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STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS

(2025-26)

(EIGHTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

Review of Role, Functions and Duties of National Pharmaceutical Pricing Authoriy (NPPA) with specific reference to increase in prices of medicines in the Country

THIRTY- THIRD REPORT



LOK SABHA SECRETARIAT

NEW DELHI

August, 2026/ Sravana 1948 (Saka)

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Presented to Lok Sabha on 6 August, 2026

Laid in Rajya Sabha on 6 *August,* 2026

LOK SABHA SECRETARIAT
NEW DELHI

August, 2026/*Sravana*, 1948 (*Saka*)

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COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2025-2026)

Shri Azad Kirti Jha - Chairperson

MEMBERS
LOK SABHA

2. Shri Brijmohan Agrawal
3. Shri Ajay Bhatt
4. Shri Robert Bruce C.
5. Shri Bharatsinhji Shankarji Dabhi
6. Smt. Kriti Devi Debbarman
7. Dr. Kalyan Vaijinathrao Kale
8. Shri Malvinder Singh Kang
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16. Shri Rajesh Ranjan
17. Shri Daggumalla Prasada Rao
18. Shri Tharaniventhan M.S.
19. Shri Nalin Soren
20. Shri Shivmangal Singh Tomar
21. Vacant*

RAJYA SABHA

22. Shri Naresh Bansal
23. Shri Subhash Barala
24. Shri Ramesh Lingamaneni$
25. Shri Rwngwra Narzary
26. Shri Manmohan Samal&
27. Shri Arun Singh
28. Shri Akhilesh Prasad Singh
29. Shri Tejveer Singh
30. Shri L. K. Sudhish%
31. Vacant

* Vacant *vice* Dr. Ricky Andrew J. Syngkon, MP(LS), passed away on 19.02.2026 *vide* LS Table Office Notification No.21/4(8)/2026/TO(B) dated 20.02.2026.
& Nominated w.e.f. 03.06.2026 *vide* L.S. Bulletin-Part II dated 04.06.2026 Para No. 5267.
% Nominated w.e.f. 03.06.2026 *vide* L.S. Bulletin-Part II dated 04.06.2026 Para No. 5267.
$ Nominated w.e.f. 23.07.2026 *vide* L.S. Bulletin-Part II dated 24.07.2026 Para No. 5724.

Shri Subhash Chandra Bose Pilli, MP(RS) retired from the membership of Rajya Sabha w.e.f. 21.06.2026 vide Committee Branch note dated 19.02.2026.
Dr. Bhagwat Karad, MP(RS) retired on 02.04.2026 *vide* Committee Branch note dated 19.02.2026.
Shri G.K. Vasan, MP(RS) retired on 02.04.2026 *vide* Committee Branch note dated 19.02.2026.

SECRETARIAT

1. Smt. Maya Lingi — Joint Secretary
2. Ms. Miranda Ingudam — Director
3. Shri Kulvinder Singh — Deputy Secretary
4. Smt. Preeti Negi — Committee Officer

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals & Fertilizers (2025-26) having been authorized by the Committee do present on their behalf, this Thirty–third Report (Eighteenth Lok Sabha) on 'Review of Role, Functions and Duties of National Pharmaceutical Pricing Authoriy (NPPA) with specific reference to increase in prices of medicines in the Country' pertaining to the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals.

2. The Committee had a briefing by the representatives of the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals on 3rd November, 2025 and oral evidence on 24th November, 2025.

3. The Committee considered and adopted this Report at their Sitting held on 3rd August, 2026.

4. The Committee wish to express their thanks to the officers of the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals for tendering evidence and placing before the Committee all the requisite information related to examination of the subject.

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

6. For ease of reference and convenience, the Observations/ Recommendations of the Committee have been printed in bold letters in the body of the Report.

NEW DELHI;
3 August, 2026
12 Sravana, 1948 (Saka)

AZAD KIRTI JHA
Chairperson
Standing Committee on Chemicals and Fertilizers

REPORT

PART-I

A. Introduction

The Committee learnt that Government through various policy interventions since early 1960s had ensured the availability, affordability and accessibility of drugs. The price control over drugs was first introduced in the Country in 1962 under the Defence of India Act, 1915 with the promulgation of the Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963. These orders led to freezing of the prices of drugs with effect from 1.4.1963. Thereafter, a series of price control orders were notified through various orders in the Country from time to time based on different principles. The span of control of prices as well as the nature of control of prices under various orders has varied as per the underlying principles in the respective drug policies.

2. The National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012) was notified on 7.12.2012 with the objective of putting in place a regulatory framework for the pricing of drugs with the following objectives:

(a) Ensuring availability of required medicines at reasonable prices;

(b) Providing sufficient opportunity for innovation and competition;

(c) Supporting industry growth; and

(d) Meeting goals of employment and shared economic well-being for all.

3. The key principles of NPPP, 2012, statedly, are as follows:

(a) Essentiality of drugs: This criterion is to be met by considering the list of medicines specified in the National List of Essential Medicines (NLEM) declared and revised from time to time by the Department of Health and Family Welfare (DoHFW) under the Ministry of Health and Family Welfare (MoHFW). NLEM is prepared by the Standing Committee on Medicines (SNCM) constituted by the Ministry of Health and Family Welfare out of the World Health Organization model list of essential medicines, Essential Drugs Lists of various States, medicines used in various national health programmes and emergency care drugs, and contains such medicines that satisfy the priority health needs of the Country's population.

(b) Control of prices of formulations only: This refers to control of price of only the final end-product.

(c) Market-based pricing: Market-based pricing refers to pricing based on widely available information in the public domain as against individual manufacturer level production costing data, as the same would result in more transparent and fair pricing.

B. Setting up of National Pharmaceutical Pricing Authority (NPPA)

4. The National Pharmaceutical Pricing Authority (NPPA) was constituted by the Government of India *vide* resolution published in the Official Gazette no. 159 dated 29.8.1997. NPPA is an attached office of the Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers (MoC&F),

Government of India. Prior to setting-up of NPPA, the implementation of Drugs Price Control Orders (DPCOs) was with the Government itself. The Tariff Commission and its predecessor bodies, that is, Tariff Board, Interim Tariff Board, first Tariff Commission (TC) and the Bureau of Industrial Costs and Prices (BICP) (constituted in 1970) were closely associated with the costing and pricing of drugs with the charter of advising the Government on industrial costs and prices, and on issues relevant to cost reduction, improvement in industrial efficiency and pricing of industrial products.

5. With the formation of NPPA in 1997, the task of price fixation, revision and other related matters for Bulk Drugs and Formulations along with related manpower was transferred from BICP to NPPA. With the setting-up of DoP in 2008 in MoC&F, NPPA is now under DoP.

C. <u>Functions of National Pharmaceutical Pricing Authority</u>

6. As per the resolution and powers delegated from time to time, NPPA, *inter alia*, statedly, performs the following functions:

(a) Implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.

(b) Deal with all legal matters arising out of the decisions of the Authority.

(c) Monitor the availability of drugs, identify shortages, if any, and to take remedial steps.

(d) Undertake and/or sponsor relevant studies in respect of pricing of drugs/pharmaceuticals.

(e) Render advice to the Central Government on changes/revisions in the drug policy.

(f) Render assistance to the Central Government in the parliamentary matters relating to the drug pricing.

7. The Committee were informed that functions of NPPA, *inter alia*, include fixation and revision of prices of scheduled formulations as per the provisions of the DPCO including monitoring and enforcement of prices. The extant DPCO, i.e., DPCO, 2013 aims to make the essential medicines available at reasonable prices through their price regulation. Further, MoHFW *vide* SO 648 (E), dated 11.2.2020 notified all the medical devices intended for use in human beings or animals as Drugs under the Drugs and Cosmetics Act 1940 with effect from 1.4.2020. Accordingly, NPPA *vide* SO 1232 (E) dated 31.3.2020 has notified that all medical devices shall be governed under the provisions of DPCO, 2013 with effect from 1.4.2020.

8. The NLEM published by MoHFW is adopted as the primary basis for determining essentiality and is incorporated in the Schedule-I of the DPCO, 2013, as scheduled medicines for the purpose of price control. The Committee were informed that under NLEM, 2022, there are 388 medicines specified which correspond to over 900 formulations.

9. As regard the role of Department of Pharmaceuticals and NPPA in updation/revision of NLEM, the Department submitted as under:

> "Standing National Committee on Medicines (SNCM) consists of all stakeholders and experts and is chaired by the Director General, Indian Council of Medical Research (ICMR). A representative from DoP is a member of SNCM while a representative from NPPA is a special invitee."

10. The Committee further sought details regarding frequency of revision of the National List of Essential Medicines (NLEM) and criteria which guided inclusion/exclusion of medicines/drugs in this List. In response, the Department submitted as under:

> "NLEM is released by the Ministry of Health and Family Welfare (MoHFW). The inclusion/exclusion of the drugs in NLEM is done based on the recommendation of Standing National Committee on Medicines (SNCM) constituted by MoHFW. The process of inclusion or deletion in NLEM is done by the SNCM so constituted, from time to time, after comprehensive review to address the evolving healthcare needs of the Country as arrived at through wide stakeholder consultation and expert opinion. MoHFW *vide* order dated 3.7.2018 constituted the SNCM to review and revise the National List of Essential Medicines and published the revised NLEM in September 2022.

As per NLEM 2022 report[1], the criteria for inclusion of a medicine are listed below:

(a) The medicine should be approved/ licensed in India.
(b) The efficacy and safety profile of the medicine should be based on robust scientific evidence.
(c) The medicine should be useful in disease which is a public health problem in India.
(d) All medicines enlisted in National Health Programmes/National Disease Control Programmes are as such essential and hence included in the NLEM, 2022.
(e) The medicine should be affordable to the community in the Indian context.
(f) The medicine should be readily accessible at Primary, Secondary and Tertiary healthcare levels.
(g) When more than one medicine are available from the same therapeutic class, preferably one prototype/ best suited medicine of that class to be included after due deliberation and careful evaluation of their relative safety, efficacy, availability and affordability.
(h) Overall cost of therapy was considered and not just the unit cost of the medicine.
(i) A Fixed Dose Combination (FDC) was generally not included unless the combination had unequivocally proven advantage over individual ingredients administered separately, in terms of increasing efficacy, reducing adverse effects and/or improving compliance.

The criteria for deletion of a medicine from the existing NLEM are listed below:

(a) The medicine has been banned in India by the regulatory authority.
(b) There are reports of serious concerns on the safety profile of a medicine.
(c) Another medicine with better efficacy or favourable safety profile or better accessibility and affordability is now available.
(d) The disease burden, for which a medicine is indicated, is no longer a national health concern for India.
(e) In case of antimicrobials, if the resistance pattern has rendered an antimicrobial ineffective in the Indian context."

11. The Committee further desired to know that considering the current system of multiple categories of medicines—essential, non-essential and others, whether a unified regulatory framework for all medicines which would enhance clarity, transparency and ease of enforcement of price controls would be a more desirable option. In this regard, the Department submitted as under:

[1] NLEM Report 2022- https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/reportnlem2022.pdf

"The National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012) strives to achieve a balance between affordability and availability of drugs on the one hand and promotion of growth of industry on the other. Since the present framework is based on market data, it is a fair and transparent mechanism and is available in the public domain. Under the existing policy framework, NPPA controls the prices of essential formulation by fixing ceiling prices of scheduled formulation and retail prices of new drugs. However, with a view to keep a check on overall drugs prices, the prices of non-scheduled drugs are monitored as per provisions of paragraph 20 of DPCO, 2013. The existing framework has given impetus to the sustained growth of the sector that has made India the third largest producer of drugs in volume terms. However, the Department and NPPA remain engaged with stakeholders with a view to understanding issues and resolving them either under extant mechanism or by making appropriate provision."

12. During the course of oral evidence, on the same issue of categorization of medicines as essential and non-essential, scheduled and non-scheduled, the representative of the Department of Pharmaceuticals deposed as under:

"As you know, business and investment for business ultimately flows wherever you get better returns. So, if we reduce returns across the board on a particular sector, while immediate effect of that would be that prices may become lower, investment will also dry up because investors' money comes with expectation of return and they will go wherever they can earn a higher return. What are the likely consequences? If you look at the National Pharmaceutical Pricing Policy, it explicitly mentions this fact. It is a speaking policy and it says that in the medium and long term, an investment crisis is created with the result that capacities are not created to meet the supply for availability. Fresh investments in technology, delivery systems, innovations etc. do not happen. These are the problems which arise when we regulate the prices tightly according to today's technology and today's volumes. It is because then fresh investment in the sector stops.

The fresh investment does not only come from the industries which are there. They invest elsewhere. If all sectors were under price control – which takes us back to the license permit raj – from the commanding heights of the economy, you direct the flows of investment to any given sector. But if only one sector is under regulation and that is very tightly controlled, then that sector will stop getting investment and it may stop growing. That is the policy risk. And as was mentioned, the policy has not only price control, but also availability, innovation, employment and industrial growth as well as its objectives. So, it is a multi-dimensional policy and there is a need to balance various concerns. The idea of the essential medicine list is a very old idea. It is a well-recognized idea not just in India but across the globe. It is something which emanates from the essential drug list which the WHO brings out. And that is a baseline kind of a list for not just India but for other countries. Even Indian Public Health Standards (IPHS) recognize it. So, that is the basis for this distinction. ….Whatever I stated is there in the Gazette notified policy of the Government of India as approved by the Cabinet of the day. Back in 2012, it was issued with the approval of the Union Cabinet. It was examined before it went to the Union Cabinet. It was recommended upon by the Prime Minister's Economic Advisory Council under Dr. Rangarajan. They also had a very transparent consultation for almost 8-9 months on this policy before coming out with the recommendation. So, that is the background."

13. To a pointed query of the Committee that whether the Pharmaceuticals sector was in the hands of the private sector, the Department submitted as under:

> "India in 1991 initiated economic liberalization that, *inter alia*, involved reforms to reduce government control, open sectors to private and foreign investment, and integrate India with the global economy as against the mixed economy policy followed earlier. Accordingly, at present, India's pharmaceutical industry is predominately private-sector driven – with private pharmaceutical companies operating across formulations, APIs, vaccine, biosimilars, etc. As per the India Brand Equity Foundation (IBEF)[2], The domestic pharmaceutical ecosystem comprises around 3,000 drug companies and roughly 10,500 manufacturing units. The public sector involvement through government PSUs in pharma sector remains limited to five Central Public Sector Enterprises (CPSEs) i.e. Indian Drugs and Pharmaceuticals Limited (IDPL), Rajasthan Drugs and Pharmaceuticals Limited (RDPL), Hindustan Antibiotics Limited (HAL), Karnataka Antibiotics and Pharmaceuticals Limited (KAPL) and Bengal Chemicals and Pharmaceuticals Limited (BCPL). As per the Cabinet decisions, these PSUs are either in the process of closure/transfer or strategic disinvestment.
>
> Government's role is primarily regulatory, policy-making, facilitative and welfare-oriented, while production and marketing are largely handled by the private sector."

D. NPPA COMPOSITION

14. The Committee learnt that NPPA is a five Member body comprising Chairman (in the rank of Secretary or Additional Secretary of Govt. of India), Member Secretary (in the rank of Joint Secretary to the Govt. of India), three ex-officio Members, one each from the Department of Economic Affairs, O/o Chief Adviser Cost, Department of Expenditure and Drug Controller General of India, M/o H&FW. The Committee further learnt that the functions of NPPA are to implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it, to monitor the availability of drugs, identify shortages, if any, and to take remedial steps, to render advice to the Central Government on changes/ revisions in the drug policy, to render assistance to the Central Government in the parliamentary matters relating to the drug pricing. The ex-officio members enable NPPA to discharge its functions by providing the expert opinion relating to their expertise on the above matters.

15. The details of (a) number of meetings of NPPA held in the last three years; (b) attendance of each ex Officio Member in these meetings; and (c) agenda and significant decisions taken, especially for benefit of the public in these meetings, as furnished by the Department are as under:

> "During the last three years (December, 2022 to November, 2025), 36 Meetings were held. These meetings have been attended by all the ex-officio members or their representative except 6 meetings were not attended by Economic Advisor or his representative. In these meetings, Authority considered various agenda relating to fixation of ceiling price in respect 776 scheduled formulations, 1425 retail prices of new drugs, issuance of direction to companies to ensure continued production and other matters requiring discussion/decision of the Authority etc. The minutes of the Authority meeting are uploaded on NPPA website www.nppa.gov.in."

[2] https://www.ibef.org/industry/pharmaceutical-india

16. When asked to explain CDSCO's role in NPPA, the Department submitted as under:

" Drug Controller General of India (DCGI), CDSCO, Ministry of Health and Family Welfare is one of the members of NPPA. In addition, representative of DCGI is a member of the Multi-Disciplinary Committee of Experts (MDC). CDSCO also provides technical/ expert inputs on various issues such as licensing requirement of the drug, composition of the drugs, approval status of the drugs, Drugs and Cosmetics Act, 1940, etc."

17. When further queried that whether any formal mechanisms or inter-agency frameworks existed to ensure regulatory convergence, coordination, and consistency in the quality standards, enforcement, and market surveillance of pharmaceuticals across the Department of Pharmaceuticals (DoP), Ministry of Health and Family Welfare (MoHFW) and Ministry of AYUSH, the Department submitted as under:

"NPPA itself is constituted as an inter-agency body with the Drugs Controller General (India), Central Drugs Standard Control Organisation (CDSCO), office of Chief Adviser (Cost), Department of Expenditure and the Department of Economic Affairs represented on it. Further, it refers matters to a number of inter-departmental committees for various purposes, such as the Committee on Affordable Medicines and Health Products, the inter-ministerial committee, the Multi-Disciplinary Committee of Experts and the Standing National Committee on Medicines.

As per the information received from Ministry of Health and Family Welfare (MoHFW), CDSCO and MoHFW are involved in regulation to ensure quality, safety and efficacy of drugs in accordance with the Drugs and Cosmetics Act, 1940 and rules made thereunder. CDSCO coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee (DCC) meetings as well as other regular interactions held with State Drugs Controllers for uniformity in administration of the Drugs and Cosmetics Act to ensure drug quality. CDSCO conducts joint inspections and enforcement activities with State Licensing Authorities and other law enforcement agencies. Ayush vertical has been created in the CDSCO since 5.2.2018 to oversee the regulation of Ayurvedic, Siddha, Unani and Homeopathy (AYUSH) drugs from Central level."

18. When asked about method of NPPA's coordination with Central Drugs Standard Control Organisation (CDSCO) and State Drug Controllers to ensure holistic regulation of drugs and pharmaceuticals in the Country, the Department submitted as under:

"NPPA is a five-member body, and DCGI, CDSCO, Ministry of Health and Family Welfare is one of the three *ex-officio* members.

Further, in order to disseminate information on functioning of NPPA and create awareness among the consumers of pharmaceutical products, NPPA has established Price Monitoring and Resource Units (PMRUs) in 32 States / Union territories (UTs) as registered societies under the overall supervision and guidance of respective State Drugs Controllers (SDCs). This facilitates NPPA's engagement with SDCs as and when required."

