GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 4102
TO BE ANSWERED ON THE 20th March, 2018

Generic Medicines

4102. SHRI MOHD. SALIM:

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

(a) the details of countries that are prescribing generic medicines in place of branded ones;
(b) whether it is a fact that as per a study conducted by Indian Journal of Pharmacology, the retail margin on generic drugs is as high as 1000 per cent of manufacturing cost;
(c) if so, the response of the Government on the above study; and
(d) the response of the Government on the views expressed by some doctors that all generic drugs are not as effective as the branded ones?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a): Every country has its own standards and its own laws and regulations for prescribing medicines which are done keeping in view of the particular requirements of the country.
(b): A Research Article published in Indian Journal of Pharmacology in April 2011 said that margins for retailer were very high for branded-generics. The retailer margin for five branded medicines examined in the study was in the range of 25-30%, but for their branded-generics versions manufactured by the same company, it was in the range of 201-1016%.
(c): Both generic and branded medicines are treated alike for fixation of ceiling price under the provisions of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). As per DPCO, 2013, all manufacturers of Scheduled medicines (branded or generic) have to sell their products within the ceiling price fixed by the Government. The DPCO, 2013 provides that 16% of price to retailer shall be allowed as a margin to retailer, while fixing ceiling prices of scheduled formulations and retail prices of new drugs.
(d): Manufacturing, sale and distribution of Drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 made thereunder through a system of licensing and inspection. License for manufacturing, sale and distribution of Drugs are granted by State Licensing Authorities appointed by respective State Governments. All the drugs manufactured in the country, whether branded or generic are required to comply with the same standards as prescribed in the Drugs & Cosmetics Act, 1940 & Rules made thereunder. The State Licensing Authorities are empowered to take action in case of any violation of above requirements.

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