

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

LOK SABHA  
UNSTARRED QUESTION NO. 450  
TO BE ANSWERED ON 4<sup>th</sup> February, 2020

**Price Control by NPPA**

**450. SHRIMATI APARAJITA SARANGI:**

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

- (a) the criteria adopted by the National Pharmaceutical Pricing Authority (NPPA) for placing of drugs under price control regime;
- (b) the details of life saving drugs placed under price control and the prices of such drugs compared to the market prices; and
- (c) the details of the support being provided by the Government for research and development of life saving drugs in the country?

**ANSWER**

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

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(a): The Pharmaceutical Policy announced by the Government from time to time envisages making available quality medicines at reasonable prices to the masses. National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012) was notified with the objective to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – “essential medicines” at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of pharma industry thereby meeting the goals of employment and shared economic well-being for all.

Pursuant to the announcement of National Pharmaceuticals Pricing Policy, 2012, Government notified Drugs (Prices Control) Order, 2013 (DPCO, 2013) on 15th May, 2013. All the medicines specified in the National List of Essential Medicines, 2011 (NLEM) were included in the First Schedule of DPCO, 2013 and brought under price control.

Under DPCO, 2013, prices of drugs are fixed on ‘Market based pricing’ methodology. ‘Market based pricing’ methodology has been adopted in accordance with the principles outlined in the NPPP, 2012. NLEM 2015 contains 949 scheduled drug formulations spread across 31 therapeutic groups.

(b): Life saving drugs is not defined in DPCO, 2013. However, all medicines specified in the National List of Essential Medicines 2011 (NLEM) have been included in the First Schedule of Drugs (Prices Control) Order, 2013 for the purpose

of price regulation. NPPA fixed the ceiling prices of 530 scheduled formulations on market based pricing methodology. The details of reduction in prices of scheduled formulations effected under DPCO, 2013 as compared to the highest price prevailed prior to the price fixation is as below:

<b>% reduction with respect to Maximum Price</b>	<b>No. of drugs</b>
0<= 5%	80
5<=10%	50
10<=15%	57
15<=20%	43
20<=25%	65
25<=30%	49
30<=35%	26
35<=40%	34
Above 40%	126
	530

Further, Schedule I of DPCO, 2013 was amended by adopting NLEM, 2015. Accordingly, NPPA has fixed the ceiling prices of 860 scheduled formulations on market based pricing methodology. The details of reduction in prices of scheduled formulations effected under DPCO, 2013 as compared to the highest price prevailed prior to the price fixation is as below:

<b>% reduction with respect to Maximum Price</b>	<b>No. of formulations</b>
0<= 5%*	236
5<=10%	138
10<=15%	98
15<=20%	100
20<=25%	92
25<=30%	65
30<=35%	46
35<=40%	26
Above 40%	59
Total formulations in NLEM 2015	860

Details of ceiling price fixed is available on the website of NPPA i.e. [www.nppaindia.nic.in](http://www.nppaindia.nic.in).

(c): The Department of Science and Technology has been implementing the Drugs and Pharmaceuticals Research Programme (DPRP) since 1994-95 having activities of collaborative projects (Industry-academia Partnership) and National facility projects (state-of-the-art infrastructure projects). During 2004-05, the programme started extending soft loans to Indian Pharma Industries. Further, this programme supported Grants-in-aid to Indian Pharma Industries for Clinical Trials in neglected diseases such as malaria, kala-azar, Tuberculosis, Filariasis, etc. from 2008-09 onwards.

The loan component of DPRP was discontinued from 2018-19 onwards, as similar type of programmes are being implemented in Technology Development Board (TDB) and Biotechnology Industry Research Assistance Council (BIRAC) of Department of Biotechnology. The other components of DPRP such as collaborative projects, facility projects and Grants-in-aid to Indian Pharma Industries for clinical trials are being continued.

The Department of Biotechnology (DBT), towards strengthening the product development for Biopharmaceuticals, has initiated a Mission entitled: Industry-Academia Collaborative Mission for Accelerating Discovery Research to Early Development for Biopharmaceuticals – “Innovate in India (*i3*) Empowering biotech entrepreneurs & accelerating inclusive innovation”. The National Biopharma Mission approved by the Cabinet at a total cost of US\$ 250 million for five years with 50% funding through World Bank loan is being implemented by Biotechnology Industry Research Assistance Council (BIRAC) - a Public Sector Undertaking of Department of Biotechnology (DBT). The Mission is focusing on development of (i) Vaccines for Pneumococcus, Dengue, HPV and candidates for other diseases of high burden in India (ii) Biosimilars for cancer, diabetics and rheumatoid arthritis and (iii) Medical devices and diagnostics (iv) Process Development Laboratory; Chemistry, Manufacturing, Control Units and cGLP validation facility for Bio therapeutics. DBT has supported R&D projects in disease areas covering Japanese Encephalitis, Chikangunya, Dengue, Malaria, Visceral Leishmaniasis and Anti-Microbial Resistance.

The Department of Pharmaceuticals has set up seven National Institutes of Pharmaceutical Education & Research (NIPERs) as Institutes of national importance all over the country to impart masters and doctorate education and conduct research in various specializations of pharmaceuticals.

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