E. Affordability of medicines

19. The Committee were informed that NPPA has contributed to affordable medical care in the Country through the effective regulation of pricing of drugs/ medical devices and ensuring availability of essential drugs at affordable prices. Some of the steps taken by NPPA towards this end, as furnished by the Department, are as follows:

(a) Fixation of ceiling price of scheduled formulations: NPPA fixes the ceiling prices of scheduled medicines specified in Schedule-I of the DPCO, 2013, in accordance with the provisions of paragraphs 4 and 6 of the DPCO, on the basis of market- based data. All manufacturers of scheduled medicines have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. Further, prices fixed by NPPA are applicable to all the manufacturers/marketers selling the said formulation, whether generic or branded. The ceiling prices of scheduled drugs are revised every year on the basis of Wholesale Price Index (WPI). As on 23.10.2025, ceiling prices are in effect for 933 formulations. Four medical devices (Bare metal stents, drug eluting stents, condoms and intra-uterine devices) have been included in the NLEM and hence are in Schedule-I of DPCO, 2013 and their ceiling prices have been fixed too. The average price reduction due to refixation of prices after inclusion NLEM, 2022 in Schedule-I is about 16.80% leading to total savings of around ₹3,801 crore to public.

(b) Revision of Ceiling Prices based on Wholesale Price Index (WPI): Paragraph 16 of DPCO, 2013 provides that 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. Although, the annual permitted increase in the prices of Scheduled drugs is based on the increase in WPI (all commodities), WPI increase is the maximum increase permissible and may or may not be availed by the manufacturers.

(c) Retail price fixation of new drugs: NPPA also fixes the retail price of new drug. As per paragraph 2(1)(u) of DPCO, 2013, the expression “new drug” means a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in NLEM by combining such drug with another drug that may or may not be listed in NLEM, or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the NLEM. The retail price of new drugs is fixed as per paragraph 5 of DPCO, 2013, for existing manufacturers of scheduled formulations and is applicable to the applicant manufacturer and marketer. The applicant manufacturer cannot sell the new drug above the price notified by NPPA. Till 23.10.2025, NPPA has fixed approximately 3,570 retail prices of new drugs under DPCO, 2013.

(d) Monitoring the prices of drugs: For non-scheduled formulation, NPPA monitors prices as per the provisions of DPCO 2013, and manufacturers are required to not increase the maximum retail price (MRP) of such formulations by more than 10% of the MRP during preceding 12 months. However, this is the maximum permissible increase and price increase, if any, by manufactures may be lower also. The average annual price increase by such manufacturers of non-scheduled drugs over the five-year period from April 2020 to March 2025 is at 5.6%, which is broadly in line with the Wholesale Price Index (WPI) rise of 5.4% over the same period and is significantly lower than the permissible 10% increase.

(e) Price fixation in public interest: Paragraph 19 of DPCO, 2013 provides for fixation of prices of drugs in extraordinary circumstances in public interest to ensure the availability of drugs at affordable prices. NPPA has invoked paragraph 19 in the following cases, in public interest and fixed the prices as below:

(i) The MRP of 106 non-scheduled drug formulations were capped in 2014, which includes 22 diabetic and 84 cardiovascular drugs.

(ii) Ceiling prices of coronary stents were fixed and notified on 13.2.2017 for the first time.

(iii) Ceiling price of knee implants, which is one of the components under 'Orthopaedic Implants', was notified on 16.8.2017.

(iv) Vide order S.O. 1041 (E) dated 27.2.2019, a cap on Trade Margin @ 30% on 42 selected non-scheduled anti-cancer medicines was put under 'Trade Margin Rationalisation' approach. Under this, price of 526 brands of medicines were reduced by an average of around 50% leading to annual savings of ₹ 984 crore to the patients.

(v) During COVID-19, the price of Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer were regulated under "Trade Margin Rationalisation" approach by fixing trade margins on these devices in June/July 2021 under paragraph 19 of DPCO, 2013.

(vi) Prices were revised for Heparin to ensure its availability during COVID- 19, vide S.O. 2151(E) dated 30.6.2020.

(vii) Vide notification S.O. 3322 (E), dated 25.9.2020, prices were capped for Liquid Medical Oxygen (LMO) and the Oxygen Inhalation (Medicinal gas) to ensure their continued availability during COVID.

20. The Committee were informed that NPPA has been delegated the power of executing and implementing the DPCO, 2013, except powers under Para 17, 22(2) and 31, by the Department of Pharmaceuticals. The Department of Pharmaceuticals under the Ministry of Chemicals and Fertilizers is the competent authority that drafts, frames, amends and issues the DPCOs.

21. Keeping in view significant growth and transformation of India's Pharmaceutical sector, the Committee desired to know whether there was any plan to review and revise/update the extant National Pharmaceutical Pricing Policy 2012 and DPCO, 2013 to reflect current realities. The Department, in this regard, submitted as under:

"The National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012) strives to achieve a balance between affordability and availability of drugs on the one hand and promotion of growth of industry on the other. The objective of the policy is to put in place a regulatory framework for pricing of drugs with a view to ensure availability of required medicines — "essential medicines" — at reasonable prices while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic wellbeing for all.

The policy framework is based on three principles, *viz.*, essentiality of drug, control of formulations prices only and market-based pricing. The essentiality criteria for drugs under

NPPP, 2012 is met by considering the medicines specified in NLEM, as revised from time to time by MoHFW. The same is incorporated in Schedule-I to DPCO, 2013.

The policy framework as given effect to through DPCO, 2013 protects and balances interests of various stakeholders. Revisions/updates to the same are an ongoing activity. The Department, from time to time, holds consultations with stakeholders and takes appropriate action on suggestions received with a view to address them through appropriate implementation and strengthening of the extant framework, issuance of appropriate instructions and guidelines, and making suitable fresh provisions."

22. The Committee were informed that the scheduled medicines, for which NPPA fixed the ceiling price or imposed a cap, constituted only 18 per cent of the overall market size. As per the extant policy, in case of non-scheduled formulation, prices are fixed by manufacturers themselves. However, the same are monitored as per Para 20 of DPCO, 2013 wherein manufacturers are not permitted to increase the maximum retail price (MRP) of such formulation by more than 10% of their MRP during the preceding 12 months.

23. When asked about percentage of increase in the prices in non-NLEM medicines, the Department submitted that from the market-based data, it was observed that in case of non-scheduled formulation the average annual price rise over last five years (FY2020-21 to FY2024-25) is approximately 5.6%, as against permitted annual increase of 10%.

24. When enquired about the Department's suggestions for further bolstering the existing regulatory structure to make medicine pricing more transparent, predictable and effective for both consumers and industry, the Committee were apprised as under:

"Under the existing framework of DPCO, 2013 NPPA uses a formula-based approach to fix ceiling prices/retail prices. The draft working sheets of the ceiling and retail prices proposed are uploaded on the NPPA website for 10 working days for information of public and invitation of comments. Comments and representations received are examined and considered before prices are notified. Further, all price notifications and minutes of the Authority's meetings are uploaded on its website (www.nppa.gov.in). This methodology is fair, transparent and predictable, bringing certainty for industry and consumers. As and when requirement is felt, the same are sought to be addressed through appropriate amendment or administrative instruction."

25. On being asked to provide data regarding comparison of drug prices in India vis-a-vis with countries like UK, USA, Germany, which were major pharmaceutical manufacturers and exporters, the Department submitted as under:

"IQVIA, a leading global life sciences consulting firm, has informed on the basis of analysis of market data for drugs and dosage forms that have large market share in various therapeutic categories and are available in at least three identified countries, that prices of drugs in India are generally the lowest across categories."

F. Shift from cost-based pricing to market-based pricing under DPCO 2013

26. DPCO, 2013 marked a shift from cost-based pricing to market-based pricing. When asked whether there were any possibilities/opportunities for the pharmaceutical companies to exploit any regulatory gaps in current market-driven pricing policy and whether shifting from cost-based pricing to market-based pricing had any adverse effect on prices of these medicines, the Department submitted as under:

> "As per NPPP, 2012, under market-based pricing, the pricing would be based on widely available information in the public domain as against individual manufacturer production costing data which would result in more transparent and fair pricing. Thus, market-based pricing is a well thought out decision as evident from NPPP, 2012. As and when any regulatory gaps are noticed, they are addressed through suitable amendments or administrative instructions."

27. The Committee desired to know why cost audit, despite being a statutory tool, was not being effectively utilized by NPPA for price fixation. In this regard, the Department submitted as under:

> "As per the existing framework, the mandate of NPPA is to fix the prices based on market data considering the average Price to retailer (PTR). Further, for the purpose of trade margin rationalisation, market-based data is considered. There is no provision in DPCO, 2013 to consider cost-based data."

28. When asked about the policy or statutory limitations presently restricting NPPA from conducting backward costing or cost-audit exercise to verify the substantial disparity between Price to Supplier (PTS), Price to Retailer (PTR) and Maximum Retail Price (MRP) in case of certain medicines, and whether any proposal had been made to empower it accordingly, the Department submitted as under:

> "As per the existing framework, prices of a formulation are fixed based on market data, by considering the average PTR of all brands having a market share equal to or more than 1% of that formulation and adding a margin of 16% to it. The methodology for price fixation is laid down in DPCO, 2013 and there is no concept of backward working in DPCO, 2013. There is no provision in DPCO, 2013 to consider cost-audit-based data for price fixation."

29. Regarding the feasibility of cost audit of medicines, the representative of NPPA during evidence deposed as under:

> "I have no power to do cost audit. The pricing used to be on cost basis earlier. Right now, it is based on the market data. Whatever is the market price, I have to fix the price on that. It is a policy issue. If the changes come in the DPCO, if I am given the mandate, we will do that. Earlier, as you said rightly, it used to be cost-based pricing. Whatever is the cost of producing that medicine, they used to add up margin and sell. Now, from 2013 DPCO, we shifted over to the market-based pricing. So, we have to do the pricing based on the market data."

G. Price fixation of medicines by National Pharmaceutical Pricing Authority (NPPA)

30. When asked about the methodology adopted by NPPA for fixation and revision of prices of scheduled drugs and formulations, the Department submitted as under:

> "Fixation and revision of prices of scheduled drugs and formulations are governed by the provisions of the Drugs (Prices Control) Order, 2013 ("DPCO, 2013") which has been promulgated based on the principles of the National Pharmaceutical Pricing Policy, 2012 ("NPPP, 2012"). NPPA fixes ceiling prices of formulations specified in Schedule-I to DPCO, 2013 in accordance with the provisions of DPCO. Under paragraph 4 of DPCO, 2013, the ceiling price of a scheduled medicine (*i.e.*, a medicine included in Schedule-I to DPCO, 2013) is fixed based on market data, by taking the simple average of the prices to retailers (PTRs) of all brands and generic versions of medicine having market share of more than or equal to 1% of the total market turnover, reckoned on the basis of moving annual turnover of the medicine. The ceiling price is arrived at by adding a margin of 16% to the simple average of PTR for the specified medicine. As provided for under DPCO, 2013, the GST if actually paid, wherever applicable on actual basis, is to be added to the ceiling price to arrive at the maximum retail price. Further, in cases where there is no reduction in average price to retailers and there are less than five manufacturers, having one percent or more market share, the average PTR is reduced as per the methodology provided in paragraph 6 of DPCO, 2013 and thereafter 16% margin is added to the reduced average PTR to arrive at the ceiling price.
>
> Revision in the prices of scheduled drugs as per the above methodology is carried out every five years. In addition, the ceiling prices of scheduled formulations are revised every year as per annual Wholesale Price Index (WPI) (all commodities) for preceding calendar year on or before 1st April of every year, which is notified by the Government on the 1st day of April every year."

31. When asked whether the Department fixed the prices of scheduled formulations based on PTR *i.e.* Price to Retailer declared by the company, the Department submitted as under:

> Under the existing policy framework, NPPA fixes ceiling prices of scheduled formulation and retail prices of new drugs based on market data. The prices are fixed by adding 16% margin to the average of price to retailer (PTR) of all brands having market share of equal to or more than 1% of that formulation.

32. When further asked to state consequences being faced by the consumer due to this price fixation method, the Department submitted as under:

> The fixation of ceiling price as per the existing method results in reduction of prices of schedule drugs. Despite the subsequent increase in their prices based on the increase in Wholesale Price Index, as permissible under the provision of DPCO, 2013, the scheduled medicines are available at reasonable prices in the Country. The fact that the prices of essential medicines in India are lower in comparison to those in other middle and low income countries, is also indicated by the study comparing the prices of top-selling formulations in the top-selling therapeutic categories and dosage forms in India with those in such other countries.

33. NPPA's key responsibilities included fixing and revising drug prices as per the provisions of the Drugs Prices Control Order (DPCO). The Committee learnt that mandate of NPPA was to fix the price based on the market data. When asked to explain this 'market data', the Department submitted as under:

> " DPCO, 2013 defines market-based data as the data of sales related to a drug, collected or obtained by the Government as deemed fit, from time to time. Further, Para 9 of DPCO, 2013 provides that the source of market-based data shall be the data available with the pharmaceutical market data specializing company as decided by the Government. Accordingly, NPPA obtains the data from M/s. Pharmarack Technologies Pvt Ltd. The data includes Stock Keeping Unit (SKU), Maximum Retail Price (MRP), Price to Stockist/Distributor, Price to Retailer, Sales quantity and sales value.

34. When further asked whether NPPA had the cost price of all medicines/products that pharmaceutical companies were manufacturing, the Department submitted as under:

> "As per NPPP, 2012 pricing is based on market-based data that considers average PTR of all brands of a drug having 1% or more market share of that drug and addition of 16% margin to retailers for fixing the ceiling/retail prices of such drug. Therefore, the cost data of the companies are not maintained by NPPA."

35. When asked about duration it took to be implemented once the price of medicines was fixed by NPPA, the Department submitted as under:

> "The prices fixed by NPPA comes into effect immediately from the date of issue of Gazette Notification. However, in case of scheduled formulations produced or available in the market before the date of notification of ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of the notification that the maximum retail price of such scheduled formulation does not exceed the ceiling price (plus taxes as applicable).

36. On being enquired about time given by NPPA to the pharmaceutical companies to withdraw their medicines from market, the Department submitted as under:

> "For ensuring compliance with the downward revision of ceiling prices, the manufacturers are not required to withdraw the stock that are in the trade channel if they are able to ensure that such drugs are sold to the consumers at the reduced ceiling prices."

37. When asked whether there were other cases of price fixing and other issues that NPPA might had given notice of, the Department submitted as under:

> "NPPA issues notices to manufacturers if they are found violating the provisions of DPCO, 2013. Further, notices for recovery of overcharged amounts are also issued to companies. Majority of cases that NPPA is contesting before various High Courts and the Supreme Court of India are related to price fixation and overcharged amount. Companies have also contested the validity of certain provisions of the DPCO itself. Further, some companies assert exemption from price control under Paragraph 32 of the DPCO, 2013 on the grounds that their products are patented or developed through indigenous research and development. Under the earlier DPCO, 1995, companies similarly disputed the inclusion of bulk drugs in

the schedule as arbitrary and inconsistent with the Drug Policy Amendment of 1986 which are currently pending."

38. To a categorical query of the Committee whether there was an anomaly in price fixation of medicines in the Country, the Department submitted as under:

> "There is no anomaly in price fixation of medicines. Under the existing framework, ceiling prices of scheduled formulation and retail prices of new drugs are fixed based on market data by taking the average of price to retailer (PTR) of all brands having market share of equal to or more than 1% of that formulation and by adding 16% margin to this average.
>
> Further, in case of non-scheduled formulations, NPPA monitors MRP with a view to ensure that increase in MRP is not more 10% over the period of preceding 12 months.
>
> Under the existing policy, prices are fixed based on PTR."

H. <u>Fixation of Retail prices of new drugs</u>

39. The Committee were informed that NPPA also fixed the retail price of new drug. As per paragraph 2(1)(u) of DPCO, 2013, the expression "new drug" means a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in NLEM by combining such drug with another drug that may or may not be listed in NLEM, or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the NLEM. The retail price of new drugs is fixed as per paragraph 5 of DPCO, 2013, for existing manufacturers of scheduled formulations and is applicable to the applicant manufacturer and marketer. The applicant manufacturer cannot sell the new drug above the price notified by NPPA. Till 23.10.2025, NPPA has fixed approximately 3,570 retail prices of new drugs under DPCO, 2013.

40. The Department of Pharmaceuticals submitted that the retail prices of new drugs are fixed based on market data as per the formulae provided in the Drug (Prices Control) Order, 2013. Based on an application received, a draft working sheet of the retail price proposed is uploaded on the website of NPPA for 10 working days for information of general public and to invite comments. The comments and representations received, if any, are examined and considered before the prices were notified. Further, all price notifications and minutes of the Authority meetings were also uploaded on the website of NPPA, i.e., www.nppa.gov.in.

41. When asked about stakeholder consultations conducted before revising or notifying new drug prices, the Department submitted as under:

> "The retail prices of new drugs are fixed based on market data as per the formulae provided in the DPCO, 2013. Based on an application received, a draft working sheet of the retail price proposed is uploaded on the website of NPPA for 10 working days for information of general public and to invite comments. The comments and representations received, if any, are examined and considered before the prices are notified. Further, all price notifications and minutes of the Authority meetings are also uploaded on the website of NPPA, *i.e.*, www.nppa.gov.in."

42. When asked about the rationale for fixing this period of 10 days, especially when price fixation affected millions of patients and many manufacturers and companies, the Department submitted as under:

> "The draft worksheets are uploaded on NPPA website for a period of 10 working days as per the directives of Government considering that a period of 10 working days is a reasonable period for any stakeholder to file representation, if any."

43. Regarding the number of comments/representations received by NPPA on draft working sheets of the retail price of new drugs proposed during the 10-working days window in the last three years and effect of these comments/representations in the final price notification, the Department submitted as under:

> "During the period from 01.12.2022 to 30.11.2025, 1426 draft working sheets were uploaded on website for 10 working days seeking comments. Approx. 30 comments/ representations were received by NPPA on the same. Out of these, 29 representations were received from pharmaceutical companies, 1 representation from industry association. This led to revision in calculations of draft worksheet in respect of only 6 cases."

44. When asked whether there was any provision for appeal or review mechanism for consumers/stakeholders who might be dissatisfied with the outcome of price fixation done by NPPA, the Department submitted as under:

> "Para 31 of DPCO, 2013 provides review mechanism. It stipulates that any person aggrieved by any price fixation notification issued or an order made under paragraphs 4, 5 and 6 of the DPCO, 2013, may file a review application to the Department within thirty days of the date of publication of the notification in the Official Gazette or the receipt of the order by him, as applicable."

45. When asked about the average time taken from the uploading of a draft working sheet of the retail price of new drugs proposed to the final notification of prices and challenges encountered by NPPA that may delay the finalization of prices, the Department submitted as under:

> "All draft working sheets are uploaded on the NPPA website for 10 working days before being placed for the Authority's approval. Generally, Authority meetings of NPPA are held every month. Hence, all working sheets that have completed 10 days' period since their date of uploading as on the day of Authority meeting are placed in the Authority meeting. For cases where the 10 days' period is not completed till the date of Authority meeting, such draft worksheets are placed in the Authority meeting of the subsequent month. In cases where representations are received, additional time may be required for examination of the same."

46. When asked about measures taken by NPPA to ensure that the uploaded data on its website was accessible and intelligible to common stakeholders, including patients and smaller manufacturers, who might not have technical expertise as such, the Department submitted as under:

> "All draft working sheets relating to ceiling and retail price fixation are prominently displayed on the NPPA's website, www.nppa.gov.in, for a period of ten working days. The draft working sheets are keenly watched by industry and other stakeholders. The same can be accessed by general public and no special technical or legal expertise is required to access and comprehend the same. This approach protects the interest of general public. All the price notifications are published in the official gazette. NPPA also disseminates its pricing decisions

through its website and social media platforms. Price Monitoring and Resource Units (PMRUs) in 32 States/UTs organize various campaigns to spread awareness and disseminate information among general public. Pharma Sahi Daam is a mobile application launched and developed by NPPA where the composition, drug type and prices of around 98,000 SKUs of medicines are reflected."

