticed by NPPA during the last Five years and the actions that have been taken on such cases, the Department in their written reply stated that total 964 Demand Notices were issued during last 5 years (till September 2018) to the errant pharmaceutical companies. Summary showing year wise number of Demand Notices issued, amount involved and recovery made are tabulated in the table given below.

DETAILS OF DEMAND NOTICES ISSUED

PARTICULARS	YEAR 2013-14	YEAR 2014-15	YEAR 2015-16	YEAR 2016-17	YEAR 2017-18	YEAR 2018-19 (Till Sept., 2018)	Total
No. of Demand Notices issued for overcharging (including suo-moto deposits)	90	128	263	137	221	125	964
Amount of Demand Notices issued (Rs. Crore)	406.83	581.10	931.63	333.97	704.12	194.81	3152.46
Amount recovered from Pharmaceutical companies (in Crore)	40.08	90.17	12.32	302.08	148.42	17.43	610.50

3.4 When the Committee asked the Department to comment on the effectiveness of the present penalties and punishments related to violations of DPCO, 2013 and

steps that are being taken/ proposed to be taken to strengthen the system, the Ministry in their written reply had stated that action for recovery of the overcharged amount is taken by NPPA as per the provisions of Drugs (Prices Control) Order, 1995 (DPCO, 1995) and DPCO, 2013. Whenever companies are found overcharging the consumers in respect of price of medicines, demand notices are issued for recovery of overcharged amount along with 15% interest thereon for violation under various provisions of DPCO, 1995 and DPCO, 2013 read with Section 7A of Essential Commodities Act, 1955. If the manufacturers do not deposit the demanded amount within the prescribed time limit after one time- bound reminder, the matters are referred to concerned District Collector to initiate recovery proceedings against pharmaceutical companies.

3.5 In cases where the defaulting pharma companies do not submit the required sales data and Pharma Trac data is not available, the cases are referred to SDCs with a copy to the Principal Secretary/Secretary (Health) in the State where the manufacturers' headquarter is situated with a request for pressing upon them to furnish required information within a further period of 30 days and also to verify their credentials through inspection of their offices and factory premises if need be. The system of NPPA is robust where overcharging cases are identified and taken up as per the provisions of DPCO.

3.6 However, in some cases, the demands raised for overcharging have been challenged in courts due to overcharging in formulations manufactured before the date of notification and found selling at pre revised prices after date of notification and formulation claimed to be having innovative drugs delivery system. NPPA is actively pursuing these court cases. Where the demand raised by NPPA has not been challenged in the court and the concerned company does not deposit the amount of demand, the matter is referred to the respective Collector for recovery of the overcharged amount as arrears of land revenue under Essential Commodities Act, 1955. The cases referred to collectors are also followed up on regular basis by issuing D.O. reminders.

3.7 Further the Committee asked the Department to comment on online-sale of drugs/medicines at present and proposed guidelines for introduction and regulation e-pharmacies and the role envisaged for NPPA with regard to price regulation and monitoring of online-sale of drugs, the Department in their written note stated as under:

> "The ceiling prices fixed under DPCO 2013 are equally applicable to the online-sale of drugs/medicines. The online sales of drugs are being regulated by the Ministry of Health and Family Welfare through Drug controller General of India. At present, there in separate wing/division for online sale of medicines. However, the prices are being monitored through the Report of the All India Organization of Chemists & Druggists & Advanced Working, Action and Correction System (AIOCD AWACS)which provide data of the prices."

3.8 Regarding the mechanism that is in place to deal with drugs/medicines approved by Drug Controller General of India but subsequently found to have harmful side effects on consumers and also banned abroad but available in India at high prices, the Department in their written note stated that the Central Government,

has the power to regulate, restrict or prohibit manufacture and sale of drugs considered harmful or irrational in the country, under Sec. 26- A of the Drugs and Cosmetics Act, 1940 which is reproduced below-

> "26A. Power of Central Government to regulate, restrict or prohibit manufacture, etc., of drug and cosmetic in public interest. Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate, restrict or prohibit the manufacture, sale or distribution of such drug or cosmetic."

