GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA

UNSTARRED QUESTION No. 3510

TO BE ANSWERED ON THE 8th August, 2017

Quality Testing of Generic Medicines

3510. SHRIMATI RAKSHATAI KHADSE:

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

(a) whether the Government has received report of patients facing the same problems after using generic medicines purchase from open market;
(b) if so, the details thereof and the reaction of the Government thereto;
(c) whether the Government has established any mechanism for quality testing of drugs before its sale in the open market and if so, the details thereof; and
(d) whether the Doctors across the country are not prescribing the generic medicines as the medicines available in the market are not efficacious and if so, the details thereof?

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) and (b): As per the information received from Drug controller General of India no such report has been received.

(c): 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. Licensees are required to comply with all the conditions of license and follow Good Manufacturing Practices (GMP) to ensure that the drugs manufactured by them are safe and of standard quality. Recently, the Drugs and Cosmetics Rules have been amended

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vide GSR No. 327(E) dated 03.04.2017, wherein there is now a requirement that the applicant shall submit the result of bioequivalence study referred to in Schedule Y of the Rule, along with the application for grant of a license of oral dosage form of drugs specified under category II and category IV of the biopharmaceutical classification system. 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.

(d): The doctors prescribe medicines based on their wisdom keeping the best interest of the patients' health in mind. However, the Government is taking various steps for encouraging use of generic medicines. The Medical Council of India has amended the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 on 08.10.2016 to provide a new para regarding use of generic names of drugs in prescription. The Government is operating a Scheme, 'Pradhan Mantri Bhartiya Janaushadhi Pariyojna' (PMBJP) for providing quality generic medicines at affordable prices in the country. Various publicity media are being used to popularize the PMBJP and for creating awareness of generic medicines.

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