I. <u>Impact assessment of pricing interventions by NPPA</u>

47. The representative of the Department of Pharmaceuticals, during oral evidence, highlighted the reduction in prices of medicines as under:

> "The ceiling price are fixed periodically as per the existing provisions. Once a formulation or medicine is included in the schedule, the NPPA fixes its ceiling price based on prevailing market data. After that, the prices are again revised every five years based on the prevailing market data. Based on the NLEM, 2022, we have revised the prices of about 933 formulations, which resulted in an average reduction of 17 per cent in the overall price of the medicines. …When the prices were revised in 2011, about ₹ 2,423 crore savings were made. Similarly, in 2015, ₹ 2,643 crore and in 2022, about Rs 3,801 crore savings were made to the public at large."

48. To a query of the Committee that whether NPPA had recently undertaken any impact assessment of its pricing interventions on public health outcomes, it was submitted that as per information provided by the Department of Health and Family Welfare, in the Total Health Expenditure of the Country between the financial years 2014-15 and 2021-22, the share of Out of-Pocket Expenditure (OOPE) in Total Health Expenditure declined from 62.6% to 39.4%, indicating improved accessibility to healthcare and decline in financial burden on households.

49. When further asked to quantify how much of the Out of-Pocket Expenditure (OOPE) in Total Health Expenditure reduction was specifically due to medicine price fixation and monitoring undertaken by NPPA, the Department submitted as under:

> "The fixation of ceiling prices/MRP under various NLEMs under DPCO, 2013 and invoking of paragraph 19 from time to time have resulted in substantial savings to consumers. Based on NPPA's assessments, there has been an average annual total saving of more than ₹ 25,000 crore to the public due to implementation of DPCO, 2013. The break-up of the total annual savings through various measures taken by NPPA are as follows:

Particulars	Saving to consumer (in crore ₹)
Under NLEM, 2011	2,423
Under NLEM, 2015	2,643
Under NLEM, 2022 (till 23.10.2025)	3801
Coronary stents (calendar year 2024)	12,747
Anti-diabetic and cardiovascular drugs under paragraph 19	350
Orthopaedic knee implants	1,500
Anti-cancer drugs	984
Trade margin rationalisation of 6 medical devices during covid	1,000
Total	25,448

Note: The total savings calculated are in the nature of additional savings since prices of many scheduled drugs are historically under price control. Additionally, consumers are also benefited due to 10% cap on annual increase in MRP of non-scheduled drugs. Therefore, absolute savings on account of price regulation under DPCO, 2013 are likely to be much more than the above estimate."

50. The Committee were also informed that while ensuring affordability, access cannot be jeopardized and the life-saving essential drugs must remain available to the general public at all times. Therefore, unviability of formulations should not lead to a situation where these drugs become unavailable in the market and the public is forced to switch to expensive alternatives. Hence, NPPA, statedly, in public interest invoked paragraph 19 under DPCO, 2013 in the following instances: (i) Allowed 50% increase on 21 formulations of 12 medicines on the then applicable ceiling price to ensure the availability of medicines (notified vide S.O. 4461(E) dated 13.12.2019) (ii) Allowed 50% increase on 9 scheduled formulations of 3 drugs on the then applicable ceiling price (notified vide S.O. 2654(E) dated 1.7.2021) (iii) 11 scheduled formulations of 8 drugs were given one-time increase of 50% of the present applicable ceiling price (notified vide S.O. 4498(E) dated 14.10.2024).

51. During oral evidence, the Committee desired to know the reasons for allowing increase in prices of certain medicines by NPPA. The representative of NPPA submitted as under:

"These are the formulations which are very critical and over a period - because of the price fixation, repeated price fixation - their prices have gone down. This is number one. The number two is that they are either sole agency producing or there are only one or two agencies producing. Based on a certain criteria, this was examined at NITI Aayog long back. Then a criteria was evolved for those cases where it has become extremely unviable and they are going out of the market, there are no alternatives available. Also, taking into fact the API price increases. In some cases, the API increase has been so much - active pharmaceutical ingredient - the prices have gone up so much, which we confirm from the Ministry of Health and Family Welfare over a period of time. It has become extremely unviable for these medicines to continue. We are extremely conservative. We receive large number of requests, hundreds of requests for price increase. But we are extremely conservative in giving price increase. But if you also see the actual prices, though it mentions 50 per cent, that 50 per cent may be from ₹ 1 to ₹ 1.50. Most of these medicines are very low cost medicines. That is why they become extremely unviable to continue to produce. In those cases only, over a period of since 2019 to 2024, price increase has been allowed."

J. <u>Margins in sale of certain medicines</u>

52. It came to notice of the Committee that several hospitals and retailers offered discounts on medicines ranging from 20% to 60% on MRP. When asked how such pricing behaviour, which reflected huge profit margins being earned by companies, stockists and retailers, existed when MRP was fixed under regulation by NPPA, the Department submitted as under:

"NPPA fixes the ceiling prices of scheduled formulation and retail prices of new drugs based on market data as per the provisions of DPCO, 2013. Further, prices of non-scheduled formulation are determined by the manufacturers but as per paragraph 20 of DPCO, 2013 they are required to not increase the maximum retail price of these medicine by more than 10 percent in a year.

Further, discounts offered by hospital and retailers are guided by marketing and cost considerations of various business entities in the supply chain. The extent of trade margin differs across drugs depending on a variety of factors, such as:

(a) Drug dosage form[3] (for dosage forms that require special handling for reasons such as maintenance of sterilisation, cold chain, vials, ampoules, glass bottles, etc., trade channel costs are higher);
(b) Volume of sales of the drug (for low sales volume, fixed costs of distribution get apportioned over a smaller quantity resulting in higher per unit trade channel costs);
(c) *Ex* factory price (for low *ex* factory price, the per unit distribution channel costs are relatively larger and are higher when expressed as percentage of *ex* factory price); and
(d) Marketing and distribution model (for MSME manufacturers, market development costs are often borne not by the manufacturer but by the trade channel; for sale in remoter areas, trade channel costs are higher due to lower turnover and higher costs of inventory and logistics).

As per data available in the Pharmarack database, the average markup for common dosage forms of non-scheduled drugs[4] is around 43% for distributors, stockists, wholesalers and retailers collectively."

53. In their 14th Report (18th Lok Sabha), the Committee had noted that the PTS of Ciprofloxin 500 mg and Tinidazole 600 mg which came to notice of the Committee, was ₹ 450/- but its MRP was ₹ 3500/- hence a whopping difference of ₹ 3050. Similarly, PTS of Ibrufin and Labocof was ₹ 831/- and ₹ 316/- but their MRP was ₹ 4560/- and ₹ 2850/- respectively, hence again a big difference of ₹ 3729/- and ₹ 2534/-. When asked to provide factual details in this regard alongwith the reasons for such price increases and the steps being taken to control them, the Department submitted as under:

"The formulation Ciprofloxacin 500 mg and Tinidazole 600 mg is a non-scheduled formulation and NPPA has notified the price for the existing manufacturer. The last retail price notified was ₹10.64 per tablet (excluding taxes), *vide* S.O. 1990(E), dated 15.5.2025. Further, as per market data available, the highest MRP per tablet (including taxes) for the said formulation in the month of October 2025 was ₹ 19.46 and the price to stockist was ₹13.34 (excluding taxes).

NPPA has fixed ceiling prices of the formulation Ibuprofen as under:

S. No.	Dosage and strength	Unit	Ceiling price (in ₹, excluding taxes)
1	Tablet 200 mg	1 tablet	0.72
2	Tablet 400 mg	1 tablet	1.22
3	Oral liquid 100 mg / 5mL(p)	1 ml	0.22
4	Capsule 400 mg	1 capsule	1.33
5	Capsule 200 mg	1 soft gelatin capsule	3.39

[3] Common dosage forms such as tablets, capsules, sachet, gums and strips, and other dosage forms that require special handling for reasons such as maintenance of sterilisation, cold chain, vials, ampoules, glass bottles, etc.
[4] Tablets, capsules, sachet, gums and strips

All manufacturers are required to sell the formulation within the notified ceiling prices (plus applicable taxes).

Labocof is not a scheduled formulation. The formulation is not captured in Pharmarack, the principal source database used for monitoring market information in respect of over 14,000 formulations."

54. When asked whether it was a fact that the PTS of paracetamol was ₹ 180 but it was being sold at ₹ 4,560 and PTS of Combiflam was ₹ 480 but PTR was around ₹ 4,560 per strip of 10 tablets, the Department submitted as under:

"Paracetamol is a scheduled formulation and NPPA has fixed ceiling prices for the same. The currently applicable ceiling prices of Paracetamol tablet are as under:

S. no.	Dosage form and strength	Unit	Ceiling price (in ₹, excluding taxes)
1	Tablet 650 mg	1 tablet	2.04
2	Tablet 500 mg	1 tablet	0.92

Combiflam is a non-scheduled formulation containing Ibuprofen 400 mg and Paracetamol 325 mg, which is a new drug formulation. NPPA has notified the price for existing manufacturers. The last retail price notified was ₹1.59 per tablet (excluding taxes), *vide* S.O. 1990(E), dated 15.5.2025. Further, as per market data available, the highest MRP per tablet price for the said formulation in the month of October 2025 was ₹4.64 (including taxes) and PTS (excluding taxes) was ₹3.18 per tablet."

55. On being enquired whether stents and other medical devices were being sold on-line or on other e-pharmacy platforms at lesser prices than MRP, the Department submitted as under:

"Stents are scheduled medical device and NPPA has fixed the ceiling price for stents. No manufacturer including his trade channel (which may include online pharmacies) can sell the stent at MRP higher than the ceiling prices (plus applicable taxes) fixed by NPPA. Discounts, if any, offered by retailers are guided by commercial considerations."

56. The representative of NPPA during the oral evidence submitted that "there may be a huge difference between the Price to Stockist (PTS) and the PTR for the final price that is sold to the consumer at the MRP in some cases".

57. Regarding margins in the prices of medicines, the representative of the Department of Pharmaceuticals apprised the Committee as under:

"It is important to note that the average mark-up for common dosage forms of non-scheduled drugs, that is, tablets, capsules, sachets, gums and strips, is around 43 per cent when taken collectively across distributors, stockists, wholesalers and retailers. This indicates that high trade margins are not the norm. The fact that over the last three financial years, in nominal GDP growth terms, the Indian pharmaceutical sector has grown at 9.9 per cent, which is significantly lower than the nominal GDP growth of 11.8 per cent for the economy as a whole, also indicates that the sector is not earning outlier profitability, as higher profitability would typically result in greater investment and faster growth."

58. The Committee sought details of stages of the pharmaceutical supply chain—manufacturer, stockist, distributor, or retailer—where such excessive margins might be predominantly concentrated. Given the oral submissions of the representative of NPPA that "something needs to be done to contain these huge margins that are there in the distribution channel in some cases", the Committee also desired to know about concrete corrective/remedial/punitive actions taken by the Department so far in this regard. The Department, in response thereto, submitted as under:

"Analysis of Pharmarack database shows that majority (approximately 87%) of the non-scheduled market is availing weighted average markup (margin for distributor & retailer as a percentage of price to distributor) up to 45%. Out of total non-scheduled market, approximately 4% are having the weighted average markup more than 100% of the price to distributor. Thus, the high margin is not the industry norm but is observed only in case of small fraction of the market. So far as the issue of excessive trade margin and the stage where it exists in the supply chain is concerned, it would require analysis of various cost components specific to the business operations for the distribution of that formulation. Under the extant legal dispensation, such cost information is not available to the Department or NPPA.

Further, there is no uniform supply chain for the Pharma industry. It may differ from company to company. Supply chain may be different for MSME and MNCs. It may also be different for branded or generic products. Hence, it is not possible to ascertain the concentration of trade margin at a particular level of trade channel. However, from the feedback gathered from industry, it has emerged that supply and distribution of branded generic formulations is done through two types of marketing channels: the "branded generics" channel that typically caters to major demand centres and the "trade generics" channel that typically caters to remote and rural areas that have low-volume sales and account for about 8-9% of the market. The distribution costs for the two channels are structurally different, which translate into high difference in their per unit distribution costs in percentage terms. The following factors are pertinent in this connection:

i. Low-volume sales result in apportionment of fixed costs of distribution over a relatively smaller number of formulation units sold, which would translate into trade margins that may be high in percentage terms.

ii. In the case of formulations sold through the "branded generics" channel, the manufacturer maintains inventory for uninterrupted supply, along with associated significant inventory carrying costs, and also bears the costs of awareness activities related to these products, while the distribution channel only incurs logistics and distribution point costs. In contrast, in the case of formulations sold through the "trade generics" channel, the distribution channel incurs additionally the cost of carrying inventory and awareness.

iii. Apart from the above additional cost constituents, in the "trade generics" channel, the distribution channel costs are themselves typically higher than the corresponding costs incurred on formulations that are typically marketed through the "branded generics" channel, since the costs of logistics, staffing, expired inventory, cold chain, etc. in the "trade generics" channel are higher as sale volumes are smaller and offtake slower and uncertain and the distribution chain is longer due to this channel being typically adopted for supplies to remote and rural areas. In this connection, it is pertinent that the inventory carrying costs are higher for smaller retailers located away from main towns as they need to carry at least two months of stock to ensure availability, whereas retailers in larger towns who are supplied on daily basis carry only two to three weeks of inventory. Further, the costs of finance for the two sets

of retailers may be significantly different as smaller retailers may have smaller balance-sheets and lower credit rating assessment.

iv. Further, unlike in the case of the "branded generics" channel, where the manufacturer may maintain centralised inventory offering cost advantages accruing from economies of scale, in the case of the "trade generics" channel, there may typically be multiple smaller distributors who would not have the same scale and whose cost of distribution would, therefore, be higher.

v. The above cost related factors significantly impact the percentages for trade margin for formulations marketed through the "trade generics" channel in two ways. First, the Price to Stockist (PTS) at which the manufacturer sells becomes lower, reducing the denominator on which the percentage is calculated and, secondly, the absolute trade margin becomes higher, raising the numerator in the percentage calculation.

Thus, the trade margins for the two channels may differ considerably in percentage terms and may serve to offset higher distribution costs, which enable uninterrupted supply of essential medicines despite inherently high costs and logistical challenges.

In past, NPPA invoked an exceptional clause under DPCO, 2013 in public interest to cap the trade margin for 42 high-priced anti-cancer medicines as a pilot under a Trade Margin Rationalisation (TMR) approach and on Covid essential 6 medical devices during Covid pandemic. Further, in light of experience, DoP and NPPA have undertaken stakeholder consultations regarding incorporation of a suitable enabling provision for TMR in DPCO, 2013, and the feedback gathered from the consultations is under examination for formulating an appropriate policy in the matter."

K. <u>Affordable healthcare schemes/initiatives</u>

59. The Committee were apprised by the representative of the Department of Pharmaceuticals that the National Pharmaceutical Pricing Policy, 2012, recognised price control as only one element of a broader strategy for the provision of affordable healthcare. Other elements included direct Government healthcare, insurance, and a well-spread, low-cost *Jan Aushadhi* pharmacy network. Statedly, the policy approach had been to complement price control with affordable healthcare programmes in order to achieve multiple policy objectives simultaneously.

60. The Committee were further informed that Jan Aushadhi outlets had made commonly used scheduled and non-scheduled medicines available at an average of about 80 percent lower than leading brands in the market, resulting in savings of over ₹ 40,000 crore. When asked whether the Department had any data regarding proportion of total pharmaceutical consumption in India which was actually sourced from Jan Aushadhi outlets, AMRIT Pharmacies and under the Free Drugs Service initiative, the Department submitted as under:

"Under the Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP) during FY 2024-25, total sales of ₹2,022 crore had been registered.

As per the information provided by the Ministry of Health and Family Welfare (MoHFW), the Affordable Medicines and Reliable Implants for Treatment (AMRIT) initiative, launched by MoHFW, is a pioneering intervention aimed at making essential medicines and medical

supplies affordable for the treatment of life-threatening diseases such as cancer, cardiovascular ailments, diabetes, and other critical illnesses. The initiative seeks to substantially reduce the financial burden of healthcare and improve access to quality treatment, particularly for economically disadvantaged sections of society. The AMRIT initiative has been designed primarily to serve tertiary healthcare institutions, including AIIMS, District Hospitals, General Hospitals, Medical Colleges, Super Specialty Hospitals, and Central Government institution hospitals. AMRIT Pharmacies function as a single-point solution for the medical requirements of tertiary healthcare centres, catering to both Outpatient (OPD) and Inpatient (IPD) needs.

The product basket includes medicines, medical devices, implants, surgical items, and consumables, thereby supporting comprehensive patient care. Over the years, AMRIT has significantly expanded its scope and now covers a wide range of specialties such as oncology, cardiology, orthopaedics, medical implants (including stents), and medical disposables, in addition to both branded and generic medicines.

As on date, 255 AMRIT Pharmacies are operational across 24 States and 4 Union Territories. These pharmacies offer more than 8,000 medicines and medical products, including drugs for cardiovascular diseases, cancer, diabetes, implants, stents, surgical disposables, and other consumables. Products are sold at discounts of up to 50% on the Maximum Retail Price (MRP) against authentic prescriptions issued by registered medical practitioners, including prescriptions from institutions other than where the AMRIT pharmacy is located.

As on 15th December 2025, approximately 70.17 million patients have benefitted from the AMRIT initiative. The total value of medicines dispensed at MRP through AMRIT Pharmacies stands at ₹17,673.94 crore, resulting in direct savings of ₹8,691.42 crore to patients. This has significantly contributed to the reduction of out-of-pocket expenditure on healthcare, particularly for patients undergoing treatment for chronic and life-threatening conditions. The scale of operations, patient coverage, and cumulative savings clearly demonstrate the substantial role played by AMRIT Pharmacies in enhancing access to affordable medicines and reducing healthcare costs in the Country.

For Free drugs service initiative as informed by NHM-I Division, MoHFW, they do not maintain this information."

61. When further asked about the steps taken by the Department to monitor quality compliance and uninterrupted availability of medicines supplied by Jan Aushadhi outlets, AMRIT Pharmacies and under the Free Drugs Service initiative, the Department submitted as under:

"Jan Aushadhi Kendras (JAKs)

The following measures are in place to ensure quality of medicines supplied through JAKs:

(i) Supply only from WHO Good Manufacturing Practices (GMP) certified plants: Only plants that are certified as WHO-GMP compliant by the Central Drugs Standard Control Organisation (CDSCO) after direct inspection are eligible for supply.

(ii) Distribution only after 100% pre-testing of all medicine batches: Samples are drawn from 100% of batches supplied at PMBI's warehouses for testing anonymously, and medicines are dispatched for supply to JAKs only after the quality test is passed.

(iii) Testing only at labs compliant with Good Laboratory Practices (GLP): Samples are tested only at labs accredited and periodically inspected by the National Accreditation Board for Testing and Calibration Laboratories (NABL) and, in addition, assessed by PMBI for GLP compliance.

Number of steps have been taken to ensure effective and regular supply of medicines at JAKs, including the following:

(i) Since September 2024, stocking by JAKs of 200 commonly used medicines, consisting of the 100 top-selling medicines in the scheme product basket and 100 fast-selling medicines in the market, has been incentivised, under which JAK owners are eligible for monthly incentive based on the stocks that they maintain of these medicines.

(ii) An end-to-end information-technology-enabled supply chain system is in place to connect a robust supply chain system consisting of one central warehouse, four regional warehouses and a growing network of distributors across the Country, currently numbering 39.

