

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 4699
TO BE ANSWERED ON 28TH MARCH, 2025**

INTRODUCTION OF NEW DRUGS

4699 SHRI MURASOLI S:

Will the **Minister of HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether the National Pharmaceutical Pricing Authority (NPPA) has received any information/complaint regarding introduction of new drugs by some of the Pharma companies without its approval and if so, the details thereof;
- (b) the number of drugs that have been introduced in the market without NPPA approval along with the details of the name of the companies which have introduced drugs without NPPA approval;
- (c) whether the Government is likely to take appropriate action against such companies under Essential Commodities Act and if so, the details thereof; and
- (d) the manner in which the NPPA is likely to identify the said “New Drugs” introduced in the market as the components of the new drug is having a drug listed under the National List of Essential Medicines (NLEM)?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY
WELFARE
(SMT. ANUPRIYA PATEL)**

(a) to (d): As informed by National Pharmaceutical Pricing Authority (NPPA) under Department of Pharmaceuticals, Ministry of Chemicals, NPPA fixes the retail price of new drug as defined in para 2(1)(u) of DPCO 2013. The retail price of a new drug is applicable to the applicant manufacturer and marketer, who are required to sell the new drug within the price notified by NPPA.

A total of 45 cases have been received in NPPA during the financial year 2023-24 and till 25.03.2025 in financial year 2024-25, where New Drugs were launched by the manufacturers without price approval (WPA). The details are attached as **Annexure**.

Where an existing manufacturer fails to apply for prior price approval for New Drug to NPPA, such manufacturer shall be liable to deposit the overcharged amount over and

above such price fixed and notified (Plus local taxes as applicable) by the Government along with interest thereon from the date of launch of the new drug along with penalty.

The WPA cases are identified based on the inputs from Price Monitoring & Resource Units (PMRUs)/State Drug Controllers (SDCs)/samples purchased from the open market/based on consumer complaints and analysis of market-based data available with NPPA.

Annexure

Annexure referred to in reply to parts (a) to (d) of Lok Sabha Unstarred Question No. 4699 for answer on 28.03.2025

S. No.	Name of New Drug (Formulation)	Company Name
1	Sitagliptin 50mg + Metformin 500mg	M/s Corona remedies Pvt Ltd.
2	Sitagliptin 50mg + Metformin 1000mg	M/s Corona remedies Pvt Ltd.
3	Sitagliptin 100mg + Metformin 1000mg	M/s Corona remedies Pvt Ltd.
4	Telmisartan 40mg + Chlorthalidone 6.25mg tablet	M/s Corona remedies Pvt Ltd.
5	Telmisartan 40mg + Hydrochlorothiazide 12.5mg + Amlodipine 5mg tablet	M/s Corona remedies Pvt Ltd.

6	Telmisartan 40mg + Cilnidipine 10mg + Chlorthalidone 6.25mg	M/s Corona remedies Pvt Ltd.
7	Telmisartan mg+ Amlodipine , Telmisartan + Chlorthalidone	M/s LA Renon Healthcare Pvt Ltd.
8	Sitagliptin + Dapagliflozin + Metformin	M/s Macleods Pharmaceuticals Pvt. Ltd.
9	Sitagliptin + Dapagliflozin + Metformin	M/s Macleods Pharmaceuticals Pvt. Ltd.
10	Sitagliptin + Dapagliflozin + Metformin	M/s Macleods Pharmaceuticals Pvt. Ltd.
11	Sitagliptin + Dapagliflozin + Metformin	M/s Macleods Pharmaceuticals Pvt. Ltd.
12	Vildagliptin + Metformin	M/s Torrent Pharmaceuticals Ltd.
13	Vildagliptin + Metformin	M/s Torrent Pharmaceuticals Ltd.
14	Vildagliptin + Metformin	M/s Torrent Pharmaceuticals Ltd.
15	Vildagliptin + Metformin	M/s Torrent Pharmaceuticals Ltd.
16	Diphtheria Toxoid (30IU) + Haemophilus Type B Conjugate Vaccine (10mcg) + Pertussis Toxoid (4IU) + Tetanus Toxoid (60IU)	M/s Panacea Biotec Ltd.
17	Diphtheria Immune Globulin (30IU) + Haemophilus Type B Conjugate Vaccine (10mcg) + Pertussis Toxoid (4IU) + Tetanus Toxoid (60IU) + Poliomyelitis Virus Type 1 (40D Antigen Unit) + Poliomyelitis Virus Type 2 (8D Antigen Unit) + Poliomyelitis virus type 3 (32D Antigen Unit)	M/s Panacea Biotec Ltd.
18	Cholecalciferol 60000IU (in Nano droplet form) per 5 ml	M/s LA Renon Healthcare Pvt Ltd.
19	Ceftazidime (As Ceftazidime pentahydrate) IP 2gram + Avibactam Sodium eq. to Avibactam 0.5gram	M/s BDR Pharmaceuticals Internationals Pvt Ltd.
20	Sitagliptin 100mg+ Metformin 500mg	M/s Corona Remedies Pvt Ltd.
21	Telmisartan 40mg + Cilnidipine 10mg	M/s Corona Remedies Pvt Ltd.
22	Ceftazidime 2gram + Avibactam0.5g	M/s Protech telelinks/Samarth Life Sciences
23	Teneligliptin 20mg +Dapagliflozin 10mg +Metformin SR 500mg	M/s Synokem Lifesciences Pvt Ltd./Glenmark
24	Teneligliptin 20mg +Dapagliflozin 10mg +Metformin SR 1000mg	M/s Synokem Lifesciences Pvt Ltd.