Drugs, for which harmful effects are reported in the published literature or in the media or in other country or if therapeutic justification is considered inadequate in the context of current medical evidence, are examined by Expert Committees/Drugs Technical Advisory Board (DTAB) to review the status of the drug formulation. The use of the drug is assessed on the basis of available technical information benefit - risk ratio, local needs and availability of the safer alternatives etc. Considering the recommendation of Expert Committee/ DTAB, if the Central Government is satisfied, that the use of any drug is likely to involve any risk to human beings or animals or that any drug does not have therapeutic justification, the manufacture, sale and distribution of such drug is regulated/ restricted/ prohibited under Section 26A of the Said Act. Banning of any drug in a country is based on a risk assessment process undertaken by the respective country. There could be number of reasons as to why some of the drugs continued to be used in one country though banned in other country. Certain drugs banned in other country (ies), have been allowed for continued marketing in the country with certain conditions/restrictions under Section 26A of the said Act based on examination of their benefit-Risk profile through Expert Committee/Drug Technical Advisory Board. Such drugs includes Nimsulide, Analgin, Dextropropoxyphene, Pioglitazone etc.

SPURIOUS DRUGS ISSUE

3.9 In regard to spurious drugs, the Committee were informed that the manufacture and sale of spurious drugs is a clandestine activity generally indulged in by anti-social elements and carried out by unlicensed or sometimes by the licensed manufacturers to exploit the confidence enjoyed by certain fast selling branded drugs by making their imitations. Use of spurious drugs may results in harmful side effects or allergies and sometimes leads to death. If contaminated with pathogens (bacteria, virus) or other toxic elements can cause further illness or poisoning. As a consequence of such damaging effects of spurious drugs, confidence of public may go down in health care systems, health care professionals, the suppliers and sellers of genuine drugs, the pharmaceutical industry etc. Reports of availability of spurious drugs in the country shake the confidence of indigenous as well as foreign buyers

and prestige of the country's pharmaceutical trade interests with negative impact on export of drugs from India.

3. 10 The Committee enquired about the spurious medicines/drugs in the market and its effect on pharmaceuticals industry and prices of drugs/medicines. In this regard, the Department in its written reply had stated that drugs are regulated under Drugs and Cosmetics Act, 1940 and Rules made there under. The regulatory control over the drugs imported is exercised by the Central Government through the Central Drugs Standard Control Organization (CDSCO). The manufacture, sale and distribution of drugs are regulated by the State Drugs Control Authorities appointed by the State Governments through a system of licensing and inspection. The inspector is authorized to institute prosecution in respect of breaches of the Act and Rules there under. Schedule M to the Drugs and Cosmetics Rules provides requirements for Good Manufacturing Practices and requirements of plant and equipment for manufacture of drugs. The manufacturer is required to comply with the requirements of plant and equipments, facilities as per Schedule M. As per the **section 9B** of Drugs and cosmetics Act, 1940 a drug shall be deemed to be spurious:-

(a) if it is imported under a name which belongs to another drug; or

(b) if it is an imitation of, or a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(c) if the label or the container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by another drug or substance; or

(e) if it purports to be the product of a manufacturer of whom it is not truly a product.

As per the **section 17B** of Drugs and cosmetics Act, 1940 a drug shall be deemed to be spurious:-

(a) if it is manufactured under a name which belongs to another drug; or

(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug , which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by another drug or substance; or

(e) if it purports to be the product of a manufacturer of whom it is not truly a product.

The Committee were further informed that the drugs inspectors are authorized under section 22 of the provisions of Drugs & Cosmetics Act, 1940, to take samples of any drugs/vaccines and send to Central Drugs Laboratories for test and analysis. In case any sample is declared as sub-standard quality, spurious/adulterated/Misbranded drugs, action is required to be taken against the earring firms as per the provisions of said Act and Rules.