(iii) In addition, with a view to ensure availability of commonly used products, 400 fast-moving products are monitored regularly by the scheme implementing agency Pharmaceuticals and Medical Devices Bureau of India (PMBI) and demand for the same is forecasted on an ongoing basis. Further, steps have been taken to digitise the forecasting method to augment the procurement process through automation.

Pharmaceuticals and Medical Devices Bureau of India (PMBI), the implementing agency of the scheme, has informed that due to reduced prices under Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana, estimated savings of over ₹40,000 crore have accrued to citizens.

Free Drugs Service Initiative (FDSI)

As per the information provided by MoHFW, under FDSI, Government of India supports procurement of drugs and strengthening robust systems of procurement, Quality Assurance, Supply chain management and warehousing, Prescription audit, grievance redressal, dissemination of Standard Treatment Guidelines and Establishment of IT enabled platform DVDMS (Drugs & Vaccine Distribution Management System) for monitoring the real status of procurement and availability of essential medicines.

MoHFW has recommended facility wise Essential Medicines List (EML) to be made available at the public healthcare facilities which includes 106 drugs at Sub Health Centre level, 172 at Primary Health Centre level, 300 at Community Health Centre level, 318 at Sub-district Hospital level and 381 drugs at district Hospital level.

Quality of drugs procured, under FDSI, is ensured through the operational guidelines of the initiative that

(i) All drugs must be sourced from Good Manufacturing Practices (GMP) compliant manufacturers through robust procurement mechanism.

(ii) Post supply testing of every batch before distributing to the health facilities.

The alert mechanism to monitor expiry dates of medicines involves robust tracking systems i.e. Batch Tracking, Inventory Management Systems and Barcode/RFID Technology. States/UTs monitor expiry dates at the district and local levels, ensuring no expired products are distributed.

In cases where products are approaching their expiry date, they are often redistributed to areas where they can be used before expiry.

The Affordable Medicines and Reliable Implants for Treatment (AMRIT)

As per the information provided by MoHFW, HLL Lifecare Limited, has put in place a robust and transparent mechanism to ensure quality compliance of medicines supplied through AMRIT Pharmacies and to maintain uninterrupted availability of essential medicines and medical supplies under the various schemes and initiatives.

Monitoring of Quality Compliance of Medicines Supplied by AMRIT Pharmacies:

1. Structured Vendor Registration and Evaluation

The Procurement Services Division (PSD) of HLL Lifecare Limited is responsible for the identification, development, registration, and approval of vendors, including manufacturers, importers, marketers, suppliers, and distributors.

All vendor development activities are executed through the Online Vendor Registration Portal of HLL Lifecare Limited (https://vendorregistration.lifecarehll.com/).

2. Online Vendor Registration Process

Interested vendors are required to access the online portal, create a profile, and upload documents for Pan-India or regional registration. The registration process ensures transparency, traceability, and standardisation across suppliers.

3. Comprehensive Document Verification

The Vendor Registration Team of PSD thoroughly evaluates the documents uploaded by vendors prior to approval. For manufacturers, the mandatory documents include:

- Supply category details
- GST Registration Certificate
- PAN Card
- Valid Manufacturing Licence
- Quality Certifications (at least one mandatory), such as:
  - FDA Certificate
  - CE Certificate
  - WHO-GMP Certificate
- Certificate of Incorporation / Licence issued by the Local Authority
- MSE-related documents, wherever applicable, including Udyog Aadhaar, MSE Certificate, NSIC/KVIC/UAM Certificate, and ownership details
- Non-Conviction Certificate
- Details of previously executed supply orders (minimum three)
- Company profile

4. Techno-Commercial Evaluation and Rate Finalisation

Upon successful registration, vendors are invited to submit their rates through the vendor portal. The rates are evaluated and finalised through a Techno-Commercial Negotiation process, ensuring compliance with technical specifications, quality standards, and commercial competitiveness.

5. Rate Contract and Supply Controls

After finalisation of rates, HLL enters into a Pan-India Rate Contract with the approved manufacturers. Supplies are accepted strictly against valid purchase orders and must be accompanied by:

- Certificate of Analysis (CoA) from the manufacturer for each batch
- NABL-accredited laboratory testing certificates for generic medicines, wherever applicable

6. Quality Assurance and Traceability

These multi-layered controls-ranging from vendor qualification, certification requirements, batch-wise testing, and documentation-ensure that only quality- compliant medicines and medical supplies are dispensed through AMRIT Pharmacies.

(i) Pan-India Rate Contracts with Multiple Vendors

Rate contracts are generally entered into with multiple qualified manufacturers on a Pan-India basis, reducing dependency on a single supplier and ensuring continuity of supplies.

(ii) Centralised and IT-Enabled Procurement System

The online vendor portal and integrated procurement systems enable real-time monitoring of supplies, orders, and vendor performance, facilitating timely replenishment.

(iii) Advance Planning and Demand Forecasting

Procurement planning is based on consumption patterns of AMRIT Pharmacies located in tertiary healthcare institutions, covering both OPD and IPD requirements, thereby minimising stock-out risks.

(iv) Strict Purchase Order and Supply Monitoring

Supplies are made strictly against purchase orders, and adherence to delivery timelines is monitored. Non-compliance by vendors attracts corrective measures as per contract terms.

(v) Quality-Linked Supply Acceptance

Acceptance of supplies is conditional upon submission of required quality documents, including CoA and laboratory test reports, ensuring that availability is not compromised by sub-standard products.

(vi) Single-Point Supply Support to Tertiary Healthcare Institutions

AMRIT Pharmacies function as a single-point solution for medicines, implants, surgical items and consumables for tertiary healthcare centres, further strengthening availability and operational efficiency."

L. <u>Trade Margin Rationalization (TMR)</u>

62. As per the existing framework, the mandate of NPPA was to fix the prices based on market data. The methodology provides for fixing the ceiling price of scheduled drugs, retail prices of new drugs and monitoring the increase in prices of non-scheduled drugs. Trade margin rationalisation

(TMR) approach for regulating prices was undertaken by exercising extraordinary powers available under paragraph 19 of DPCO, 2013 for a limited period.

63. The details of prices fixed under Para 19 in public interest in the last 5 years, as furnished by the Department, are as follows:

NPPA invoked the provision of Para 19 in public interest to address the exigencies arising out during COVID pandemic by regulating the prices of following drugs and medical devices:

- Ceiling Prices were fixed for Liquid Medical Oxygen (LMO) at ₹15.22 per cubic meter and the Oxygen Inhalation (Medicinal gas) at ₹ 25.71 per cubic meter vide S.O. 3322(E) dated 25.09.2020.
- The prevailing ceiling prices for Heparin Injection 1000IU/ml and 5000IU/ml were revised upward by 50% to ₹24.39 and ₹60.54 per ml respectively vide S.O. 2151(E) dated 30.06.2020 to ensure its continued availability during COVID.
- The trade margins of Oxygen Concentrators and five other medical devices viz., (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer at first point of sale of product (Price to Distributor) were capped at 70% of PTD vide S.O. 2161(E) dated 03.06.2021 and S.O. 2808(E) dated 13.07.2021.

64. Observing that non-scheduled drugs constituted a significant portion of the pharmaceutical market, the Committee desired to know whether Para 19 of DPCO 2013 needed to be invoked more frequently to address excessive pricing especially in cases where consumers/ patients faced severe affordability burdens. In response, the Department submitted as under:

"As per Pharmarack database for financial year 2024-2025, which covers about 98000 SKUs, the market share of the scheduled formulations is approximately 18% of the total value and the market share of the non-scheduled formulations is approximately 82% of total value. Further, analysis of Pharmarack database shows that majority (approximately 87%) of the non-scheduled market is availing weighted average markup (margin for distributor & retailer as a percentage of price to distributor) up to 45%. Out of total non-scheduled market, approximately 4% are having the weighted average markup more than 100% of the price to distributor. Thus, huge margin in the sector is not a norm but may be only in a small segment of this market.

A. The mandate of NPPA is to ensure availability of drugs at affordable prices. However, while ensuring affordability, access cannot be jeopardized and the lifesaving essential drugs must remain available to the general public at all times. Therefore, unviability of certain formulations should not lead to a situation where these drugs become unavailable in the market and the public is forced to switch to costly alternatives. Based on the recommendation of Committee on affordable Medicines and Health Products (CAMHP) under Chairmanship of Member (Health), NITI Aayog and Inter-Ministerial Committee on Para 19 constituted under NPPA, Authority invoked para 19 under DPCO, 2013 twice in last 5 years for upward revision of prices. The details are as follows:

- Prices of 9 scheduled formulations of 3 drugs revised by giving one-time increase of 50% on the then applicable ceiling price (notified vide S.O.2654(E) dated 1.07.2021).
- Prices of 11 scheduled formulations of 8 drugs revised by giving one-time increase of 50% on the then applicable ceiling price (notified vide S.O.4498(E) dated 14.10.2024).

B. Orthopaedic Knee Implants- The ceiling prices of orthopaedic knee implants for knee replacement therapy were first notified in 2017 vide S.O.2668(E) dated 16.08.2017. However, its prices are extended or revised every year under Para 19. The last extension of ceiling prices was made vide S.O. 5190(E) dated 14.11.2025 for a further period of one year up to the 15th November, 2026, or until further orders."

65. The Committee desired to know the details of the current trade margin in respect of non-scheduled drugs and formulations for stockists, distributors, retailers and wholesalers. The Department submitted as under:

"The market data available with NPPA (*i.e.*, Pharmarack database) captures the price points only at the level of distributor and retailer, and not for intermediate dealers in the trade channel such as stockists and wholesalers.

The extent of trade margin differs across drugs depending on a variety of factors, such as:

(i) Drug dosage form[5] (for dosage forms that require special handling for reasons such as maintenance of sterilisation, cold chain, vials, ampoules, glass bottles, etc., trade channel costs are higher);
(ii) Volume of sales of the drug (for low sales volume, fixed costs of distribution get apportioned over a smaller quantity resulting in higher per unit trade channel costs);
(iii) *Ex* factory price (for low *ex* factory price, the per unit distribution channel costs are relatively larger and are higher when expressed as percentage of *ex* factory price); and
(iv) Marketing and distribution model (for MSME manufacturers, market development costs are often borne not by the manufacturer but by the trade channel; for sale in remoter areas, trade channel costs are higher due to lower turnover and higher costs of inventory and logistics).

As per data available in the Pharmarack database, the average markup for common dosage forms of non-scheduled drugs[6] is around 43% for distributors, stockists, wholesalers and retailers collectively."

66. When asked what framework or methodology would NPPA use to determine appropriate levels of trade margins across different therapeutic categories, the Department submitted as under:

"Taking into account the suggestions of different stakeholders and after detailed analysis of the market data, a considered view will be taken for formulating an appropriate policy view in the matter by the Department."

67. On being queried whether NPPA was considering amendments to DPCO, 2013 or proposing a new rule under the Essential Commodities Act to incorporate TMR explicitly, the Department submitted as under:

"DPCO, 2013 is issued under section 3 of the Essential Commodities Act, 1955. The Department has held consultations with all stakeholders. The feedback gathered from the consultations and experience gathered from implementation of the pilot on TMR, the

[5] Common dosage forms such as tablets, capsules, sachet, gums and strips, and other dosage forms that require special handling for reasons such as maintenance of sterilisation, cold chain, vials, ampoules, glass bottles, etc.
[6] Tablets, capsules, sachet, gums and strips

Department in association with NPPA is examining the issue regarding incorporation of a suitable enabling provision for applying a TMR approach in DPCO, 2013."

68. When asked whether it was a fact that the Department was working on TMR issue from the last 5-6 years and it had not yet been finalised and about the reasons therefor, the Department submitted as under:

"Implementation of TMR would affect different stakeholders differently and hence require extensive consultation with all stakeholders and a well-calibrated approach. Accordingly, TMR approach of capping trade margin has been implemented as a pilot in respect of 42 high-priced anti-cancer medicines. Further, TMR was also implemented on six covid-related devices during the pandemic. Also, the Department held extensive consultations with all stakeholders on various issues concerning the existing pricing framework including, *inter alia,* incorporation of a suitable enabling provision in DPCO, 2013 for a TMR approach.

The proposal for a TMR approach for drugs/formulations is supported by number of pharmaceutical industry associations and consumer groups, with certain recommendations on various aspects such as formula for the same, percentage of trade margin, phasing of implementation, period of sales data to be taken into consideration, implication for lower value and lower volume products, etc. However, concerns have also been raised by some stakeholders regarding certain implementation aspects, including the span and extent of TMR. Further, associations of MSME pharmaceutical manufacturers have expressed concern regarding applicability of TMR on non-scheduled formulations. They have expressed the concern that TMR approach will be detrimental to MSMEs, resulting in loss of employment, and will affect the outreach of medicines to remote areas due to reasons such as different marketing/trade channels and manufacturing setups, dependence on small traders to sell their products mostly in remote areas and the need to shell out margin at every stage, resulting in high trade margins, and at the same time making medicines available at competitive prices.

In view of the above, the Department is engaged with stakeholders and is examining the issues flagged by them with a view to mitigate the concerns flagged, while formulating the policy proposal and amendments to DPCO, 2013."

69. When further asked whether the Department could conduct cost audit until the TMR issue was finalized, the Department submitted as under:

"As per the existing framework, the mandate of NPPA is to fix the prices based on market data. There is no provision in DPCO, 2013 to consider cost-audit-based data for price fixation."

70. To a pointed query about the expected timeline for finalizing the policy decision on TMR integration into DPCO, 2013, the Department submitted as under:

"There is no set time frame for finalising the policy decision on TMR integration into DPCO, 2013. However, the matter is under active examination of the Department. "

71. The Committee were informed that while the Department of Pharmaceuticals (DoP) was working on the TMR engaged with all kinds of stakeholders, industry, other stakeholders in the system, the trade generics issue is cropping up for attention because of involvement of most of the

Micro, Small, and Medium Enterprises (MSMEs). In this regard, the Committee sought details regarding: (a) estimated market size of pharmaceutical sector which is catered by MSMEs and number of MSME manufacturers in this sector; and (b) trade margin structure along the trade channels of 'trade generics'. The Department submitted as under:

> "Trade Generics are not defined in the DPCO, 2013. As per the inputs gathered from the industry, 'trade generics' refer to generic pharmaceutical formulations that are primarily distributed through a separate marketing channel focused on remote, rural, and low-volume markets. The distributors and retailers in the trade-generic channel bear significant additional cost, including higher logistics expenses, greater inventory carrying costs, slower offtake, increased risk of expired stock, and higher financing costs due to smaller retail balance sheets and weaker credit access.
>
> Further, the data of trade generics and trade margin structure along the trade channels of 'trade generics' is not specifically captured by the department or Pharmarack database. However, as informed by Indian Federation of Pharma Generics, the number of MSMEs in the pharma sector is estimated to be about 7500 with a market size of ~ 10%."

M. <u>Pharmaceutical companies</u>

72. Elaborating on the Department's plans and policies to support the growth of Pharmaceutical industries to meet employment goals and promote economic wellbeing for all, the Department submitted as under:

> "In addition to the overall policies aimed at for promotion of industry, the Government has also undertaken measures and initiatives to supports the pharmaceuticals and medical devices industries through various schemes, including the following:
> (a) Promotion of Research and Innovation in Pharmaceutical MedTech sector (PRIP) scheme;
> (b) The Production Linked Incentive (PLI) Scheme for Pharmaceuticals;
> (c) The PLI Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates (DIs) / Active Pharmaceutical Ingredients (APIs) in India, also known as the PLI Scheme for Bulk Drugs;
> (d) Scheme for Promotion of Bulk Drug Parks; and
> (e) Strengthening of pharmaceutical industry scheme, which consists of the following three sub-schemes:
> (i) Assistance to pharmaceutical industry for Common Facilities;
> (ii) Revamped Pharmaceutical Technology Upgradation Assistance Scheme; and
> (iii) Pharmaceutical and Medical Devices Promotion and Development Scheme."

73. The Committee observed that NPPA's role as a regulator is to work towards a healthy Nation by making medicines accessible and affordable while creating an enabling environment for the Indian pharmaceutical industry to develop into a world leader. When asked about measures being taken to maintain a balance between consumer welfare and Pharmaceutical industrial growth, the Department submitted as under:

> "The mandate of NPPA is to ensure availability of drugs at affordable prices. It strives to strike a balance between the interests of the consumers and the pharmaceutical industry within the ambit of DPCO, 2013. NPPA regulates the prices of scheduled formulations and new drugs

by fixing the ceiling and retail prices. Further, as per the provisions of DPCO, 2013 manufacturers are required to not increase the maximum retail prices (MRP) of non-scheduled formulation by more than 10% of the MRP during the preceding 12 months. Further, with a view to support innovation and research and development, DPCO, 2013 provides exemption from provision of DPCO under paragraph 32. There also exists provisions of fixing separate ceiling or retail prices under paragraph 11(3) to encourage incremental innovation. In addition, the Government is implementing number of schemes to support research, innovation and self-reliance in the pharmaceutical sector as detailed in the reply above."

When sought details regarding formal representations or grievances from pharmaceutical industry received by the DoP in the last three years, main grievances and relief/resolution which was given by DoP, the Department submitted as under:

"Representation and suggestions are received from time to time from various stakeholders, including Pharmaceutical industry and associations. Some grievances are received directly by the Department whereas some are received through other Ministries/Departments. All such representations are examined on case- to-case basis in consultation with concerned Divisions, implementing agencies or other Ministries/ Departments, as required. Wherever the issue raised, fall within the scope of the Department, appropriate action is taken. Matters falling outside the mandate of the Department are referred to the concerned Authorities for necessary action. The Department do not maintain the consolidated year-wise data of all such representation received or their disposal."

74. The Committee further sought number of requests from the pharmaceutical companies for increase in prices of medicines that had been received by NPPA in the last three years. In response, the Department submitted as under:

"In the last three years, NPPA has received applications for increase in prices in respect of 77 formulations. Against these, price increase was given for 11 formulations, while requests for increase in 47 formulations were rejected and those of the remaining 19 formulations are under examination."

N. <u>Monitoring of unfair practices that have come to notice of NPPA</u>

75. When asked about the extant mechanism for monitoring price rise in case of non-scheduled drugs and formulations, the Department submitted as under:

"Increase in prices of non-scheduled formulation is monitored by NPPA through analysis of the available market-based data, Form-V filed by pharmaceutical companies, samples purchased by Price Resource Monitoring Units (PMRUs). Also, the complaints received from individuals and organisations through various channels like Pharma Jan Samadhan PMO Grievance Portal, etc. are sources of information with respect to any price increase that is in violation of the provisions of the DPCO, 2013."

76. The various unfair practices being employed by certain pharmaceutical companies to escape/violate NPPA enforcement were stated to be as under:

"Some instances of unfair practices that have come to notice of NPPA are as under:

(a) Sale of drugs above the ceiling prices fixed by NPPA, especially sale of pre-manufactured stocks at pre-revised maximum retail price (MRP);
(b) Launch of a new drug by the existing manufacturer of scheduled formulation without prior price approval from NPPA;
(c) Increase of the price of non-scheduled formulation by more than 10% over the period of preceding 12 months; and
(d) Misclassification of a scheduled drug as a non-scheduled drug based on claim of such drug having a novel drug delivery system.

