GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 4522
TO BE ANSWERED ON THE 8th January, 2019

Generic Medicines

†4522. DR. RAMESH POKHRIYAL "NISHANK":

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

(a) the details of steps taken/being taken by the Government to address the lack of quality in the Generic Medicines being used in the country at present;
(b) the steps taken/being taken by the Government to strengthen the supply chain of Generic Medicines in the backward, rural, hilly and inaccessible areas;
(c) whether the country has adequate availability of laboratories and human resources to test the medicines; and
(d) the manner in which the quality of medicine is proposed to be ensured in view of lack of testing laboratories in remote areas of the country?

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): 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. 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 same 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, CDSCO & Ministry of Health has taken various steps to ensure the quality of drugs including generic drugs manufactured/ marketed in the country.
Details are as under:

1. The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.

2. The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 22 States have already set up designated special Courts.

3. Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were forwarded to the State Drugs Controllers for uniform implementation.

4. The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 510 in 2018.

5. The testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened to expedite testing of drug samples in the country.

6. On 3.4.2017, in order to ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing licence of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.

7. On 10.04.2018, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 360 (E), making it mandatory for all drugs, that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of product manufacturing license by the Authority.

8. Draft Rules have been published vide GSR 999 (E), dated 5th 10.2018 to amend the Schedule M of the Drugs and Cosmetics Rules, 1945 to make it more comprehensive at par with the WHO-GMP guidelines

9. On 27.10.2017, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 1337 (E) making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government.

The licensed manufacturing premises shall be inspected jointly by the Drugs Inspectors of Central Government and State Government to verify the compliance with the conditions of license and the provisions of the Drugs & Cosmetics Act and Rules for not less than once in three years or as needed as per risk based approach.

(b): Under ‘Pradhan Mantri Bhartiya Janaushadhi Pariyojana’ (PMBJP), quality generic medicines are made available at affordable prices to all. As on 03.01.2019, 4735 PMBJP Kendras are functional in 35 States/Union Territories and 646 districts of the country in order to make available more than 800 medicines and 154 surgicals and consumables. In order to strengthen supply chain of the scheme across the country, following steps have been taken by the Government:

(i) 1 Central Ware House (CWH) is established at Bilaspur, Gurugram, Haryana for stocking and supplying the medicines, surgicals and consumables with an IT enabled supply chain management system.

(ii) 52 Distributors have also appointed in different parts of the country for ensuring continuous supply of medicines, surgicals and consumables to PMBJP Kendras functioning across the country.

(iii) Recently, an IT enabled end-to-end supply chain system has also been introduced for making available full range of medicines directly from Central Ware House (CWH) to PMBJP Kendras to save time and cost, through auto ordering and dispatching. To implement this system, a professional agency namely M/s Ethics Infinity Pvt. Ltd. has been appointed by BPPI for providing end-to-end supply chain management solution for the scheme under which the products are supplied directly from CWH to PMBJP Kendras to save time and cost.

(iv) Installation of 'Point of Sale' (POS) software application at all PMBJP Kendras is under process. As on date, more than 3000 PMBJP Kendras have been connected with POS software out of 4735 PMBJP Kendras functioning across the country.

(v) Recently, BPPI has also set up 2 Regional Ware Houses (RWHs), one each at Guwahati and Bengaluru for ensuring uninterrupted supply of the products.

(c) & (d): There are total 31 Govt. Drug testing Laboratories set up by State Governments and total 07 Drug testing Laboratories set up by Central Government.

- The testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened to expedite testing of drug samples in the country.

- The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 510 in 2018.

- The Government has decided to strengthen both the Central and States drug regulatory system during the 12th Five Year Plan enabling them to keep more effective watch on unscrupulous elements indulging in unlawful activities relating to quality of drugs. The Cabinet Committee on Economic Affairs (CCEA) has approved the proposal for strengthening the drug regulatory system in the country, both under the Central and State Governments at a total expenditure of Rs. 1750 crores. Out of this, Rs. 850 crore is the Central Government's share. The share of the Centre and the States in case of state component will be in the ratio of 60:40 for all States except Jammu and Kashmir, Himachal Pradesh, Uttarakand, Sikkim and North-Eastern States, for which the ratio will be 90:10.

- One of the major components of the State scheme is to upgrade State Drug Testing Laboratories. Accordingly, the activities planned in the States and the Union Territories include setting up of 10 drug testing laboratories and up-gradation of 31 existing drug testing laboratories.

xxxxxx