## GOVERNMENT OF INDIA MINISTRY OF CHEMICALS AND FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

## RAJYA SABHA STARRED QUESTION No. 46 TO BE ANSWERED ON 7th February, 2023

#### Action plan for generic medicine

### 46 # Ms. Saroj Pandey:

Will the Minister of Chemicals and Fertilizers be pleased to state:

- (a) the total consumption of generic medicines in the country in the last three years; and
- (b) the action plan that has been prepared by Government to increase its production and to provide cheap and quality medicines to the public?

### **ANSWER**

# MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (Dr. MANSUKH MANDAVIYA)

(a) to (b): A Statement is laid on the Table of the House.

XXXXX

Statement referred to in reply to parts (a) to (b) of the RAJYA SABHA STARRED Q. NO. 46 (1st POSITION) for answer on 07.02.2023 raised by Ms. Saroj Pandey regarding Action plan for generic medicine

As per information provided by the National Pharmaceutical Pricing Authority, the total sale of medicines by stockists/ dealers to retailers in the country is as under:

Year	Sales Value
	(in Cr.)
2019-2020	1,44,485.08
2020-2021	1,47,586.41
2021-2022	1,69,234.82
April 2022 - December 2022	1,40,865.31

No separate data, is however, maintained regarding consumption of generic medicines in the country.

Department of Pharmaceuticals has taken various steps for increase of production of drugs in the country. In order to encourage the domestic manufacturing of pharmaceutical drugs, including generic medicines, two Production Linked Incentive (PLI) schemes have been launched, viz., PLI Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs) within an outlay of Rs. 6,940 crores and PLI Scheme for Pharmaceuticals with an outlay of Rs. 15,000 cr. Under the PLI Scheme for Pharmaceuticals, 20 out of 55 selected applicants are MSMEs. The formulations manufactured by these applicants mostly fall under off-patent generic drugs.

In order to provide quality generic medicines at affordable prices to all citizens, especially the poor and the deprived ones, *Pradhan Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP) has been launched by the Department of Pharmaceuticals wherein about 9,082 dedicated outlets known as *Pradhan Mantri Bhartiya Janaushadhi Kendras* (PMBJKs) have been opened till 31.01.2023. A mobile application '*Janaushadhi Sugam*' provides information to public about location of kendras, help them search *Janaushadhi* medicines and compare the MRP of Generic vs. Branded medicines, etc.

Ministry of Health & Family Welfare has also taken various regulatory measures to promote and ensure the quality of generic medicines. These include instructions to Licensing Authorities to grant/ renew licenses to manufacture for sale or for distribution of drugs in proper/generic names only, amendment in the Drugs and Cosmetics Rules, 1945 for making it mandatory to grant license for a drug formulation containing single active ingredient in proper name only, and inclusion of provision in the said Rules for submission of the result of bioequivalence study along with application for grant of manufacturing license in the case of certain drugs.

Clause 1.5 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prescribes that every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drug. Registered Medical Practitioners have been directed from time to time to comply with the aforesaid provisions. States have also been advised to ensure prescription of generic drugs and conduct regular prescription audits in public health facilities.

Further, under National Health Mission (NHM), support is provided for providing essential generic drugs free of cost in public health facilities.