GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA

UNSTARRED QUESTION No. 2708

TO BE ANSWERED ON THE 1st August, 2017

Generic Medicines

†2708. DR. RAMESH POKHRIYAL "NISHANK":

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

(a) the details of steps taken by the Government to encourage the maximum usage of generic medicines in the country;
(b) whether any directives are likely to be issued by the Government in this regard;
(c) whether any system has been put in place in order to bring about improvement in the quality of generic medicines in the country;
(d) if so, the details thereof; and
(e) whether quality of generic medicines is ensured by establishing coordination with State Governments?

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) & (b): The Government is taking various steps for encouraging the 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 more than 2000 PMBJP Kendras under the 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.

(c) & (d): 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. Recently, the Drugs and Cosmetics Rules have been amended 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, 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. The State Licencing Authorities are empowered to take action in case of any violation of above requirements.

(e): The meetings of Drugs Consultative Committee (DCC), a Statutory Committee under the said Act, comprising of all States /UTs Drugs Controllers as members are held from time to time and various issues related to manufacturing, sale and distribution of drugs (including quality of drugs) are discussed/deliberated and decisions are taken for effective and uniform implementation of the various provisions of the said Act & Rules.

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