3. 11 A Statement Showing No. of Samples tested, No. of Samples declared Not of Standard Quality/Spurious/ Adulterated drugs, No. of Prosecution Launched, and No. of cases decided and No. of persons arrested States / UTs wise during last three years i.e. 2015-16 to 2017-18, as per the information made available by the States is given in the table below:

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

S. No	Year	No. of drugs samples tested	No. of samples declared not of standard quality	No. of samples declared spurious / adulterated	No. of prosecutions launched for manufacture, sale and distribution of spurious / adulterated drugs	No. of case (as mentioned in the earlier column) decided	No. of persons arrested
1.	2015-16	74586	3703	234	289	2	59
2.	2016-17	76721	2780	123	186	17	106
3.	2017-18	82599	2783	236	131	16	163

3.12 Details of no. of samples tested declared Not of Standard Quality/Spurious/ Adulterated drugs and Percentage of Not of Standard Quality/Spurious/Adulterated drugs in the country since 2015-16 to 2017-18, as per the information made available by the various Zonal/Sub-Zonal offices of CDSCO is given in the table below:

S. No.	Year	No. of drugs samples tested	No. of 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.	**2015-16**	**2897**	**115**	**3.96**	**5**	**0.17**
2.	**2016-17**	**5207**	**146**	**2.80**	**Nil**	**0.0**
3.	**2017-18**	**7088**	**381**	**5.37**	**2**	**0.028**

The Ministry of Health & Family Welfare, Govt. of India had conducted a country wide survey in the year 2014-2016 to determine the extent of spurious /Not of Standard Quality (NSQ) drugs in the country. Total 47012 drug samples were tested/ analyzed, out of which 1850 samples were declared as NSQ and 13 samples were declared as spurious by the Govt. analyst. Percentage of NSQ drugs reported is 3.16 %, while a spurious drug is 0.0245 %.

3.13 During the oral evidence before the Committee on 22.10.2018, Drug Controller General of India made the following submission regarding spurious drugs:-

"As you know, this comes under the concurrent list of the Constitution. Both, the Central Government and the State Governments are involved in

monitoring the quality of the products. As a part to ensure quality of the drugs moving in India, we draw samples from all parts of India by the Drug Inspectors of the State Government as well as the Central Government. So, I have three years of data regarding the number of samples drawn across India and how many samples failed/ not of standard quality and how many spurious drugs we have found. In the year 2017-18, 82,599 samples have been drawn, out of which the number of samples declared as spurious is 236. In the year 2016-17, we have drawn 76,721 samples, out of which 123 samples were found to be spurious. In the year 2015-16, 17,586 samples have been drawn, out of which 234 samples have been declared as spurious. In addition to this, in the year 2016-17, the Government of India conducted a special national drug survey for which the samples have been drawn all across India. Samples were not drawn by the Drug Inspectors alone. Samples were drawn by the third party, that is, Consumer Associations to prevent bias and 47,000 samples have been drawn and the spurious drugs are found to be of 0.3 per cent. This is the survey conducted by the Government of India with the help of the NGOs and the samples are tested in the Government Drug Testing Laboratories."

MEASURES TAKEN FOR ENSURING QUALITY OF DRUGS

3.14 Details of various measures that have been taken by the Department to ensure the quality of drugs are as under:-

(i) 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 Aug, 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, 22 States and UT's have set up the courts.

List of States having Designated Special Courts

1. Karnataka
2. Madhya Pradesh
3. Delhi
4. Tripura
5. Lakshadweep
6. Arunachal Pradesh
7. Goa
8. Meghalaya
9. Bihar
10. Mizoram
11. J&K
12. Daman & Diu
13. Dadra & Nagar Haveli
14. Tamil Nadu
15. Uttarakhand
16. Uttar Pradesh
17. Rajasthan
18. Puducherry
19. Punjab
20. Kerala
21. Andhra Pradesh
22. Haryana

The details of enhancement of penalties through amendment in the Act in 2008 are mentioned below:

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 license	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* year** 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 spurious under section 17B, but not being a drug referred to in clause (*a*)	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 *five thousand rupees*:**	imprisonment for a **term which shall not be less than 7 years** but which may **extend to imprisonment for life** 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*) or clause (*c*), in contravention of any other provision of this Chapter or any rule made there under,	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.**

(ii) WHISTLE BLOWER SCHEME

Whistle Blower Scheme was announced by Government of India in August, 2009 to encourage vigilant public participation in the detection of movement of spurious drugs in the country. Under this scheme 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 under:

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 Rs 25 Lakh in each case.
- In respect of an officer of the Government / CDSCO, the reward should not in any case exceed Rs 5 Lakh for one case and a maximum of Rs 30 Lakh in his / her entire service.
- With a view to ensure 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.

