

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

LOK SABHA
UNSTARRED QUESTION NO. 1396
TO BE ANSWERED ON 11th February, 2020

High Prices of Medicines

1396. SHRIMATI SAJDA AHMED:

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

- (a) whether the medicines which are manufactured at a very low cost are sold at very high prices due to negligence of authorities in controlling the rate and if so, the details thereof;
- (b) whether specific mark to distinguish between generic and ethical drug has been introduced; and
- (c) the measures taken/being taken by the Government to check exorbitant pricing for generic medicines?

ANSWER

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

(a): There is no provision in Drugs (Prices Control), 2013 (DPCO, 2013) to examine and regulate the actual cost of production of medicines with reference to the ceiling prices / retail prices, as it follows a market based methodology and not cost-based one.

(b): No, Sir. As per para 2(j) of DPCO, 2013 generic version of a medicine means “a formulation sold in pharmacopeial name or the name of the active pharmaceutical ingredient contained in the formulation, without any brand name”. However, ethical drug is not defined in DPCO, 2013. Drugs imported, manufactured and sold in the country are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder.

The medicines, whether branded or generic, imported or manufactured for sale, distribution in the country, are required to comply to the same standards as specified in the Second Schedule to the Drugs and Cosmetics Act, 1940.

(c): DPCO, 2013 doesn't differentiate between generic and branded medicines for price fixation. The prices fixed by National Pharmaceutical Pricing Authority (NPPA) are applicable on both the generic and branded medicines. NPPA has taken the following action for making the medicines affordable:

(i) NPPA fixed the ceiling prices of 530 scheduled formulations under National List of Essential Medicines, 2011 (NLEM, 2011).

- (ii) NPPA has notified the ceiling prices of 860 scheduled formulations under NLEM, 2015.
- (iii) NPPA has fixed prices of 106 Anti-diabetic and Cardiovascular drugs under Para 19 of DPCO, 2013 in Public interest.
- (iv) NPPA has fixed ceiling price of Cardiac Stents being scheduled formulation under DPCO, 2013 affecting price reduction for Coronary Stents.
- (v) NPPA has fixed ceiling price of Orthopedic Knee Implants under Para 19 of DPCO, 2013 in Public interest effecting price reduction up to 69%.
- (vi) NPPA has capped the Trade Margin of non-scheduled formulations of 42 select Anti-cancer medicines under "Trade Margin Rationalization" approach as a Pilot for proof of concept, wherein price of above 500 brands of medicines were reduced upto 90%.
