

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

LOK SABHA
UNSTARRED QUESTION No. †4509
TO BE ANSWERED ON 23rd March, 2021

Generic Medicines

†4509. SHRI BHANU PRATAP SINGH VERMA:

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

- (a) whether the generic medicines are helpful for all especially for the poor and the deprived ones as they bring down the health care cost and if so, the details thereof;
- (b) whether the Government has taken adequate measures to manufacture quality medicines in the name of generic medicines and to ensure their availability to the common people at affordable rates;
- (c) if so, the details thereof;
- (d) whether a legal framework is required to be developed to ensure quality in the testing of generic medicines;
- (e) if so, whether the Government is taking any measure in this regard; and
- (f) if so, the details thereof?

ANSWER

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

(a) Yes Sir. As per the 71st Round (January-June 2014) of the National Sample Survey Office (NSSO) on Health in India, the purchase of medicines account for around 72% in rural sector and 68% in urban sector, of the total expenditure on non-hospitalized treatment of ailments. As such, with an objective of making quality generic medicines available at affordable prices to all especially for the poor and the deprived ones, *Pradhan Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP) was launched by the Department of Pharmaceuticals. Under the scheme, dedicated outlets known as *Pradhan Mantri Bhartiya Janaushadhi Kendras* (PMBJK) are opened all over the country to provide generic medicines to the masses. As on 17.03.2021, 7523 PMBJKs are functional across the country. At present, the product basket of PMBJP comprises of 1450 drugs and 204 surgical instruments.

A medicine under PMBJP is priced on the principle of a maximum of 50% of the average price of top three branded medicines. Therefore, the cost of the Jan Aushadhi Medicines is cheaper at least by 50% and in some cases, by 80% to 90% of the market price of branded medicines. During the financial year 2019-20, PMBJP has achieved sales of Rs. 433.61 crores (at MRP). This has led to savings of approximately Rs. 2500 crores of the common citizens of the country. During the current financial 2020-21, sale of Rs. 613.23 crore has been made till 13.03.2021, which has led to savings of about Rs. 3700 crore to the citizens.

(b) & (c) The manufacturing, sale and distribution of Drugs in the country are regulated under the provisions of the Drugs & Cosmetics Act, 1940 and Rules, 1945 made thereunder through a system of licensing and inspection developed by the Ministry of Health & Family Welfare. The license for manufacturing, sale and distribution of Drugs are granted by State Licensing Authorities appointed by respective State Governments. The manufacturers are required to comply with the conditions of license and follow Good Manufacturing Practices (GMP) to ensure that the drugs manufactured by them are of standard quality. All drugs manufactured in the country are required to comply with the standards prescribed under the said Act and Rules. The State Licensing Authorities are empowered to take action in case of any violation of above requirements. Further, *Central Drugs Standard Control Organisation (CDSCO)* & Ministry of Health & Family Welfare have taken various steps to ensure the quality of drugs including generic drugs manufactured/ marketed in the country.

In order to ensure the adequate availability of medicines at the PMBJKs under the *Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)*, the logistics systems have been strengthened. At present, three **warehouses are functional at Gurugram, Chennai and Guwahati** and fourth one is under construction at Surat. Further, 37 distributors have been appointed across the country to support the supply of medicines to remote and rural areas.

(d) (e) & (f) The Government is committed to ensure that the quality, safety and efficacy of drugs are not compromised. With this in view, the Government has taken a series of measures including strengthening of legal provisions, organizing workshops and training programmes for manufacturers and regulatory officials and conducting risk-based inspections. As regard the *Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)*, the medicines listed in the product list are procured only from World Health Organization – Good Manufacturing Practices (WHO-GMP) certified suppliers for ensuring the quality of the products. Apart from this, each batch of drug is tested at laboratories accredited by the ‘National Accreditation Board for Testing and Calibration Laboratories’ (NABL). Only after passing the quality tests, the medicines are dispatched to PMBJP Kendras.