  However, so far the complaints were found to be fictitious and no person has been rewarded under this Scheme till date as per the information furnished by the Department.

(iii) INTRODUCTION OF GOOD LABORATORY PRACTICES

The Department informed the Committee that 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.

(iv) SUBMISSION OF BIOEQUIVALENCE STUDY RESULT

The Committee were also informed that in order to ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended w.e.f. 3.4.2017 providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.

(v) JOINT INSPECTION OF MANUFACTURING FACILITIES BEFOR GRANT OF LICENSE

On 27.10.2017, the Drugs and Cosmetics Rules, 1945 have been amended by the Department vide Gazette notification no. G.S.R. 1337 (E) making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government. The licensed manufacturing premises shall be inspected jointly by the Drugs Inspectors of Central Government and State Government to verify the compliance with the conditions of license and the provisions of the Drugs & Cosmetics Act and Rules for not less than once in three years or as needed as per risk based approach.

(vi) SUBIMISSION OF EVIDENCE OF STABILITY, SAFETY OF EXCIPIENTS ETC OF ALL DRUGS

The Committee were further informed that on 10.04.2018, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 360 (E), making it mandatory for all drugs, that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of product manufacturing license by the Authority.

3.15 With regard to the list of 349 Fixed Dose Combinations, which were banned by the Government, the Chairman NPPA informed the Committee as under during oral evidence held on 22.10.2018:-

> "Against that banning of those drugs by the Government, many persons, pharmaceutical people went to different High Courts of the country. The Government, against that, approached the Supreme Court and requested the Supreme Court to hear all the cases together. Luckily, the Government's request was allowed by the Supreme Court and in last December, 2017, the Supreme Court passed an order that drugs can be banned with due process of law. The due process of law, as the Supreme Court recommended, is all these pharmaceutical companies will be given hearing by Drug Technical Advisory Board, which is constituted as per the Drugs and Cosmetic Rules. Duly hearing was given to them. An expert in the field of clinical pharmacology was Chair of that sub-Committee which heard all the companies. After hearing all the companies, 343 drugs were banned and 6 drugs were considered rational and they were allowed. Saridon was one of those 343 drugs. But as soon as this list was out on 7th of September, the companies again approached the Supreme Court saying that these drugs were available and they were permitted before 1988. Since, they were there for the last 30 years, they should be allowed. The Supreme Court then ordered that these 15 combinations which included saridon should be looked afresh because they were available in the country and they were approved 30 years ago. That can be looked separately and the Government can go ahead with others. So, 328 drugs were banned. But even after banning, pharmaceutical companies again approached different High Courts of the country and there are approximately 80 cases lodged by different pharmaceutical companies in different High Courts. On request of the Government, the Supreme Court itself, in one of the cases directed that this situation cannot go on. In one of the company's request, the Supreme Court itself ordered that all these cases will be combined and the Government has requested Attorney General of India to present the Central Government in this case. The Supreme Court itself has fixed the date of 23rd October for next hearing of this case."

CONSUMER ISSUES

3.16 The Government has helped the consumers since May, 2014 by implementing the provisions of DPCO, 2013 made the following savings:-

Particulars	Saving to Consumers in Rs. Crores
NLEM-2011	
Under NLEM-2011 upto May 2014	2221.23
Under NLEM-2011 from May-2014 to Feb-2016	201.01
NLEM-2015	
Under NLEM-2015 from Mar-2016 till 21.9.2017	2643.00
Coronary Stents in Feb-2017	4547.00
Under Para 19 (extraordinary circumstances) in July, 2014	350.00
Knee Implants in Aug-2017	1500.00
TOTAL	**11462.24**

3.17 In view of the above data provided by the Department, the Committee asked about the satisfaction of the Department with the present rate of saving or there is still potential to enhance such savings on this account keeping in view the increasing number of diseases, the Department in their written reply stated that the savings accrued to consumers is dependent on the number of medicines that are included in the NLEM.

