GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 1376
TO BE ANSWERED ON THE 18th December, 2018

Quality of Generic Drugs

†1376. SHRI JANARDAN MISHRA:
SHRI NAGAR RODMAL:

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

(a) whether the Government has received any complaints regarding the quality of generic drugs;
(b)if so, the number of complaints received in Madhya Pradesh and the action taken thereon by the Government;
(c) the steps taken by the Government to improve the quality of drugs; and
(d) the measures taken/being taken by the Government to further improve the quality of generic drugs?

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): Yes, Madam. Isolated complaints regarding suspected quality of medicines have been received. As and when such complaints are received, based on the merit, the matter is taken up by Central Drugs Standard Control Organization (CDSCO) in coordination with concerned State Licensing Authority for action as per the provisions of Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945.
(b): As per information obtained from Food & Drugs Authority, Madhya Pradesh in this regard, no complaints have been received by them.
(c) & (d): The Government of India has taken various measures to ensure 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 05.10.2018 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.

10. 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.

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