25	Dapagliflozin 10mg+ Vidagliptin 100mg SR+ Metformin 500mg SR Tablet	M/s Mascot Health Series Pvt Ltd./ Macleods
26	Dapagliflozin 10mg+ Sitagliptin 100mg+ Metformin 1000mg Extended release Tablet	M/s Synokem Pharmaceuticals Ltd.
27	Montelukast 4mg+ Bilastine 10mg	M/s. Mascot Health Series Pvt. Ltd /M/s. Biological E. Ltd
28	Ceftriaxone 1000mg + Tazobactam 125mg	M/s. East African overseas/FDC Ltd
29	Phenylephrine Hydrochloride Ip 5 mg + Chlorpheniramine Maleate IP 2 mg per 5ml	Vapi Care Pharma Pvt. Ltd/Apex Laboratories Pvt. Ltd.
30	Each 100ml contains: Paracetamol 1000mg Water for injection'	M/s. Pure and Cure Healthcare Pvt Ltd. (Manufacturer), M/s. Abaris Healthcare Pvt. Ltd. (Manufacturer) & M/s Hetero Healthcare Ltd.
31	Remogliflozin Etabonate100mg + Vildagliptin 50mg+ Metformin 500mg and Remogliflozin Etabonate100mg + Vildagliptin 50mg+ Metformin 1000mg	M/s Glenmark Pharmaceuticals Ltd.
32	(Vitamin D3(Cholecalciferol IP 400 I.U) with DHA Multivitamins & Multiminerals drops)	Indoco Remedies Ltd/ Solistaa Pharmaceuticals Pvt. Ltd.
33	Cholecalciferol 400 I.U./0.5ml)	Tirupati Medicare Ltd./Alkem Laboratories Ltd.
34	L-Carnitine + Folic Acid + Mecobalamin Tablet 500mg/1.5mg/1500mcg	Ozone Pharmaceuticals Limited/Merril Pharma Pvt Ltd.
35	ORS with different strength	Schreiber Dynamix Dairies Pvt. Ltd./ Mankind Pharma Ltd.
36	ORS with different strength	Cipla Ltd.
37	ORS with different strength	Schreiber Dynamix Dairies Pvt. Ltd./ Dr. Reddy Laboratories
38	ORS with different strength	Schreiber Dynamix Dairies Pvt. Ltd./ Wallace Pharmaceuticals Pvt. Ltd.
39	PACLITAXEL 100 MG Injection	Alkem Laboratories Ltd.
40	Rosuvastatin20mg Aspirin IP75mg Clopidogrel Bisulphate IP equivalent to Clopidogrel75mg	Unimed Technologies Ltd.
41	Rosuvastatin10mg Aspirin IP75mg Clopidogrel Bisulphate IP equivalent to Clopidogrel75mg	Unimed Technologies Ltd.

42	Rosuvastatin 20mg Aspirin IP75mg (as enteric coated) Clopidogrel Bisulphate IP equivalent to Clopidogrel 75mg	Unimed Technologies Ltd.
43	Paclitaxel Injection Concentrate Nanodispersion 100mg	Sun Pharma Laboratories Ltd.
44	Rosuvastatin 10mg Aspirin75mg Clopidogrel 75mg	Unimed Technologies Ltd.
45	Atropine Sulphate IP 1% w/v, Chloramphenical IP 0.5%w/v, Dexamethasone Sodium Phosphate IP 0.1% w/v	Jawa Pharmaceuticals (India) Pvt Ltd.