3.18 Concerned about low consumer awareness the Committee asked the Department regarding the rules and regulations that govern the packaging, labeling and sale of drugs/medicines including price-labeling on drugs/medicines packets in the country, the Department in their written reply stated that the rules and regulations for the packaging, labeling and sale of drugs/medicines are governed by the Drugs and Cosmetics Act 1955. The price labeling is governed by the Drug (Prices Control) Order 2013. As per para 24(2) of DPCO 2013, every manufacturer of a schedule formulation intended for sale shall display in indelible print mark, on the label of container of the formulation and the minimum pack thereof offered for retail sale, the maximum retail price of that formulation based on the ceiling price notified in the Official Gazette or ordered by the Government in this behalf with the words "Maximum Retail Price" preceding it and the words 'inclusive of all taxes' succeeding it.

3.19 Further the Committee also asked about consumers demanding for price list of scheduled and non-scheduled medicines being sold by a chemist/retailer and is it mandatory for a chemist/retailer to have such list, the Department in their written reply stated -"Yes, as per para 24(4) of the DPCO 2013, every retailer and dealer shall display the price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same."

3. 20 Regarding steps that are being taken to conduct awareness campaign through print and electronic media to spread awareness among the public in this regard, the Department in their written reply stated that NPPA is running a Central Sector Scheme i.e. Consumer Awareness, Publicity and Price Monitoring vide which creation of general awareness about the availability of medicines, ceiling prices of medicines fixed by the Government, precautions to be taken while purchasing medicines and about the functioning of NPPA.This will be done through issue of advertisements in the print media and through radio jingles and tele-films. Further, for dissemination of information on ceiling price, NPPA is promoting the Mobile App “Pharma Sahi Daam” whereby the consumer can verify the ceiling prices of the medicine instantly.Pharma Sahi Daam is a Mobile App was developed by NPPA and launched officially by Hon’ble Minister (Chemicals & Fertilizers/Parliamentary Affairs) on 29th August, 2016 on the occasion of NPPA Foundation Day. This app provides information to consumers on prices of scheduled medicines which are under price regulation as well as prices of non-scheduled medicines. This app helps consumers to check the ceiling prices of medicines and to verify whether medicines are being

sold within the approved price range and also to detect any case of overpricing by pharmaceutical company/ chemist. In case of overpricing the consumer can lodge a complaint through Pharma Jan Samadhan website (http://nppaindia.nic.in/redressal.html).

Recommendations/Observations

4.1 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.

4.2 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.

4.3 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.

4.4 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.

4.5 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.

4.6 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.

4.7 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.

4.8 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 non-standard 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.

4.9 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.

New Delhi;
11 February, 2019
22 Magha 1940 (Saka)

ANANDRAO ADSUL
Chairperson
Standing Committee on
Chemicals and Fertilizers

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

(2017-18)

The Committee sat on Thursday, the 24th May, 2018 from 1100 hrs. to 1230 hrs. in Committee Room 'E' , Parliament House Annexe, New Delhi.

PRESENT

Shri Anandrao Adsul - Chairperson

MEMBERS

LOK SABHA

2. Shri George Baker
3. Shri R. Dhruvanarayana
4. Shri S. Rajendran
5. Dr. Krishna Pratap Singh
6. Shri Pankaj Chaudhary
7. Shri B.N. Chandrappa
8. Smt. Veena Devi

RAJYA SABHA

9. Shri Prem Chand Gupta
10. Shri Ranvijay Singh Judeo
11. B. K. Hariprasad

SECRETARIAT

1. Shri Vinod Kumar Tripathi - Joint Secretary
2. Shri U. C. Bharadwaj - Deputy Secretary
3. Shri N. Amarthiagan - Committee Officer