77. Regarding details pertaining to concrete cases detected by NPPA in the last five years for each unfair practice listed (a–d) above and penalties or recoveries resulted from each category, the Department submitted as under:

"Category-wise list of number of Cases, Detected Amount (Principal Overcharged Amount including Penalty, if applicable and Interest) and Recovered Amount for the last five years (1st April 2020 to 31st March 2025) is as below:

Category	No. of Cases	Principal Overcharged Amount including Penalty, if applicable and Interest (₹ in Crore)	Recovered Amount (₹ in Crore)
Ceiling Price Violation (including pre-manufactured stock)	366	177.14	21.89
New Drug launch without Price approval	19	2.62	7.60
Violation in Non-Scheduled drugs	40	35.22	20.54
Misclassification as a non-scheduled drug	9	37.52	2.38
Total	434	252.50	52.41

"

78. On being asked that in view of above-mentioned instances of unfair practices, how could the regulatory framework for scheduled and non-scheduled drugs/medicines/formulations be tightened to ensure fair pricing and accessibility of medicines in the Country, the Department submitted as under:

"The existing policy and regulatory regime balances the objective of facilitating availability and accessibility of drugs in the Country. Thus, the regulatory regime has facilitated availability of drugs in India as is reflected by the fact that India is one of the few countries which is net exporter of medicines in the world. The policy regime has also led to a price structure / levels of medicine that is also amongst one of the lowest in the world. However, further strengthening of PMRUs at the grassroots level, creation of more awareness among consumers, enhanced collaboration with other stakeholders such as the Directorate General of Health Services (DGHS), Indian Pharmacopoeia Commission, Central Drugs Standard Control Organisation (CDSCO) etc., may help in better compliance of provisions of DPCO, 2013."

79. On being asked about number of cases of overpricing have been identified in the last five years, and punitive action/penalties or recoveries that had been enforced in such case, the Department submitted as under:

> "During the period from FY 2020-21 to FY 2024-25, demand notices for overcharging have been issued in 436 cases involving ₹ 406.85 crore. An amount of ₹ 133.19 crore has been recovered during the same period."

80. When further asked as to how NPPA monitored and enforced price compliance at the hospital pharmacy levels, the Department submitted as under:

> "Hospital pharmacies are like any other pharmacies and any price violation, if reported, is acted upon as per the provisions of DPCO, 2013.

O. <u>Recovery of overcharging amount from the violators</u>

81. It was submitted by the Department of Pharmaceuticals that as on 30.9.2025, total overcharging demand amount from the violators was ₹ 10,013.30 crore and ₹ 8,526.10 crore was outstanding. Out of the same, an amount of ₹5,944.16 crore was under litigation at various stages in the High Court / Supreme Court and 282 cases involving outstanding overcharged amount of ₹ 223.80 crore had been referred to the District Collector for initiating recovery proceedings. Further, entire overcharged amount of ₹ 190.92 crore in respect of 1,022 cases had already been recovered. The balance amount of ₹ 2,358.20 crore had been disputed by the companies against whom the demand notices had been issued.

82. When queried about the reasons for 85% of overcharging demand amount remaining unrecovered as on 30.9.2025, the Department submitted as under:

> "As on 30th September 2025, ₹ 8526.10 Crore is outstanding for recovery out of which 69.72% i.e., ₹ 5,944.16 Crore is under litigation in various High Courts / Supreme Court. "

83. Observing that an amount of ₹ 5,944.16 crore was under litigation at various stages in the High Court / Supreme Court, the Committee sought details regarding average duration of these litigations. In response, the Department submitted as under:

> Age-wise details of Cases are as under:

Duration of Cases	No. of Cases
Less than 5 years	65
6 to 10 years	142
11 to 15 years	51
16 to 20 years	44
More than 20 years	43
Total	345

84. When asked whether there was a dedicated legal cell within NPPA/DoP to vigorously pursue and resolve such cases, the Department submitted as under:

> "To assist the Authority in legal work, consultants are hired on contractual basis with the approval of government. The consultants regularly follow up with the concerned government counsels for effective and timely hearings of pending cases."

85. When further asked about the grounds on which companies against whom the demand notices had been issued were disputing ₹ 2,358.20 crore in overcharged amounts, the Department submitted as under:

> "An amount of ₹ 2,358.20 crore is outstanding in respect of 436 cases in which Demand Notices have been issued. In these cases, the companies dispute the demand on various grounds including non-acceptance of violation, dispute in data considered for calculation, classification of drugs as scheduled drugs, deduction of trade margin from overcharging amount, calculation of interest from the date of demand notice instead of date of overcharging."

86. When further asked that whether any loopholes had come to the notice of DoP/NPPA which were being exploited by these companies, the Department submitted as under:

> "No loopholes have been noticed by NPPA which are exploited by the companies."

87. When asked about the preventive measures or monitoring systems, apart from recovery mechanisms, in place to ensure that companies do not overcharge in the first place and steps being taken to deter recurrence of such violations within the industry, the Department submitted as under:

> "As per the extant provisions of the DPCO, 2013, every manufacturer of a scheduled/ Non-scheduled formulation is required to print the maximum retail price on the label of the container of such formulation. Further, no person shall sell any formulation to any consumer at a price exceeding the price specified in the current price list or price indicated on the label of the container or pack thereof, whichever is less. The companies are also required to furnish Form-II/ V to NPPA with a copy to State Drug Controller and dealers, whenever any change in the prices is carried out by them. Further, all the notifications of Ceiling Price of scheduled drug and notification regarding price revision after WPI are placed on the NPPA's website immediately for information to all stakeholders.
>
> PMRUs established in the States/UTs conduct IEC activities for dissemination of information relating to price changes. Further, PMRUs monitor the compliance of notified prices of medicines and detect likely cases of violation of the provisions of DPCO. In addition, increase in prices of drugs is also monitored by NPPA through analysis of the available market-based data, the complaints received from individuals and organisations through various channels like Pharma Jan Samadhan PMO Grievance Portal, etc."

P. Pharmarack Technologies Private Limited

88. The Committee were informed that NPPA obtained market-based data and information relating to pharmaceutical products from Pharmarack. This included reports on Sales values, Sales Quantity, Moving Annual Turnover (MAT) Units, MAT Values, MRP, Price to Retailer (PTR), Price to Stockists (PTS) Trend Reports, Price violation reports and market statistics reports on monthly basis through email and Compact Disk. NPPA analysed and examined the data to effectively implement and act to discharge its duties for price fixation and monitoring in accordance with the provisions of the DPCO, 2013. The agency had been hired through open and competitive tendering process. Pharmarack has been providing services to NPPA since 2021."

89. It was also clarified that Pharmarack did not fix or decide prices. Pharmarack is a third-party pharmaceutical market data specialising company and its services were engaged only for sourcing market-based data on drugs. Prices were fixed by NPPA in accordance with the provisions of DPCO, 2013.

90. A brief overview, as furnished by the Department, of Pharmarack Technologies, including its history, core business areas and leadership structure was as under:

> "As per the information provided by Pharmarack, it evolved over the years, beginning with the establishment of All India Organisation of Chemists and Druggists (AIOCD) Pharma 2007. Later, Pharmarack was incorporated in September 2015 as another separate entity. In 2021, AIOCD/AWACS and Pharmarack were merged to form a single unified entity under the name Pharmarack.
>
> The core business activities focus on data-driven analytics and digital platforms that support pharmaceutical companies in strengthening both top-line and bottom-line performance, with Pharmanalytics forming the foundation by providing PharmaTrac audit data that captures product-wise pharmaceutical sales projections. Building on these insights, Pharmconnect automates transactions such as orders, returns, ledgers, and reconciliation between distributors and CFAs. Pharmretail enables retailers to place orders with distributors while supporting digital brand promotion and retailer engagement initiatives. Pharmscan digitizes stock return (expiry and breakage) management through mobile-based scanning, and Pharmsupply streamlines discounted pharmaceutical sales to prevent revenue leakage and operational inefficiencies.
>
> The leadership structure of Pharmarack comprises a Board of Directors with four members. The investors of the company are Aarogya Bharat Digital LLP (formerly Digi Health Technologies LLP) and Trikaal Medi Infotech Pvt. Ltd.
>
> The Promoter in Pharmarack Technologies Pvt. Ltd. is Aarogya Bharat Digital LLP (formerly known as Digi Health Technologies LLP). The Aarogya Bharat Digital LLP is the shareholder of Pharmarack Technologies Private Limited."

91. The Committee further desired to be apprised regarding details of (i) size of the company of the investors and promoters of Pharmarack and whether these promoter/investor companies are Listed companies; (ii) Manpower in Pharmarack; and (iii) auditing and validation of the data collection process and accuracy, robustness and neutrality of data collected by Pharmarack. In this regard, the Department submitted as under:

> "(i) As per the information provided by the Pharmarack, the investors in the Pharmarack Technologies Pvt. Ltd. are Aarogya Bharat and Trikaal Medi Infotech Pvt. Ltd. who are not listed. The size of the above investor companies by capital is ₹ 750 crore.
>
> (ii) The manpower in Pharmarack is 468 as on 30th November, 2025.
>
> (iii) Pharmarack ensures accuracy and neutrality through automated data collection from nearly 16,000 stockists via 100+ ERP integrations, eliminating manual intervention. With coverage of 70% of the Indian Pharmaceutical Market (IPM), data from 2,000+ corporates and 3 lakh SKUs, and strengthened validation processes post the AWACS– Pharmarack merger, the system provides comprehensive, reliable, and unbiased market information."

92. When asked which authority in the Department/Ministry had authorised to take services of a private agency for providing data on such an important issue, the Department submitted as under:

> "NPPA can source the market-based data which shall be available with the pharmaceutical market data specializing companies. Further, NPPA fixes the ceiling prices and retail price of drugs for which the data on stock keeping unit, MRP, price to stockist/ distributor, price to retailer, sales quantity and sales value is required. Hence, to address data requirements, NPPA issues tenders as per extant rules for inviting companies/agencies who can provide data and information related to pharmaceutical products. The service provider was selected though open and competitive tendering process through the Central Public Procurement Portal with due approvals from competent authorities."

93. When asked whether the Department relied upon the data/information provided by the agency or it cross-checked/verified from other sources also, the Department submitted as under:

> "NPPA also cross-verifies the data against other sources, as and when required."

94. When asked to explain the methodology used for data collection from manufacturers, distributors, retailers and other supply-chain participants, the Department submitted as under:

> "As per the information provided by Pharmarack, it captures real-time data from an integrated network of digitally enabled distributors across the Country through 100+ ERP integrations, covering approximately 16,000 stockists and eliminating manual intervention. Primary sales, representing transactions from pharmaceutical companies to distributors, form a key component of the data shared with NPPA. The data also captures secondary sales, reflecting stock movement and liquidation from distributors to retailers. With coverage of about 70% of the Indian Pharmaceutical Market (IPM), the data spans 2,000+ corporates and nearly 3 lakh Stock Keeping Units (SKUs)."

95. When queried whether it could be said that Pharmarack was not independent of pharma influence, directly or indirectly, as Pharmarack was dealing with all the distributors or suppliers from where it is collecting the data, the Department submitted as under:

> "As per the information provided by the Pharmarack, Pharmarack collects data from a wide base of distributors, stockists across the pharmaceutical supply chain. The data collection by Pharmarack is fully automated from nearly 16,000 stockists via 100+ ERP integrations."

96. To a pointed query of the Committee that whether it could be said that Pharmarack did not have an independent revenue model, the Department submitted as under:

> "As per the information provided by the Pharmarack, the company has an independent revenue model by providing services of data and analytics products and B2B Commerce platform Software as a Service (SaaS) Revenue."

97. The Committee further sought details regarding main users of Pharmarack platform and user charges. In this regard, the Department submitted as under:-

> "As per the information provided by the Pharmarack, subscribers of the Pharmarack products which includes the Pharma Companies, investing institutions, Rating Agencies, Consulting/Research firms, NPPA, DCGI, IPA, USAID, BMGF, AIIMS, Educational institutions,

etc. are the main users of the platform. Charges depend on required data & subscription period."

98. As regard details of the geographical coverage and product coverage of Pharmarack's network, the Department submitted as under:

"As per the information provided by Pharmarack, it captures pharmaceutical sales data across 22 region and 78 markets, spanning the North, East, West, and South Zones. The data includes granular market-level information across over 78 markets, with regional data contributing to nearly 90% of the Indian Pharmaceutical Market (IPM). This zonal, state-wise, and regional granularity enables comprehensive pharmaceutical distribution insights and allows Pharmarack to provide strong and reliable national market coverage. Pharmarack covers about 70% of the Indian Pharmaceutical Market (IPM) data, sourced from 2,000+ corporates and approximately 3 lakh Stock Keeping Units (SKUs). It achieves maximum and highly reliable data coverage from regions that are digitally enabled and actively use ERP or order-management systems."

99. To a specific query of the Committee regarding gaps in data coverage pertaining to pharmaceutical sector in rural and remote areas of the Country, the Department submitted as under:

"Non-digitised rural and remote areas may face challenges such as manual operations and limited connectivity, which can impact data availability. However, as these areas continue adopting digital tools, data coverage from these regions is steadily improving."

100. When asked whether Pharmarck was able to capture/collect data pertaining to the entire pharmaceutical market in the Country efficiently, the Department submitted as under:

"As per the information provided by the Pharmarack, the company efficiently captures real-time data from its integrated network of digitally enabled distributors and retailers across the Country. Currently, it collects around 70% of real-time market data, which is projected to 100% using robust state-level projection methodologies to account for regions with lower digital adoption. Overall, Pharmarack provides strong and reliable national market coverage, with continuous improvement as more distributors and regions are onboarded into the digital ecosystem. The audit by Pharmarack does not capture:

- Specific Stockist Sell Out to: Hospitals, Dispensing Doctors, Generic, Jan Aushadi
- Direct Company to Online platform
- Direct to Patient Supplies"

101. The Committee were informed that there were 30,000 distributors out of which data regarding 16000 distributors was captured by Pharmarack, which contributed to 70 percent of the Indian pharma market. When asked how the Department of Pharmaceuticals gets data for the remaining 30 percent market, the Department submitted as under:

" As per NPPP, 2012, the prices are fixed on the basis of market-based data. Considering the volume of industry and large number of partner in trade channel, Pharmarack collects data from around 16,000 distributors for about 98000 SKUs which contributes to 70% of the Indian pharma market. It is extrapolated by using time tested scientific statistical models to arrive at representative prices of pharma industry. Prices worked out by using such data is expected

to be representative of Indian Pharma industry. Other economics indices like GDP[7] calculation etc, also use the extrapolation techniques to arrive at final value."

102. The Committee were informed that Pharmarack did not capture data pertaining to segments such as hospitals, dispensing doctors, Jan Aushadhi, trade generics and direct to e commerce supplies. When asked whether lack of data pertaining to these segments had any impact on fair price fixation of medicines, the Department reiterated the reply given to above query.

103. When asked about the global practice in this regard, it was submitted that the Department was not aware of such practice.

104. Regarding following CVC guidelines during the tender process, the Department submitted as under:

> "It is submitted that all applicable provisions of the General Financial Rules (GFR), relevant CVC guidelines, and the Manual for Procurement of Consultancy Services were duly adhered to.
>
> Further, an adequate response period of three weeks was provided in the advertised open tender, thereby ensuring full compliance with the principles outlined in Rule 173—transparency, competition, fairness, and elimination of arbitrariness in the procurement process—as well as the requirements stipulated under Rule 161 'Advertised Tender Enquiry'."

105. When asked whether the 'single-bid' tender process for engaging Pharmarack was undertaken by NPPA, the Department submitted as under:

> "The tender was not processed under a 'single-bid' system. It was floated as an open tender following the 'Two-Bid System', and the QCBS evaluation methodology was adopted in strict accordance with the provisions of the GFR, 2017 and the Manual for Procurement of Consultancy Services."

106. When asked whether any CVC observations were received regarding the process for engagement of Pharmarack by NPPA, the Department replied in negative.

107. During evidence, the representative of Pharmarack submitted that they captured the most commonly reported pricing by the stockists in their database. When asked about the reason of stockists giving different prices of same medicines to Pharmarack and method of fixation of price of the medicine when stockists provide different rates, the Department submitted as under:

> "At a particular point of time, different batches of the same medicines of same company with different prices may be available in the market.
>
> Pharmarack reports to NPPA the price details which are commonly reported by stockist. Accordingly, as per the methodology provided under DPCO, 2013, NPPA fixes ceiling prices of scheduled formulations and retail prices of new drugs based on market data considering PTR of all brands of such drug having 1% or more market share of that drug and adding 16% margin to it."

108. During oral evidence, the Committee were informed that data from 3 crore sources is collected/processed by Pharmarack every month and turnover of the company last year was ₹ 40

[7] https://www.mospi.gov.in/sites/default/files/publication_reports/Methodology_doc_for_compilation_qrt_GDP_14aug13.pdf

crore with manpower of around 500. When asked how Pharmarack was able to execute and manage collection/processing of such huge amount of data in a month with around 500 employees, the Department submitted as under:

> "As per the information provided by the Pharmarack, the company efficiently manages and process approximately 3 crore records every month with a manpower strength of around 500 employees due to automated data ingestion, processing and mapping framework.
>
> The entire process, starting from data flow from stockist ERP systems to the servers and followed by data cleaning and processing, is automated. Through APIs, all stockist files received from ERP systems are automatically saved in an S3 Bucket. From the S3 Bucket, these files are continuously processed through Python scripts which is being called by Glue Jobs to load the data into Snowflake. Once the data resides in Snowflake, it undergoes a structured Data Cleaning and Mapping process aimed at aligning distributor- level product data with Pharmarack's Golden Master records.
>
> The mapping workflow is executed in two stages. Auto-Mapping is carried out using an advanced matching engine that processes distributor product names using complex patterns. This process is currently being enhanced with an AI-based engine to further improve accuracy and reduce manual effort. Manual Mapping is undertaken for unmapped or ambiguous records, which are routed to a dedicated Data Steward team. These records are reviewed and mapped manually through a specialized front-end interface and then tagged to the Golden Master records."

109. To a pointed query of the Committee that whether there was any possibility of vulnerability to data manipulation or any fudged data that is put/supplied to Pharmarack database to follow a certain direction or certain trend for a medicine, the Department submitted as under:

> "As per the information provided by Pharmarack, the possibility of vulnerability to data manipulation or submission of fudged data to influence any specific direction or trend for a medicine is minimal. Pharmarack's system directly and automatically captures data points from stockist ERP systems."

110. When asked whether safeguards were employed by Pharmarack to detect if pharmaceutical companies/stockists/distributors tried to manipulate data intentionally to influence pricing or demand patterns, the Department submitted as under:

> "As per the information provided by the Pharmarack, the company employs the following safeguards to detect and prevent intentional data manipulation by pharmaceutical companies, stockists, or distributors:
>
> i. Independent Panel Stockists: The identities of panel stockists used for projections are not disclosed to anyone.
>
> ii. Automated Data Validation Checks: The system runs automated checks to flag abnormal entries such as sudden price jumps, unusual quantities, mismatched pack sizes, or deviations from historical patterns. Using Techniques such as Box Whisker and Factor Distancing.
>
> iii. Pharmarack employs automated outlier detection, pattern analysis, and consistency checks to identify unusual demand or pricing trends.

iv. All data entries carry traceable audit logs, timestamps, and source-level attribution, making manipulation easily detectable.

v. Periodic data-quality audits, ERP integration, and RBAC-based access controls ensure only authentic, validated data influences market insights."

