

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION NO. 4800
TO BE ANSWERED ON 23rd July, 2019

Complaint to NPPA

4800. SHRI SHANMUGA SUNDARAM K.:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

- (a) whether the National Pharmaceutical Pricing Authority (NPPA) has received any information/complaint regarding introduction of new drugs by the Pharma companies without its approval;
- (b) if so, the details thereof;
- (c) the number of drugs introduced in the market without NPPA approval and the details of the name of the companies;
- (d) whether the Ministry will take appropriate action against these companies under the Essential Commodities Act; and
- (e) the manner in which NPPA will identify the 'New Drugs' when the components of the new drugs are having a drug listed under the National List of Essential Medicines (NLEM)?

ANSWER

**MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)**

(a), (b) & (c): Yes, Sir. A list of 22 drugs introduced in the market without prior approval of the National Pharmaceutical Pricing Authority (NPPA) alongwith names of the companies introducing these drugs, where demand notices have been issued by the NPPA is at Annexure.

(d): The NPPA regularly takes action against such companies as per provisions of the Drugs (Prices Control) Order, 2013 (DPCO) which has been issued under the Essential Commodities Act, 1955. The NPPA has so far issued demand notices for an amount of Rs. 101 crore against defaulting companies. Out of this, an amount of Rs. 5.56 crore has been recovered and demand notices amounting to Rs. 89.31 crore are under litigation.

(e): Cases of new drugs are identified from the market-based data being referred to by the NPPA. In addition, new drug cases are also identified through complaint or information received from other sources.

Annexure

List of New Drugs launched by pharmaceutical companies without prior price approval where demand notices have been issued by the National Pharmaceutical Pricing Authority

S. No.	Name of the Company	Name of the Drug
1	Alembic Pharmaceuticals Ltd	Resync 75/50 mg
2	Alembic Pharmaceuticals Ltd	Trivogo tablet
3	Biocon limited	Blisto Trio 0.2/500/2 mg
4	Biocon limited	Blisto Trio 0.2/500/1 mg
5	BoehringerIngelheim India Pvt. Ltd and Kemwell Biopharma Pvt. Ltd	Buscogast plus Tablets
6	Cipla Limited	Hepcvel Tablets
7	Dr. Reddy,s Laboratories Ltd	Resof total 400/100 mg
8	Eris Life Sciences Pvt Ltd	Cyblex MV 80.3
9	Eris Life Sciences Pvt Ltd	Cyblex M 30
10	Eris Life Sciences Pvt Ltd	Cyblex M 60
11	Eris Life Sciences Pvt Ltd	Cyblex MV 80.2
12	Eris Life Sciences Pvt Ltd	Cyblex M 80
13	Eris Life Sciences Pvt Ltd	Cyblex M 40
14	Hetero Healthcare Limited	Velasof Tablets
15	Hetero Healthcare Limited / Cadila Healthcare Limited	Sovip V Tablets
16	Ipca Laboratories Limited	Pacimol Active
17	lupin limited	Gluconorm VG pluse-1
18	lupin limited	Gluconorm VG pluse-2
19	Sanofi India Limited	Amaryl MV 0.2 mg /500/1 mg
20	Sanofi India Limited	Amaryl MV 0.2 mg /500/1 mg pack of 15 tabs
21	Unichem Laboratories pvt.ltd	Tritelsar-80+5 similar formulation
22	Wockhardt Liited and Medibios Laboratories Limited	Alphadopa 500mg tab