LIST OF WITNESSES

I. MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

1. Shri Jai Priye Prakash Secretary
2. Shri Navdeep Rinwa Joint Secretary

II. REPRESENTATIVES OF NATIONAL PHARMACEUTICALS PRICING AUTHORITY (NPPA)

1.	Shri Rakesh Kumar Vats	Chairman, National Pharmaceuticals Pricing Authority (NPPA)
2.	Ms Rittu Dhillon	Member Secretary, National Pharmaceuticals Pricing Authority (NPPA)
4.	Sh. Kalyan Nag	Adviser, National Pharmaceuticals Pricing Authority (NPPA)

2. At the outset, Hon'ble Chairperson welcomed the Members of the Committee and representatives of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) and other officials to the sitting.

Their attention was invited to the provisions contained in Direction 55(1) of the Directions by the Speaker regarding confidentiality of the Committee's proceedings.

3. After the witnesses introduced themselves, the official from Department of Pharmaceuticals made power point presentation on the subject "Pricing of drugs with special reference to Drug Price Control Order 2013" covering *inter-alia* the following Points:-

(i) Setting up of NPPA and its composition;
(ii) Salient features of DPCO, 2013;
(iii) National List of Essential Medicines
(iv) Price fixation for medicines in NLEM
(v) E-initiative -Pharma Janm Samadhjan
(vi) E-initiaive Pharma Data Bank(IPDMS)
(vii) Pharma Sahi Dham

4. During the discussion, the Hon'ble Chairperson and Members of the Committee *inter-alia* raised following issues/points namely-:

(i) Reasons for replacing the cost based pricing to market based pricing;
(ii) Mechanism for deciding essentiality of a medicine;
(iii) Measures taken to control prices of non scheduled drugs/medicines/formulation;
(iv) Issue related to availability of drugs in indian markets which are banned in foreign countries;
(v) Price difference of medicines being manufactured by big and small pharma companies;

(vi) Fair profit margin and difference in cost of promoted and non-promoted drugs; and

(vii) Incentives for small pharma companies to undertake research projects

(viii) Need for more full time members in NPPA to strengthen its effective functioning.

4. The Secretary, Department of Pharmaceuticals replied to the above issues/points. Thereafter, the Chairperson thanked the witnesses for appearing before the Committee as well as for furnishing valuable information to the Committee. They were also asked to provide required information which was not readily available with them to the Committee at the earliest.

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

The Committee then adjourned.

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

(2018-19)

The Committee sat on Monday, the 22nd October, 2018 from 1100 hrs. to 1230 hrs. in Committee Room 2, Parliament House Annexe Extension Building, New Delhi.

PRESENT

Shri Anandrao Adsul - Chairperson

MEMBERS

LOK SABHA

2. Shri George Baker
3. Shri K. Ashok Kumar
4. Shri Chhedi Paswan
5. Dr. Kulamani Samal
6. Shri Pankaj Chaudhary
7. Dr. (Smt.) Ratna De (Nag)
8. Shri Sarfaraz Alam

RAJYA SABHA

9. Shri Biswajit Daimary
10. Shri Prem Chand Gupta
11. Shri Ranvijay Singh Judev
12. Shri B. K. Hariprasad

SECRETARIAT

1. Shri Vinod Kumar Tripathi - Joint Secretary
2. Shri A. K. Srivastava - Director
3. Shri C. Kalyanasundaram - Deputy Secretary

LIST OF WITNESSES

I. MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

1. Shri Jai Priye Prakash Secretary
2. Shri Navdeep Rinwa Joint Secretary

II. REPRESENTATIVES OF NATIONAL PHARMACEUTICALS PRICING AUTHORITY (NPPA)

1.	Shri Rakesh Kumar Vats	Chairman, National Pharmaceuticals Pricing Authority (NPPA)
2.	Ms Rittu Dhillon	Member Secretary, National Pharmaceuticals Pricing Authority (NPPA)
3.	Sh. Kalyan Nag	Adviser, National Pharmaceuticals Pricing Authority (NPPA)
4.	Shri APS Sawhney	Director , National Pharmaceuticals Pricing Authority (NPPA)

III. DRUG CONTROLLER GENERAL OF INDIA

1.	Dr. S. Eswara Reddy,	DCGI
2.	Sh. A. K. Pradhan	DDC, DCGI

2. At the outset, Hon'ble Chairperson welcomed the Members of the Committee and representatives of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) and other officials to the sitting.