111. When asked about the existing mechanism to validate the accuracy, completeness and neutrality of Pharmarack-generated data prior to its use for price fixation by NPPA, the Department submitted as under:

"Presently, pricing is done based on market-based data provided by the pharmaceutical market data specializing company i.e., M/s. Pharmarack Technology Pvt. Ltd. The draft worksheets uploaded on NPPA's website are keenly examined by the industry and other stakeholders. In case any discrepancy is observed, NPPA takes up the matter with M/s Pharmarack for reverification of the same. The data available with the Integrated Pharmaceutical Database Management System 2.0 (IPDMS 2.0), a cloud-based application developed by NPPA, is also used for cross verification. In addition, as and when required information is sought from manufacturers. Further, as per the directions issued by the government when no market data is available, the ceiling price may be calculated on the basis of institutional data obtained from one central government hospital, two state government hospital with at least 500 bed capacity and two private sector hospitals with at least 500 bed capacity. Further, in case of retail prices, where no market data is available, retail prices are recommended by Standing Committee of Experts based on principles of "Pharmacoeconomics" as per the provisions of DPCO, 2013."

112. When asked how NPPA verified the data provided by Pharmarack and whether there is any provision/contractual safeguard to fix accountability of the data provider if the data is found to be inaccurate or manipulated or some discrepancies are found after cross-verification by NPPA, the Department submitted as under:

"Price fixation is done by NPPA in a fair and transparent manner. The ceiling price/ retail prices are calculated based on the methodology provided under DPCO, 2013 which is available in the public domain. The draft worksheets are uploaded on NPPA's website which are keenly examined by the industry and other stakeholders. Based on the representations or suo-moto examination, NPPA seeks clarification from the M/s Pharmarack. In addition, as and when required clarification is sought from manufacturers and also validated with the data available on IPDMS.

Thus, this mechanism of uploading the draft worksheets ensures transparency and discrepancy in the data, if any, is brought out and interest of all stakeholders including the general public are protected.

Further, there is a clause in Point c under Point 3- OWNERSHIP AND WARRANTIES of the service agreement effective from 1.11.2025 to 31.10.2026 stating that-.

"The Disclosing Party warrants that all information, data, documents, etc, furnished or made available, as per clauses 1 & 2 of this agreement, to the Recipient party are true, correct, complete, and reliable to the best of its knowledge as on the date of such disclosure. The Disclosing Party further undertakes that, prior to disclosure, it shall carry out reasonable checks, validations, in accordance with its knowledge, expertise, and standard practices, to ensure the accuracy reliability and integrity of such information, data, documents, etc."

113. On being asked how the data captured and provided to NPPA by Pharmarack was beneficial in controlling the prices of medicines in the Country, the Department submitted as under:

> "Analysis of data provided by the Pharmarack helps NPPA in monitoring compliance of price related provisions of DPCO, 2013. Whenever any violation is observed through monitoring of Pharmarack data or references received from other sources, action is initiated against such manufacturers in accordance with DPCO, 2013.

114. As regard the details regarding specific enforcement actions and price monitoring reductions that were initiated/undertaken by NPPA based on data provided by Pharmarack in the last three years, the Department submitted as under:

> "During the last three years (01.04.2022-31.03.2025), 349 cases involving overcharged amount along with Penalty/ Interest of ₹ 206.34 crores have been initiated based on data provided by Pharmarack and ₹3 7.09 crores have been recovered."

115. When asked how the data collected was validated for accuracy by Pharmarack, the Department submitted as under:

> "As per the information provided by Pharmarack, the data is updated and validated on a monthly basis. Pharmarack ensures accuracy and neutrality through fully automated data collection from nearly 16,000 stockists through 100+ ERP integrations, eliminating manual intervention. With coverage of about 70% of the Indian Pharmaceutical Market (IPM), data from 2,000+ corporates and 3 lakh Stock Keeping Units (SKUs), and strengthened validation processes post the AWACS– Pharmarack merger, the data provided is comprehensive, reliable and unbiased. The accuracy is maintained through confidential panel stockists, automated validation and outlier checks, traceable audit logs, and periodic data-quality audits with Role-Based Access Control (RBAC)."

116. To a pointed query of the Committee regarding Pharmarack Technologies ensuring security and confidentiality of sensitive pharmaceutical data shared with NPPA, the Department submitted as under:

> "As per the information provided by Pharmarack, the data confidentiality is ensured through industry-standard encryption, secure APIs, and controlled data transfer channels. The data shared with NPPA is customized data as per requirements of NPPA/DoP, it is not shared with industry. The NPPA file is exclusive for use of NPPA/DoP only. Access to NPPA-related data is strictly governed through role-based access controls, authentication, and continuous monitoring. Additionally, the platform follows ISO 27001-aligned practices, audit logging, and periodic security assessments to prevent unauthorized access or misuse."

117. It was submitted by the Department of Pharmaceuticals that the market data available with NPPA (i.e., Pharmarack database) captured the price points only at the level of distributor and retailer, and not for intermediate dealers in the trade channel such as stockists and wholesalers. When asked whether the lack of data regarding intermediate dealers in the trade channel such as stockists and wholesalers affected the NPPA's ability in any manner to formulate trade margin rationalization approach, the Department submitted as under:

"As per the price fixation framework, NPPA fixes ceiling prices/retail prices based on average Price to Retailer. Trade margin is the difference between the MRP (excluding taxes) and Price to Distributor (PTD). All these data points are available in the database obtained from Pharmarack."

118. When categorically asked whether there were any limitations in Pharmarack's data or services that might affect NPPA's functions, the Department submitted as under:

"NPPA fixes the ceiling and retail prices based on market data provided by Pharmarack. The market-based data covers 16,000 stockists and 70% of the Indian Pharmaceutical Market. However, the data shared with NPPA does not capture stockist sell-out to hospitals, dispensing doctors, generic outlets, and Jan Aushadhi stores, nor does it include direct company sales to online platforms or direct-to-patient supplies."

119. When asked whether there were other competitors in this field who could collect data pertaining to pharmaceutical sector, as done by Pharmarack and make it available to the market, so that people can take maximum advantage of it for their businesses, the Department submitted as under:

"NPPA issues tenders in accordance with the General Financial Rules (GFR), 2017 for inviting companies/agencies who can provide data and information related to pharmaceutical products. The service provider is selected through an open and competitive tendering process. In the previous tender floated by NPPA, two bidders, M/s Pharmarack Technologies Pvt. Ltd. and M/s Marg ERP Ltd. participated, out of which M/s Pharmarack Technologies Pvt. Ltd. was found to be technically qualified."

120. When further asked that whether there was any Government agency at present available in the Country to provide market data related to Pharmaceutical sector as it is currently being provided by Pharmarack, the Department submitted as under:

"NPPA has informed that to the best of its knowledge, there is no government agency that may provide data required by NPPA on pharmaceutical products."

121. When asked about rationalization for fixing the prices of medicines on reports from the market and from the private agency Pharmarack, the Department submitted as under:

"The present price fixation methodology of market-based pricing under DPCO, 2013 is based on the principles derived from the National Pharmaceutical Pricing Policy, 2012. Under market-based pricing, price fixation is based on widely available information in the public domain as against individual manufacturer's costing data, which results in more transparent and fair pricing. Paragraph 9(1) of DPCO, 2013 provides that NPPA may source market-based data available with pharmaceutical market data specialising companies. In pursuance of this provision, NPPA has engaged Pharmarack through a competitive bidding process."

122. The Committee were informed that NPPA wanted to replace Pharmarack with Integrated Pharmaceutical Database Management System (IPDMS) eventually. When asked that by what target year NPPA plans to achieve this objective, the Department submitted as under:

"IPDMS is a digital database management platform developed by NPPA to collect pharmaceutical data as per the forms specified under Schedule II of DPCO, 2013 and also supports drug price regulation and monitoring. As on 30.11.2025 the details of companies registered on IPDMS are as under:

Particular	Number
No. of registered companies	2344
No. of Forms (I-VI) submitted (January-November, 2025)	1,89,628

DPCO, 2013 specifies that the Government may in due course of time come out with other appropriate mechanism of collecting/ obtaining the market data relating to drugs. Accordingly, IPDMS is envisaged to replace Pharmarack so as to facilitate streamlined, transparent, updated and wider coverage of drug price data. NPPA is making earnest efforts by holding consultation, discussion sessions, workshops with stakeholders like Industry Associations, pharma companies to resolve the issues, if any, being faced by them in submission of data through IPDMS 2.0."

Q. <u>Availability of medicines</u>

123. The mandate of NPPA is not only to ensure affordability of drugs, but also to ensure the availability of drugs. The steps taken by NPPA to ensure availability are stated to be as under:

(a) Any manufacturer of scheduled formulation, intending to discontinue any scheduled formulation from the market has to seek permission from NPPA. There exists a set of guidelines that need to be complied with before discontinuation of the scheduled formulations. In certain cases, paragraph 3 of DPCO, 2013 is also invoked for issuing directions for continued manufacturing/importing the drugs. Action can also be initiated under DPCO, 2013 and Essential Commodities Act, 1955 for any violations.

(b) As and when the reports of shortages of particular drug(s) in any part of the Country are received, the concerned companies are immediately asked to send stocks to the affected areas and to make the drugs available. In cases where shortages are apprehended, NPPA also directs the companies to continue or increase the production under paragraph 3 of DPCO, 2013.

(c) During the COVID-19 pandemic in the Country, NPPA played an active role in addressing the exigencies arising out of the pandemic and undertaking necessary measures to ensure continued availability of life-saving essential medicines and medical devices throughout the Country. NPPA had extensive interactions with Industry, manufacturers, All India Organisation of Chemists and Druggists, State Drug Controllers, District Magistrates etc., to ensure that supply chains were not compromised.

(d) While ensuring affordability, access cannot be jeopardized and the life-saving essential drugs must remain available to the general public at all times. Therefore, unviability of formulations should not lead to a situation where these drugs become unavailable in the market and the public is forced to switch to expensive alternatives. Hence, NPPA in public interest invoked paragraph 19 under DPCO, 2013 in the following instances:

(i) Allowed 50% increase on 21 formulations of 12 medicines on the then applicable ceiling price to ensure the availability of medicines (notified vide S.O. 4461(E) dated 13.12.2019).

(ii) Allowed 50% increase on 9 scheduled formulations of 3 drugs on the then applicable ceiling price (notified vide S.O. 2654(E) dated 1.7.2021).

(iii) 11 scheduled formulations of 8 drugs were given one-time increase of 50% of the present applicable ceiling price (notified vide S.O. 4498(E) dated 14.10.2024).

124. The Committee learnt that for incentivising research and innovation, DPCO, 2013 under paragraph 32 provides for exemption of drugs from price control for certain period subject to fulfilment of certain conditions as specified in the DPCO, 2013. Till date, exemption under paragraph 32 have been granted to 11 companies by NPPA.

125. The Committee were informed that the overall framework of price regulation and monitoring has ensured the availability of medicines, both scheduled and non-scheduled, at one of the lowest prices globally, to the public in India. In this connection, it was submitted that in a study done through IQVIA, a leading global life sciences consulting firm, Indian prices were compared with those of three other low and middle income countries, *viz*., Sri Lanka, Bangladesh and Brazil for top- selling dosage forms (tablets, liquids, capsules and injections) of top-selling therapeutic categories (anti-infective, anti-cancer, cardiovascular and hormonal drugs). The study revealed that the prices of both scheduled and non-scheduled formulations in India were comparatively lower.

126. The Committee were informed that the complaints regarding non-availability of a medicine in the market were received by NPPA through various sources viz., State Drugs Controllers (SDCs), Pharma Jan Samadhan Portal, NPPA Helpline and public grievance portals like PMOPG/ CPGRAMS and individuals. When asked whether NPPA maintained a centralised database of all such complaints/grievances received, including source-wise classification, dates, action taken thereon and closure status, it was submitted that NPPA maintained a consolidated record of all complaints received from these sources.

127. The Department further submitted that action was taken immediately upon receiving a complaint. When queried about any official SOP in this regard, the Department submitted as under:

> "NPPA monitors availability of drugs in the Country and takes remedial measures whenever issue of non-availability of any medicine is brought to its notice. NPPA takes immediate measures in coordination with the State Authorities and the manufacturer of the drugs concerned to ensure availability of the said drug in the said region/ State. The complaints are generally resolved within seven days of receipt."

128. The Committee learnt that NPPA responded to reported shortages of drugs by directing companies to supply stocks to the places of reported shortage, increase production, and submit detailed production and sales data to assess supply gaps. Paragraph 3 of DPCO, 2013 empowers NPPA to direct any manufacturer to increase production and sell such formulations, with a view to achieve adequate availability and regulate distribution of drugs in case of emergency. NPPA informed that companies generally comply with directives issued by NPPA in this regard.

129. When asked about the number of such directives issued by NPPA in the last three years and follow up enforcement actions, the Department submitted as under:

> "In three cases such directives have been issued by NPPA in the last three years. The directives issued by NPPA are complied with by the manufacturers, and no instances of non-response have been observed in such cases."

130. On being further asked about enforcement mechanisms in place for pharmaceutical companies that failed to comply with NPPA's production increase directives in cases of critical shortages of medicines, the Department submitted that violation of the provisions of DPCO, 2013 may attract penalty under section 7 of the Essential Commodities Act, 1955.

131. When asked about the digital systems/ platforms used by NPPA for monitoring the availability of medicines across the Country, the Department submitted as under:

> "NPPA monitors the availability of medicines through its IPDMS platform and Pharmarack data. It also monitors availability of scheduled formulations through submissions made by manufacturers in Form-III, pursuant to the requirement under paragraph 21(1) of DPCO, 2013, regarding data on production and sales and production capacity of scheduled medicines on quarterly basis."

132. NPPA had informed that real-time tracking of medicine availability across entire supply chain is not feasible at present. When asked about the constraints being faced by NPPA in this regard, the Department submitted as under:

> "Considering the magnitude of pharma industry comprising of around 10,500 manufacturing units, 60,000 distributors and around 12,00,000 pharmacies and hospitals at primary, secondary and tertiary levels, the real-time tracking of medicine availability across entire supply chain is not feasible."

133. It was submitted during the course of briefing on the subject that sometimes shortages arise not from manufacturing gaps but from tender delays in Government hospitals and Health Departments. In this regard, when asked about proportion of complaints pertaining to non-availability of medicines received in the last three years which were attributable to procurement/tender delays rather than manufacturing or distribution issues, the Department submitted as under:

> "As informed by MoHFW, procurement in Central Government Hospitals, Institutes etc. is decentralized to ensure timely procurement. NPPA also receives issues regarding shortages of drugs in Government Hospitals, which do not fall under the purview of NPPA. However, whenever a complaint regarding shortage or non-availability of drugs in Government Hospitals is received, the same is forwarded to the concerned authorities for appropriate action."

R. <u>Price Monitoring and Resource Units</u>

134. The Committee learnt that Consumer Awareness, Publicity and Price Monitoring (CAPPM), a Central Sector Scheme of NPPA, has two components, viz. (i) Assistance to set-up Price Monitoring and Resource Units (PMRUs) in the States / UTs, and (ii) Advertisement and Publicity for CAPPM. PMRUs are societies registered under the Societies Registration Act, having their own Memorandum

of Association/ Bye laws, and they function under the direct supervision of the concerned State Drug Controllers for increasing the outreach of NPPA. Under this scheme, 100 percent funds are provided to PMRUs for their recurring and non-recurring expenditure.

135. NPPA is stated to be in the process of establishing Price Monitoring and Resource Units (PMRUs) in all 36 States / UT. As on 31.3.2025, Price Monitoring & Resource Units (PMRUs) had been set up in 31 States / UTs, namely Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram, Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa, Madhya Pradesh, Chhattisgarh, Jharkhand, Puducherry, West Bengal, Ladakh, Himachal Pradesh, Bihar, Uttarakhand, Meghalaya, Arunachal Pradesh, Chandigarh, Assam, Dadra & Nagar Haveli and Daman & Diu, and Lakshadweep. Subsequently, Delhi PMRU was established on 11.6.2025, thereby increasing the total number of PMRUs to 32. Accordingly, as of 18.12.2025, a total of 32 PMRUs have been established across the Country. The setting up of PMRUs in the remaining States/UTs is at various stages of progress.

136. The Committee desired to know that how effective have PMRUs been in assisting NPPA and State Drug Controllers (SDCs) in enforcing drug price regulation and monitoring medicine availability at the grassroots level. They also sought details regarding measurable improvements in drug price transparency and consumer grievance redressal observed since the establishment of PMRUs in respective States/UTs. In this regard, the Department submitted as under:

> "PMRUs are set up in the States/UTs under the direct supervision of the State Drug Controllers as NPPA's key collaborating partners at the grass roots level, and to provide necessary assistance to NPPA in monitoring of compliance with prices, ensuring availability, market-based data collection and sample collection. PMRUs have been effective in identification of likely violation cases and thereby, has assisted NPPA in ensuring monitoring of price regulation.
>
> PMRUs conduct Information, Education and Communication (IEC) Activities in the States/ UTs by way of seminars, webinars, training session, nukkad nataks, etc. to educate consumers, industry representatives, and institutions about the price fixation and other initiatives of NPPA. PMRUs also spread awareness about the 'Pharma Jan Samadhan' (PJS) Portal and 'Pharma Sahi Daam' (PSD) mobile App, which may be accessed by consumers to know the prices of the formulations. This also enables the consumers to report any likely violation cases to NPPA."

137. When asked about best practices which can be identified from PMRUs that have shown significant impact and how can these be scaled to States/UTs where PMRUs are yet to be established or are newly operational, the Department submitted as under:

> "Till 30.9.2025, PMRUs have been established in 32 States/UTs. Vigorous efforts are being made to set up PMRUs in the remaining States, *i.e.*, Sikkim, Manipur, Tamil Nadu, and the UT of Andaman and Nicobar Islands, at the earliest. NPPA regularly reviews the performance of PMRUs on various parameters such as IEC activities conducted, market surveys undertaken, and overall physical and financial progress. Some of the best practices that have been observed and are being adopted by other PMRUs are given as below:
>
> (a) PMRU, Jammu and Kashmir and PMRU, Tripura conduct regular executive committee meetings and make a plan and set targets for conducting market surveys for monitoring of

prices tend to identify and report more instances of likely price violations. This structured and planned approach towards identification of formulation for which surveys are to be conducted and setting a periodical target has proven to be one of the best practices that is being adopted by other PMRUs as well and may be implemented in States/UTs where PMRU is in the process of setting up.

(b) Some PMRUs have conducted IEC activities regularly and at grassroot level. PMRU, Tripura has been conducting IEC activity at hospital, block and gram panchayat level while interacting with locals and educating them about the Pharma Sahi Daam app and other initiatives of NPPA. Similarly, PMRU, Jammu and Kashmir and PMRU, Kerala have been reaching to the rural population for disseminating the information. Such wider coverage has resulted in increased awareness which also reflects in the identification of likely violation cases and ultimately results in compliance by companies.

(c) Some PMRUs have conducted IEC activities in an innovative manner which led to increased reach and interest from the audience. Goa PMRU conducted a reel-making competition on mobile where participants made reels on initiatives of NPPA and the best content was played and circulated among the students and staff of the local institute. This has also increased the reach of NPPA initiatives over social media. Such best practices may also be adopted by other PMRUs and may be extended to PMRUs of remaining States/UTs where it would be set up later.

(d) To promote cross-learning, NPPA organises seminars and webinars where all PMRUs participate and share their experiences and best practices. These interactions help newly established PMRUs adopt successful strategies demonstrated by the more effective ones, thereby improving overall performance and consistency across States and UTs."

138. When asked whether any efforts are being made by NPPA for enhancing the monitoring and reporting capacity of PMRUs, the Department submitted as under:

"Yes, continuous efforts are made by the NPPA for enhancing the monitoring and reporting capacity of PMRUs which, *inter alia*, include the following:

(a) Developed a training manual for the training of the officials of PMRUs;
(b) Conduct training, webinars and interactive sessions with all PMRUs from time to time;
(c) Prepared templates for IEC activities and shared with PMRUs;
(d) Field visits by its officials to oversee the functioning of PMRUs; and
(e) PMRUs have been integrated in the NPPA's online portal, *i.e.*, Integrated Pharmaceutical Database Management System 2.0 (IPDMS 2.0), for effective and online reporting."

