GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. 1643
TO BE ANSWERED ON 2nd July, 2019

Generic Drugs

1643. SHRI KALYAN BANERJEE:

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

(a) whether the Government has introduced generic drugs in the country;
(b) if so, whether the prices of generic drugs are cheaper than other drugs available in the open market with the same composition;
(c) the reasons behind the price variation of the same products;
(d) whether the Government proposes to fix "one product-one price" all over the country; and
(e) if so, the details thereof and if not, the reasons therefor?

ANSWER

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

(a): Drugs imported, manufactured and sold in the country are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder. There is no definition of 'Generic drugs' prescribed in the said Act & Rules made thereunder. However, generic medicines are generally those which contain same amount of same active ingredient(s) in same dosage form, and are intended to be administered by the same route of administration as that of corresponding branded medicines.

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.

Central Drugs Standard Control Organization (CDSCO) grants permission to Manufacturer/import of new drugs under the provisions of Drugs and Cosmetics Act 1940 and Rules made thereunder in proper name. Details of number of permissions granted during the last three years are as below-

Year	Number of Permissions Granted
2016	194
2017	212
2018	239
Total	645

(b) & (c): Both generic drugs without any brand name and branded drugs are treated alike for fixation of ceiling price under the provisions of Drugs (Prices Control) Order (DPCO). As per provisions of DPCO, all manufacturers of Scheduled medicines (branded or generic) have to sell their products within the ceiling price fixed by the Government. As regards non-scheduled formulations, the manufacturers are not allowed to increase the price by more than 10 % per annum. The prices are both fixed as well as monitored in case of scheduled medicines and monitored only in case of non-scheduled medicines by the National Pharmaceutical Pricing Authority (NPPA). In case a violation of an order issued under DPCO is detected, action for overcharging is taken as per provisions of DPCO.

(d): No such proposal is under the consideration of the Government.

(e): In view of (d) above, the occasion does not arise.

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