Their attention was invited to the provisions contained in Direction 55(1) of the Directions by the Speaker regarding confidentiality of the Committee's proceedings.

3. After the witnesses introduced themselves, the representative of Department of Pharmaceuticals made a power point presentation to the Committee on the subject "Pricing of drugs with special reference to Drug Price Control Order 2013" covering *inter-alia* the following Points:-

(i) Setting up of NPPA and its composition;
(ii) Salient features of DPCO, 2013;
(iii) National List of Essential Medicines
(iv) Price fixation for medicines in NLEM
(v) E-initiative -Pharma Janm Samadhjan
(vi) E-initiaive Pharma Data Bank(IPDMS)
(vii) Pharma Sahi Daam

4. The power point presentation was followed by discussion on various issues/points relating to subject. During the discussion, the Hon'ble Chairperson and Members of the Committee raised questions which were replied by the representatives of the Ministry. Some of the vital points that came up for discussion are :-

(i) Mechanism for deciding essentiality of a medicine;

(ii) Pricing mechanism for scheduled and non- scheduled medicines;

(iii) Income level and purchasing power of people belonging to below poverty line *viz-a-viz* preparation of National List of Essential Medicines;

(iv) Violation of DPCO by manufacturers and retailers and action taken thereon;

(v) New Drug Policy and reasons for delays in approval of new drugs

(vi) Supply of free medicines and prices of PMBJP medicines;

(vii) Reasons for slow progress in development of pharma industry clusters and incentives for growth of micro, small and medium pharma industries;

(viii) The status of Foreign Direct Investment in Greenfield and Brownfield projects in the pharmaceutical sector;

(ix) Functioning of mechanism to monitor quality of drugs and to check spurious drugs in the market;

(x) Issues related to availability of drugs in Indian market which are banned in foreign countries; and

(xi) Prospects of revival of Public Sector Pharma PSUs including IDPL.

5. Thereafter, the Chairperson thanked the witnesses for appearing before the Committee as well as for furnishing valuable information to the Committee. They were also asked to furnish these information which were not readily available with them to the Secretariat at the earliest.

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

The Committee then adjourned.

MINUTES OF THE FIFTH SITTING OF THE
STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2018-19)

The Committee sat on Monday, the 11 February, 2019 from 1500 hrs. to 1545 in Room No.139, Parliament House Annexe, New Delhi.

SHRI ANANDRAO ADSUL - CHAIRPERSON

MEMBERS

LOK SABHA

2. Shri George Baker
3. Smt. Veena Devi
4. Shri R. Dhruvanarayana
5. Shri K. Ashok Kumar
6. Shri Chhedi Paswan
7. Smt. Kamla Devi Patle
8. Shri S. Rajendran
9. Dr. Kulamani Samal

RAJYA SABHA

10. Shri Elamaram Kareem
11. Shri Vijay Pal Singh Tomar

SECRETARIAT

1.	Shri V.K. Tripathi	-	Joint Secretary
2.	Shri C. Kalyanasundaram	-	Additional Director
3.	Shri N. Amarathiagan	-	Under Secretary

2. At the outset, the Chairman welcomed the Members of the Committee.

3. The Committee thereafter took up for consideration and adoption the draft Report on the subject 'Pricing of Drugs with special reference to Drugs (Prices Control) Order, 2013' and draft Action Taken Report on 46th Report of the Committee on the subject 'Promotion and Co-ordination of Basic Applied and other Research in areas related to Pharmaceutical Sector' both pertaining to Department of Pharmaceuticals.

4. After deliberations, the Draft Reports were adopted by the Committee unanimously without any changes/amendments. The Committee authorised the Chairperson to finalize and present the Reports to the Parliament.

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The Committee then adjourned.