139. When further asked about the manner in which PMRUs handled discrepancies or violations identified during price and availability surveys and the follow-up process with NPPA or State Drug Controllers, the Department submitted as under:

"PMRUs monitor the prices of drugs and medical devices by conducting regular market surveys for scheduled and non-scheduled drugs and medical devices, and submits the likely violation report to NPPA through the IPDMS 2.0 portal. The same are examined by NPPA, and action is initiated against the companies as per the provisions of the DPCO, 2013, where prima facie violation is observed."

140. On being queried about challenges or resource constraints being faced by PMRUs facing in conducting regular market surveys and price monitoring activities, especially in remote or underprivileged areas, the Department submitted as under:

> "While formulating the CAPPM Scheme, the States/UTs were categorised into three categories (Category I, II and III) based on the population and resources were allocated accordingly. As per the CAPPM Scheme Guidelines, three staff are to be deployed for Category III States/UTs, five staff are to be deployed for Category II States/UTs, and seven staff are to be deployed for Category I States/UTs.
>
> Further, based on regular monitoring of the activities of PMRU through monthly reports and performance review of all PMRUs, NPPA identifies the issues, if any, raised by the PMRUs and the same are addressed suitably. "

S. <u>Pharma Jan Samadhan (PJS) Portal</u>

141. Pharma Jan Samadhan (PJS) serves as a robust e-governance tool for protection of consumer interest through effective implementation of the Drugs (Prices Control) Order, 2013 with the objective to put in place a speedy and effective complaint redressal system with respect to availability of medicines, overpricing of medicines, sale of 'new drugs' without prior price approval (WPA) and refusal to supply or sell medicines. Complaints can be registered under PJS link available at the NPPAs website i.e. www.nppaindia.gov.in or on Pharma Sahi Daam App and also at the toll free number 1800111255 & Email – monitoring-nppa@gov.in. Any individual or consumer organisation or stockiest / distributor / dealer / retailer or State Drug Controller can lodge complaints online to NPPA through PJS.

142. The details regarding total complaints which have been received through PJS portal since its inception were stated to be as under:

Financial year	Number of complaints recd through PJS portal	Total No. of complaints from all sources including PJS.
2022-23	22	308
2023-24	27	360
2024-25	9	374
2025-26 (till 7.11.2025)	8	274
Total	66	1316

143. The Committee were informed that the top three categories of complaints received on PJS portal related to overcharging, non-availability of medicines and refusal to sale. All the complaints received till date were stated to be resolved.

144. When asked about the manner in which NPPAs used grievance data from PJS to inform policy revisions, price control decisions or enforcement actions, the Department submitted as under:

> "NPPA receives complaints through different channels such as CPGRAMS, individuals, Organisations, and emails. This information helps NPPA to take necessary actions for ensuring compliance to DPCO, 2013."

145. When asked about the initiatives undertaken by NPPA to boost outreach and awareness efforts to increase consumer utilisation of the PJS portal, the Department submitted as under:

> " NPPA has taken several steps to make consumers aware of the PJS portal, including media campaigns, local outreach through state authorities, and workshops. Price Monitoring Resource Units, established across 32 states also widely disseminate information about the PJS portal. These efforts help ensure that consumers across India can easily access the portal and protect themselves from unfair pricing."

T. Integrated Pharmaceutical Database Management System (IPDMS) 2.0

146. Integrated Pharmaceutical Database Management System was launched by NPPA in 2015 which was further upgraded to a more responsive, cloud-based version, IPDMS 2.0 and launched on 29.8.2022. It is a system for online information collection, processing and communication portal to monitor and regulate the prices of medicines and medical devices, to ensure availability and affordability of drugs and medical devices in the Country.

147. On being asked whether any feedback has been taken from the pharmaceutical companies, especially small and medium enterprises, regarding facilitation of ease of doing business and regulatory compliance on IPDMS 2.0, the Department submitted as under:

> "Prior to the launch of IPDMS 2.0, wide consultations were done with stakeholders like industry associations, pharmaceutical companies, etc., wherein the proposed modules of IPDMS was displayed and based on the feedback received, necessary modifications were made so as to enable ease of doing business through IPDMS 2.0. Further, to ease the process of transition of companies from IPDMS 1.0 to IPDMS 2.0 and address incidental operational issues, following measures were implemented:
> (a) Periodic feedback was taken from stakeholders and the ATR/inputs of NPPA, in this regard was updated on official website of NPPA.
> (b) Discussion sessions/ workshops were organised to hand hold and assist Pharma companies to register and operate on IPDMS.
>
> To understand user challenges, gather suggestions and identify areas for improvement in the data submission and regulatory reporting processes, the feedback received from pharmaceutical companies, including Small and Medium Enterprises (SMEs) through multiple channels such as user interactions/meetings, email communications, and training and awareness sessions conducted by NPPA, have been examined. Based on the feedback received, necessary improvements / changes have been incorporated for system enhancements to ensure ease of doing business and regulatory compliance through IPDMS 2.0. Some of these enhancements are:
> (a) Simplification of data submission forms by reducing manual entry, introducing validations and consistency checks.
> (b) Regular updating of user manual, based on evolving processes and systems.
> (c) Improving system performance so as to handle bulk data uploads and improve response time.

Presently, NPPA is in the process of implementing system generated feedback forms to regularly capture feedback of registered companies. Based on the feedback, necessary modifications may be undertaken."

148. When asked about the mechanisms within IPDMS 2.0 to ensure data accuracy, prevent duplication and detect anomalies in price filings, the Department submitted as under:

"IPDMS 2.0 incorporates several in-built mechanisms to ensure data accuracy, prevent duplication, and detect anomalies in price filings. These include automated data validation checks at the time of submission, verifying mandatory fields, numerical consistency, format compliance, unique identification parameters such as product IDs, company registration numbers, OTP based forms submission, etc. to avoid duplication, and system-based cross-verification of submitted information with existing records. In addition, analytical dashboards and reports are used by NPPA for periodic review and detection of inconsistencies or abnormal trends in price data."

149. When further asked whether IPDMS 2.0 has contributed to NPPA's capacity to achieve time-bound pricing decisions and reduce administrative delays in price fixation processes, the Department submitted as under:

"IPDMS 2.0 is NPPA's effort to build up its own database. Presently, it supplements the market data provided by a third-party agency (Pharmarack) engaged by NPPA. In the long term, NPPA endeavours to further strengthen IPDMS 2.0 as its independent database."

150. The Committee were informed that NPPA had taken up the matter regarding integration of Integrated Pharmaceutical Database Management System (IPDMS) 2.0 with SUGAM portal of Central Drugs Standard Control Organisation. The current progress of the proposed integration between IPDMS 2.0 and the SUGAM portal was stated to be as under:

"The integration of IPDMS with SUGAM portal was envisaged to enable seamless data sharing of detailed list of manufacturers of drugs and medical devices licensed by CDSCO. This would enable wider coverage of drug price data information on IPDMS. Presently, CDSCO has provided a login ID to NPPA for viewing the list of manufacturers of Medical Devices only, that are present on the SUGAM Portal."

U. <u>Manpower strength in NPPA</u>

151. When asked whether there existed any gap between sanctioned and actual strength in NPPA, the Department submitted as under:

"At present, 15 posts are vacant out of 48 sanctioned posts of NPPA. Efforts are being made to fill up these vacancies by taking up the matter with the cadre controlling authorities, *i.e.*, the Department of Fertilizers and the Department of Expenditure, for early action. Contractual/outsourced staff have also been engaged, wherever possible, to ensure continuity of essential work."

152. When further asked about efforts being made to plug this gap, the Department submitted as under:

> "Considering the scope and extent of responsibility of NPPA as a regulatory body, a proposal for creation of 59 additional posts has been moved and is under examination of the Department of Expenditure."

PART II

OBSERVATIONS/RECOMMENDATIONS

Review of categorization and price fixation of formulations

The Committee note that the entire edifice of price control exercised by the National Pharmaceutical Pricing Authority (NPPA) rests upon the National List of Essential Medicines (NLEM) as this List is adopted as the primary basis for determining essentiality and is incorporated in the Schedule-I of the DPCO, 2013, as scheduled medicines for the purpose of price control. Under the current NLEM, 2022, there are 388 medicines specified which correspond to over 900 formulations.

The Committee, during examination of the subject, deliberated upon the larger question of whether the extant system of multiple categories of medicines, essential/non-essential, scheduled/non-scheduled, ought to give way to a more unified regulatory framework to enhance clarity, transparency and ease of enforcement of price controls. The Committee take note of the Department's submission in this regard that the National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012) strives to achieve a balance between affordability and availability of drugs on the one hand and promotion of growth of industry on the other and price regulation across the board on a particular sector could affect investment, innovation and industrial growth. However, the Committee cannot help but note that the huge market share (approximately 82%) belongs to the non-scheduled formulations whose prices are fixed by manufactures themselves and NPPA only monitors prices as per the provisions of DPCO 2013, under which manufacturers are required to not increase the maximum retail price (MRP) of such formulations by more than 10% of the MRP during preceding 12 months. The Committee opine that this mechanism may allow manufacturers to launch non-scheduled formulations at arbitrary points. In this regard, the Committee desire that the Department undertake, alongwith the Ministry/Department concerned and other stakeholders, a comprehensive review of the extant categorization of medicines to plug any possibility of arbitrary or unjustified fixation in initial prices of non-scheduled formulations. The Committee may be apprised of the action taken in the matter.

Shift from cost-based pricing to market-based pricing

2. The Committee learn that DPCO, 2013 marked a shift from cost-based pricing to market-based pricing. As per the existing framework of the National Pharmaceuticals Pricing Policy, 2012, prices of a formulation are fixed based on market data, by considering the average Price to Retailer (PTR) of all brands having a market share equal to or more than 1%

of that formulation and adding a margin of 16% to it. The methodology for price fixation is laid down in DPCO, 2013 and there is no concept of backward working in DPCO, 2013. There is also no provision in DPCO, 2013 to consider cost-audit-based data for price fixation. The Committee are of the considered view that sole reliance on market data i.e. PTR for price fixation may not be, in some cases, able to detect price distortions caused by market monopolies and unjustified or excessive markups at various levels of multi-layered pharmaceutical supply chain. In light of the above, the Committee recommend that the Ministry may examine the feasibility of reintroducing cost-based pricing mechanism, through suitable statutory amendments, in cases where significant price disparities or abnormally high markups are observed or brought to notice of the Department. The Committee desire that they be apprised of the steps taken in this regard by the Ministry.

<u>Public participation in fixation of Retail prices of new drugs by NPPA</u>

3. The Committee note that NPPA fixes the retail price of 'new drugs' based on market data as per the formulae provided in the Drug (Prices Control) Order, 2013. As per paragraph 2(1)(u) of DPCO, 2013, the expression 'new drug' means a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in NLEM by combining such drug with another drug that may or may not be listed in NLEM, or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the NLEM. Based on an application received from the manufacturer of a 'new drug', a draft working sheet of the retail price proposed is uploaded on the website of NPPA for 10 working days for information of general public and to invite comments. The comments and representations received, if any, are examined and considered before the prices are notified. Till 23.10.2025, NPPA has fixed approximately 3,570 retail prices of new drugs under DPCO, 2013.

Regarding the number of comments/representations received by NPPA on draft working sheets of the retail price of new drugs proposed during the 10-working days window in the last three years and effect of these comments/representations in the final price notification, the Department submitted that during the period from 01.12.2022 to 30.11.2025, 1426 draft working sheets were uploaded on website for 10 working days seeking comments. Approximately 30 comments/ representations were received by NPPA on the same, out of which 29 representations were received from pharmaceutical companies and 1 representation from industry association. This led to revision in calculations of draft worksheet in respect of 6 cases. The Committee, from the data furnished by the Department,

observe that the process for fixation of retail price of 'new drugs' undertaken by NPPA has not elicited participation of patients, consumer groups or the general public at all during the period from 01.12.2022 to 30.11.2025. The Committee, therefore, recommend that the Department of Pharmaceuticals and NPPA undertake steps to increase participation of general public in the process for fixation of retail price of 'new drugs'. The Committee may be apprised of the action taken in the matter.

Margins in Sale of Certain Medicines

4. It came to notice of the Committee that several hospitals and retailers offered discounts on medicines ranging from 20% to 60% on Maximum Retail Price (MRP), which indicates the existence of inbuilt margins across the supply chain. In this regard, the Department has submitted that under DPCO 2013, the NPPA regulates scheduled and new drug prices, while non-scheduled formulation price increases are capped at 10% annually. Trade margins for non-scheduled drugs vary based on factors like dosage form, sales volume, ex-factory price, and marketing and distribution model. Further, discounts offered by hospital and retailers are guided by marketing and cost considerations of various business entities in the supply chain. However, in the view of the Committee, the Department's own admission that "something needs to be done to contain these huge margins that are there in the distribution channel in some cases", warrant that the Department should look into the matter and initiate ameliorative steps in this regard. The Committee would like to be apprised regarding the steps taken by the Department.

Identifying and broadening data coverage for uncaptured Formulations

5. To a specific query of the Committee regarding difference between Price to Stockist (PTS) and Maximum Retail Price (MRP) of Labocof, the Department submitted that Labocof is not a scheduled formulation. The formulation is not captured in Pharmarack, the principal source database used for monitoring market information in respect of over 14,000 formulations. In this regard, the Committee recommend that the Department undertake an assessment to identify other such uncaptured formulations as well as reasons for this database gap, and work towards broadening its data coverage and eliminate existing blind spots. The Committee may be apprised of the steps taken by the Department in this regard at the earliest.

TRADE MARGIN RATIONALISATION (TMR) APPROACH

6. The Committee note that Trade margin rationalisation (TMR) approach for regulating prices is undertaken by the Department by exercising extraordinary powers available under paragraph 19 of DPCO, 2013 for a limited period. TMR approach of capping trade margin had been implemented as a pilot in respect of 42 high-priced anti-cancer medicines. Further, TMR was also implemented on six covid-related devices during the pandemic. Also, the Department has held extensive consultations with all stakeholders on various issues concerning the existing pricing framework including, *inter alia,* incorporation of a suitable enabling provision in DPCO, 2013 for a TMR approach. The Committee have been apprised that while various stakeholders have supported the TMR proposal, concerns have also been raised by some stakeholders regarding certain implementation aspects, including the span and extent of TMR and by associations of Micro, Small and Medium Enterprises (MSME) pharmaceutical manufacturers regarding applicability of TMR on non-scheduled formulations. To a pointed query from the Committee about the expected timeline for finalizing the policy decision on TMR integration into DPCO, 2013, the Department submitted that there was no set time frame for finalising the policy decision on TMR integration into DPCO, 2013 and the matter was under active examination of the Department. The Committee express concern over this inordinate delay in institutionalising the TMR framework and are of the firm view that while it is important to address the concerns of stakeholders and MSME pharmaceutical manufacturers, the objective of providing medicines at affordable prices for the common man, must remain paramount and should not suffer due to prolonged deliberations. The Committee, therefore, strongly recommend that the Department finalise, within a clearly defined timeframe, the proposed enabling provision for incorporating a permanent Trade Margin Rationalisation framework in DPCO, 2013 after expeditiously concluding stakeholder consultations. The Committee may be apprised of the action taken in the matter.

MONITORING OF UNFAIR PRACTICES THAT HAVE COME TO NOTICE OF NPPA

7. The Committee note that some instances of unfair practices being employed by certain pharmaceutical companies to escape/violate NPPA enforcement that have come to notice of NPPA are stated to be sale of drugs above the ceiling prices fixed by NPPA, especially sale of pre-manufactured stocks at pre-revised maximum retail price (MRP); launch of a new drug by the existing manufacturer of scheduled formulation without prior price approval from NPPA; increase of the price of non-scheduled formulation by more than 10% over the period

of preceding 12 months; and misclassification of a scheduled drug as a non-scheduled drug based on claim of such drug having a novel drug delivery system. As per the data furnished by the Department, from the period of 1st April, 2020 to 31st March, 2025, the highest number of such violation cases belong to the category of Ceiling Price Violation (including pre-manufactured stock). The Committee further note the Department's own suggestion that further strengthening of PMRUs at the grassroots level, creation of more awareness among consumers, enhanced collaboration with other stakeholders such as the Directorate General of Health Services (DGHS), Indian Pharmacopoeia Commission, Central Drugs Standard Control Organisation (CDSCO) etc., may help in better compliance of provisions of DPCO, 2013. In this regard, the Committee recommend that the Department take concrete measures to implement each suggestion to help in better compliance of provisions of DPCO, 2013 and apprise the Committee accordingly.

RECOVERY OF OVERCHARGING AMOUNT FROM THE VIOLATORS

8. The Committee note that as on 30.9.2025, a substantial portion of the overcharging demand amount i.e. ₹ 8,526.10 crore out of ₹ 10,013.30 crore (around 85%) remains outstanding. It is further noted that out of the overcharging demand amount of ₹ 8,526.10 crore, ₹ 2,581.94 crore is non-litigated outstanding demand amount, which includes amount referred to the District Collectors for initiating recovery proceedings and amount disputed by the companies against whom the demand notices had been issued. In this regard, the Committee recommend that a time-bound, fast-track dispute resolution mechanism may be instituted by the Department to finalize recovery cases outside of active court litigation. The Committee may be apprised of the action taken in the matter.

9. The Committee note that as on 30.9.2025, out of the overcharging demand amount of ₹ 8,526.10 crore, an amount of ₹ 5,944.16 crore i.e. 70 percent of the total overcharging demand amount was under litigation at various stages in the High Court / Supreme Court. The Committee find that a significant number of these litigation cases i.e. 280 out of 345 cases, have been pending for over 6 to more than 20 years. The Committee, in this regard, recommend the Department and NPPA take urgent measures to ensure expeditious disposal of these cases. The Committee may be apprised of the action taken in the matter.

Creation of a Dedicated Legal Cell in NPPA

10. The Committee learn that to assist the NPPA in legal work, consultants are hired on contractual basis with the approval of Government. The Committee, taking into account the magnitude of pending litigation cases and corresponding overcharging demand amount, recommend that the Department may examine the feasibility of creation of a dedicated legal cell within NPPA for effective and timely disposal of the litigation cases. The Committee may be apprised of the action taken in the matter.

Enhancing procedural clarity to minimize Overcharging Disputes

11. The Committee note that an amount of ₹ 2,358.20 crore is outstanding in respect of 436 cases in which Demand Notices have been issued. As submitted by the Department of Pharmaceuticals, in these cases, the companies have disputed the demand on various grounds including non-acceptance of violation, dispute in data considered for calculation, classification of drugs as scheduled drugs, deduction of trade margin from overcharging amount, calculation of interest from the date of demand notice instead of date of overcharging. To a pointed query from the Committee as to whether any loopholes had come to the notice of the DoP/NPPA which were being exploited by these companies, the Department replied in the negative. However, the Committee are of the view that the various grounds for disputes which include non-acceptance of violation, dispute in data considered for calculation, classification of drugs as scheduled drugs, deduction of trade margin from overcharging amount, calculation of interest from the date of demand notice instead of date of overcharging warrant that there are some areas where administrative and procedural clarity could be further enhanced by the DoP and NPPA. Therefore, the Committee recommend that the Department of Pharmaceuticals (DoP), in coordination with the National Pharmaceutical Pricing Authority (NPPA), take proactive steps to establish unambiguous rules/guidelines for these grounds of disputes in order to reduce the scope for litigation and expedite the recovery of outstanding dues in a timely manner. The Committee may be apprised of the action taken in the matter.

PHARMARACK TECHNOLOGIES PRIVATE LIMITED

Uncovered Pharma Segments

12. The Committee note that the Pharmarack is a third-party pharmaceutical market data specialising company hired, through open and competitive tendering process, by NPPA since 2021 for sourcing market-based data and information relating to pharmaceutical products.

This includes reports on Sales values, Sales Quantity, Moving Annual Turnover (MAT) Units, MAT Values, MRP, Price to Retailer (PTR), Price to Stockists (PTS) Trend Reports, Price violation reports and market statistics reports on monthly basis through email and Compact Disk. Pharmarack covers about 70% of the Indian Pharmaceutical Market (IPM) data, sourced from 2,000+ corporates and approximately 3 lakh Stock Keeping Units (SKUs). However, the Committee note that data pertaining to segments such as hospitals, dispensing doctors, Jan Aushadhi, trade generics and direct to e- commerce supplies is not captured by Pharmarack. It indicates that the current framework may not be able to fully track affordability and availability of medicines across all healthcare delivery channels and consumer touchpoints. The Committee, therefore, recommend that concerted efforts be made to incorporate these segments into the data collection framework and the Committee be apprised accordingly.

13. To a specific query of the Committee regarding gaps in data coverage pertaining to pharmaceutical sector in rural and remote areas of the Country, the Department has submitted that non-digitised rural and remote areas may face challenges such as manual operations and limited connectivity, which can impact data availability. Acknowledging these infrastructure-related challenges, the Committee are of the view that a lack of reliable data from rural and remote regions, where a vast majority of the Country's population still resides, leaves a gap in evaluating medicine availability and regional price variations at the grassroots level. In this regard, the Committee recommend that a targeted strategy, leveraging ongoing digital health initiatives, may be formulated to improve data capture from such regions in order to ensure wider national coverage. The Committee may be apprised of the action taken in the matter.

<u>Real-Time Tracking Mechanism regarding availability of medicines</u>

14. The Committee note that the mandate of NPPA is not only to ensure affordability of drugs, but also to ensure the availability of drugs. The Department of Pharmaceuticals has submitted that NPPA monitors the availability of medicines through its Integrated Pharmaceutical Database Management System (IPDMS) platform and Pharmarack data. It also monitors availability of scheduled formulations through submissions made by manufacturers in Form-III, pursuant to the requirement under paragraph 21(1) of DPCO, 2013, regarding data on production and sales and production capacity of scheduled medicines on quarterly basis. However, as informed by NPPA, real-time tracking of medicine availability across entire supply chain is not feasible at present considering the magnitude of pharma industry comprising of around 10,500 manufacturing units, 60,000 distributors and around

12,00,000 pharmacies and hospitals at primary, secondary and tertiary levels. While acknowledging the magnitude of the pharmaceutical supply chain in the Country, the Committee are of the view that real-time tracking of availability of life-saving and critical care medicines will prove to be a useful tool in the interest of public health, especially during pandemics or shortages of critical drugs. Therefore, the Committee recommend that the Department and NPPA may examine the feasibility of inventing a real-time inventory tracking mechanism for essential, life-saving and critical care medicines and apprise the Committee accordingly.

PHARMA JAN SAMADHAAN (PJS) PORTAL

15. Pharma Jan Samadhan (PJS) portal is stated to serve as a robust e-governance tool for protection of consumer interest through effective implementation of the Drugs (Prices Control) Order, 2013 with the objective to put in place a speedy and effective complaint redressal system with respect to availability of medicines, overpricing of medicines, sale of 'new drugs' without prior price approval and refusal to supply or sell medicines. However, the Committee note that that the number of complaints registered directly on the PJS portal from FY 2022-23 to FY 2025-26 (till 7.11.2025) remains relatively low compared to the total complaints received through other sources. In this regard, the Committee recommend that the Department intensify its targeted awareness campaigns and leverage digital platforms, healthcare institutions and pharmacies to augment visibility and accessibility of the PJS portal. The Committee may be apprised of the action taken in the matter.

INTEGRATED PHARMACEUTICAL DATABASE MANAGEMENT SYSTEM (IPDMS) 2.0

16. The Committee learn that Integrated Pharmaceutical Database Management System (IPDMS) was launched by NPPA in 2015 which was further upgraded to a more responsive, cloud-based version, IPDMS 2.0 and launched on 29.8.2022. It is a system for online information collection, processing and communication portal to monitor and regulate the prices of medicines and medical devices, to ensure availability and affordability of drugs and medical devices in the Country. The Committee have been apprised that IPDMS 2.0 is NPPA's effort to build up its own database and presently supplements the market data provided by a third-party agency (Pharmarack) engaged by NPPA. The Committee, in this regard, recommend that efforts to further strengthen IPDMS 2.0 into a robust and independent database may be expedited in order to eliminate or reduce NPPA's dependence on third-party data providers. The Committee may be apprised of the action taken in the matter.

MANPOWER STRENGTH IN NPPA

Filling Vacancies in NPPA

17. The Committee note that at present, 15 posts are vacant out of 48 sanctioned posts in NPPA. As per the Department's written submission, efforts are being made to fill up these vacancies by taking up the matter with the cadre controlling authorities, *i.e.*, the Department of Fertilizers and the Department of Expenditure, for early action. Contractual/outsourced staff have also been engaged, wherever possible, to ensure continuity of essential work. The Committee recommend that matter of filling up existing vacancies through regular appointments be regularly pursued with the cadre controlling authorities and the Committee be apprised of the progress made at the time of furnishing Action Taken Notes by the Department.

Creation of Additional Posts in NPPA

18. The Committee further note that a proposal for creation of 59 additional posts in NPPA is under examination of the Department of Expenditure. In this regard, the Committee recommend that the Department of Pharmaceuticals may pursue the matter with urgency to secure expeditious approval of the proposal of creation of 59 additional posts in NPPA commensurate with mandate and responsibilities of NPPA. The Committee may be apprised of the action taken in the matter.

NEW DELHI;
3 August, 2026
12 Sravana, 1948 (Saka)

AZAD KIRTI JHA
Chairperson
Standing Committee on
Chemicals and Fertilizers

APPENDICES

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2025-26)

Minutes of the Third Sitting of the Committee

The Committee sat on Monday, the 3rd November, 2025 from 1515 hrs to 1700 hrs in Committee Room 'C', Parliament House Annexe, New Delhi.

PRESENT

Shri Azad Kirti Jha – Chairperson

MEMBERS

LOK SABHA

2. Shri Robert Bruce C.
3. Shri Bharatsinhji Shankarji Dabhi
4. Shri Malvinder Singh Kang
5. Shri Praveen Patel
6. Shri Sachithanantham R.
7. Shri Daggumalla Prasada Rao
8. Shri Nalin Soren

RAJYA SABHA

9. Shri Subhash Chandra Bose Pilli
10. Shri Arun Singh
11. Shri Tejveer Singh

SECRETARIAT

1.	Smt. Maya Lingi	-	Joint Secretary
2.	Ms. Miranda Ingudam	-	Director
3.	Shri Kulvinder Singh	-	Deputy Secretary

WITNESSES

Representatives of Department of Pharmaceuticals

1. Shri Amit Agarwal, Secretary (Pharma)
2. Shri Awadhesh Kumar Choudhary, Senior Economic Adviser
3. Shri Satyaprakash T L, Joint Secretary

Representatives of National Pharmaceutical Pricing Authority (NPPA)

1. Shri P. Krishnamurthy, Chairman (NPPA)
2. Smt. S. Ahlladini Panda, Member Secretary, NPPA
3. Shri Sanjay Kumar, Advisor NPPA

2. At the outset, the Chairperson welcomed the Members of the Committee and the representatives of the Department of Pharmaceuticals (DoP) to the Sitting convened to have a briefing on the subject '**Review of Role, functions and duties of National Pharmaceutical Pricing Authority (NPPA) with specific reference to increase in prices of medicines in the Country'.** Drawing the attention of the representatives of the DoP to Direction 55(1) of the 'Directions by the Speaker, Lok Sabha' regarding confidentiality of the proceedings of the Committee, the Chairperson asked them to brief the Committee on the subject particularly regarding affordability and accessibility of medicines for every citizen, especially those in rural and underprivileged areas and further strengthening NPPA's regulatory capacity and effectiveness in the changing pharmaceutical landscape.

3. The Chairman, NPPA accordingly, briefed the Committee through a Power Point Presentation on various aspects highlighting regulatory framework for drugs, functions of NPPA, Price regulation under Drugs Price Control Order (DPCO), 2013, impact of price regulation on commonly used dosage forms, monitoring of prices by NPPA, measures for ensuring availability of medicines and India's drug prices vis-à-vis other low and middle income countries.

4. Thereafter, the Chairperson and Members of the Committee raised several issues/points, as indicated below and sought clarifications/information from the representatives of the Department thereon:

(i) Data regarding savings accrued to the consumers *vide* price regulation by NPPA and Jan Aushadhi Kendras;

(ii) Huge difference between Price to Supplier (PTS) and Maximum Retail Price (MRP) in case of certain medicines, as detailed in the list which was earlier supplied to the Department, reasons for such increase and mechanism to control the prices;

(iii) Measures being taken to promote the growth of Pharmaceutical Industry in the country;

(iv) Delay in implementation of Trade Margin Rationalisation in non-scheduled formulation sector;

(v) Need to undertake backward cost analysis and cost audit to trace profit margins across manufacturer, distributor and retailer level in pharmaceutical sector;

(vi) NPPA's dependence on a private data firm, Pharmarack, for market data and fixing prices of medicines on basis of this data;

(vii) Authorization of 50% price increase by NPPA on certain scheduled formulations invoking Para 19 under DPCO 2013;

(viii) Rationale for maintaining dual categories of essential and non-essential drugs and need for unified price control under DPCO;

(ix) Strengthening of Pharmaceutical Public Sector Undertakings for drug and medicine manufacturing to reduce dependence on private firms;

(x) High discount being provided to hospitals and retailers yet charging MRP from the consumers, reflecting inflated retail pricing practices;

(xi) Reported persistent instances of pharmaceutical companies overcharging for scheduled price-controlled drugs across the country, with the Government reportedly pursuing recovery of the overcharged amounts;

(xii) Preventive measures or monitoring system in place to ensure that pharmaceutical companies do not overcharge for medicines in the first place;

(xiii) Reported violations of ceiling prices by pharmaceutical companies despite NPPA's mandate to make medicines accessible and affordable in the country and status of recoveries from the violator companies;

(xiv) Relevance of National Pharmaceutical Pricing Policy 2012 and DPCO 2013 in contemporary pharmaceutical landscape;

(xv) Data regarding comparison of medicine prices of India with other countries in the world;

(xvi) Details of real-time systems used by NPPA to monitor drug availability; and

(xvii) Compliance of NPPA directives regarding ensuring availability of medicines by the pharmaceutical industries and steps to ensure elimination of banned and unsafe drugs from production and distribution.

5. The representatives of the Department of Pharmaceuticals and NPPA responded to certain queries raised by the Members. On the points requiring detailed information which was not readily available and to the queries raised by the Members which remained unanswered during the Sitting, the Chairperson asked the Secretary, DoP to furnish written replies at the earliest. The Chairperson thanked the representatives of the Department for appearing before the Committee and responding to the queries of the Members.

(The witnesses then withdrew)

The Committee then adjourned.

A verbatim record of the proceedings has been kept on record.

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2025-26)

Minutes of the Sixth Sitting of the Committee

The Committee sat on Monday, the 24th November, 2025 from 1500 hrs to 1700 hrs in Committee Room 'D', Parliament House Annexe, New Delhi.

PRESENT

Shri Azad Kirti Jha – Chairperson

MEMBERS

LOK SABHA

2. Shri Brijmohan Agrawal
3. Shri Robert Bruce C.
4. Shri Bharatsinhji Shankarji Dabhi
5. Smt. Kriti Devi Debbarman
6. Shri Babu Singh Kushwaha
7. Shri Praveen Patel
8. Shri Sachithanantham R.
9. Shri Eatala Rajender
10. Shri Daggumalla Prasada Rao
11. Shri Tharaniventhan M.S.
12. Dr. Ricky Andrew J. Syngkon
13. Shri Shivmangal Singh Tomar

RAJYA SABHA

14. Shri Subhash Chandra Bose Pilli
15. Shri Arun Singh
16. Shri Tejveer Singh

SECRETARIAT

1. Smt. Maya Lingi - Joint Secretary
2. Ms. Miranda Ingudam - Director
3. Shri Kulvinder Singh - Deputy Secretary

WITNESSES

Representatives of Department of Pharmaceuticals

1. Shri Amit Agrawal, Secretary
2. Shri Awadhesh Kumar Choudhary, Sr. Economic Adviser
3. Shri Satyaprakash T L, Joint Secretary
4. Shri Suvasis Das, Deputy Secretary
5. Ms. Khayi Leishingam, Joint Director

Representatives of National Pharmaceutical Pricing Authority (NPPA)

1. Shri P. Krishnamurthy, Chairman
2. Smt. S. Ahlladini Panda, Member Secretary
3. Shri Sanjay Kumar, Advisor

Representative of Ministry of Health & Family Welfare

1. Dr. Rajeev Singh Raghuvanshi, Drugs Controller General of India (DCGI), Central Drugs Standard Control Organisation (CDSCO)

Representatives of Pharmarack Technologies Pvt. Ltd.

1. Mr. Dhruv Gulati, CEO
2. Ms. Sujata G, Vice President

2. At the outset, the Chairperson welcomed the Members of the Committee and the representatives of the Department of Pharmaceuticals (DoP) to the Sitting convened to have oral evidence on the subject 'Review of Role, functions and duties of National Pharmaceutical Pricing Authority (NPPA) with specific reference to increase in prices of medicines in the Country'. Drawing

the attention of the representatives of the DoP and other Ministry and organization to Direction 55(1) of the 'Directions by the Speaker, Lok Sabha' regarding confidentiality of the proceedings of the Committee, the Chairperson asked them to brief the Committee on the subject particularly regarding progress and major issues being encountered by the Department with regard to finalization of Trade Margin Rationalization (TMR) approach, steps taken by the Department to remove 'anomaly' in price fixation of medicines, categorisation of medicines as essential and non-essential, scheduled and non-scheduled, data collection and price fixation process with regard to scheduled and non-scheduled formulations, the role of the private partner in ensuring accurate and neutral market information, and the need for review, revision, and updating of the extant National Pharmaceutical Pricing Policy, 2012 and Drugs Pricing Control Order, 2013 to reflect current realities.

3. The Secretary, DoP accordingly gave a brief oral submission before the Committee which included aspects of provisions of affordable healthcare which include direct Government healthcare, insurance and Jan Aushadhi pharmacy network etc., examination of concerns of the stakeholders to make suitable policy and regulatory provisions for Trade Margin Rationalisation (TMR), average mark-up for common dosage forms of non-scheduled drugs - tablets, capsules, sachets, gums and strips, which is around 43 per cent when taken collectively across distributors, stockists, wholesalers and retailers and relative pricing of non-scheduled drugs in the Country compared with other manufacturing countries.

4. Thereafter, the representatives of Pharmarack Technologies Pvt. Ltd. briefed the Committee through a Power Point Presentation on various aspects highlighting origin, background and objective of Pharmarack, engagement by NPPA tendered through open competitive bidding, efforts for digitalization of the pharmaceutical distribution ecosystem, data collection and coverage and reach, price capturing methodology, data projection and extrapolation, data sharing with NPPA and data security.

5. The Chairperson and Members of the Committee raised several issues/points, as indicated below and sought clarifications/information from the representatives of the Department of Pharmaceuticals, NPPA, CDSCO and Pharmarack Technologies Pvt. Ltd. thereon:

i. Investors/Promoters of Pharmarack and its revenue model;
ii. Accuracy, neutrality and reliability of data coverage by Pharmarack and direct consumer benefit from data collected by Pharmarack;
iii. Tendering process for selecting Pharmarack as NPPA's data provider and compliance with Central Vigilance Commission norms;

iv. Huge difference between Price to Supplier (PTS) and Maximum Retail Price (MRP) in case of certain medicines;
v. Development of a policy/framework for fixation of price of medicines so that States and other Government Departments need not issue separate tenders for medicines;
vi. Composition, role and responsibility of NPPA's ex-officio members and norms/benchmark set by NPPA;
vii. DCGI's role in NPPA;
viii. Medical stores giving huge discounts on MRP of medicines;
ix. Policy for destroying/handling expired medicines especially the ones accumulated in Government Hospitals;
x. Measures being taken to promote the growth of Pharmaceutical Industry in the Country; and
xi. Price fixation of non-scheduled drugs.

6. The representatives of the Department of Pharmaceuticals, NPPA, CDSCO and Pharmarack Technologies Pvt. Ltd responded to the above queries raised by the Members. On the points requiring detailed information which was not readily available and to the queries raised by the Members which remained unanswered during the Sitting, the Chairperson asked the Secretary, DoP and DCGI to furnish written replies at the earliest. The Chairperson also requested the Members to go through the replies given by the DoP on the List of Points on the subject, and send further questions/supplementary questions, if any, to the Secretariat for onward submission to the DoP. The Chairperson thanked the representatives of the DoP and other accompanying Officers for appearing before the Committee and responding to the queries of the Members.

A verbatim record of the proceedings has been kept on record.

The Committee then adjourned.

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2025-26)

Minutes of the Twenty-sixth Sitting of the Committee

The Committee sat on Monday, the 03rd August, 2026 from 1500 hrs to 1530 hrs in Committee Room 'B', Parliament House Annexe, New Delhi.

PRESENT

Shri Azad Kirti Jha – Chairperson

LOK SABHA

2. Shri Brijmohan Agrawal
3. Shri Ajay Bhatt
4. Shri Robert Bruce C.
5. Shri Bharatsinhji Shankarji Dabhi
6. Smt. Kriti Devi Debbarman
7. Shri Malvinder Singh Kang
8. Shri Babu Singh Kushwaha
9. Shri Praveen Patel
10. Shri Sachithanantham R.
11. Shri Eatala Rajender
12. Shri Daggumalla Prasada Rao
13. Shri Shivmangal Singh Tomar

RAJYA SABHA

14. Shri Naresh Bansal
15. Shri Subhash Barala
16. Shri Rwngwra Narzary
17. Shri Arun Singh
18. Shri Tejveer Singh
19. Shri L. K. Sudhish

SECRETARIAT

1.	Smt. Maya Lingi	-	Joint Secretary
2.	Ms. Miranda Ingudam	-	Director
3.	Shri Kulvinder Singh	-	Deputy Secretary
4.	Shri Abhishek Kumar	-	Joint Director

2. At the outset, the Chairperson welcomed the Members to the sitting of the Committee convened for consideration and adoption of the following seven draft Reports:

i. XXXXXX
ii. XXXXXX
iii. XXXXXX
iv. XXXXXX
v. XXXXXX
vi. Thirty-third Report on the subject 'Review of Role, functions and duties of National Pharmaceutical Pricing Authority (NPPA) with specific reference to increase in prices of medicines in the Country' pertaining to the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals; and
vii. XXXXXX

3. After some deliberations, the draft Reports were adopted by the Committee with slight amendments.

4. The Committee then authorized the Chairperson to finalize the Reports and present/lay them in both the Houses of Parliament in the ongoing Monsoon Session.

The Committee then adjourned.

XXXXXX Does not pertain to the Report