GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

RAJYA SABHA
UNSTARRED QUESTION NO. 522
TO BE ANSWERED ON 25TH JULY, 2023

ACTION TAKEN BY GOVERNMENT TO REMOVE HAZARDOUS PRODUCTS FROM MARKET

522: Dr. ASHOK KUMAR MITTAL:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

a) whether Government has acted in response to the World Health Organization (WHO) probe, which identified toxic syrup products in the country and if so, the detail thereof;
b) whether Government has taken specific steps to remove these hazardous products from the market and prevent their further distribution and if so, the detail thereof;
c) whether Government has planned to enhance the regulatory framework and monitoring of pharmaceutical products to avoid such safety concerns in the future and if so, the detail thereof; and
d) the steps Government has undertaken to ensure the safety and quality of pharmaceutical products in the country?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (c): WHO has issued alerts in three cases of syrup products exported from India.

Subsequent to the reports Central Drugs Standard Control Organization (CDSCO) in coordination with State Drug Controllers carried out joint investigations.

1) Based on investigations conducted, which revealed violation of Good Manufacturing Practices (GMP), State Drugs Controller, Haryana issued show cause notice to M/s Maiden Pharma under Rule 85(2) of the Drugs Rules, 1945 and order has been issued for stopping all the manufacturing activities of M/s Maiden Pharmaceuticals at Sonipat with immediate effect for violation of GMP.

2) CDSCO in coordination with State Drugs Controller, Uttar Pradesh conducted a joint investigation at M/s. Marion Biotech Pvt. Ltd., Noida, Uttar Pradesh. Drug samples were drawn from the manufacturing premises under the provisions of Drugs &

Cosmetics Act, 1940 for test & analysis. Further, manufacturing license of the firm has been suspended by State Licensing Authority, Uttar Pradesh on 09.01.2023. Further, an FIR has been lodged on 02.03.2023 in the concerned police station and three persons have been arrested.

3) In case of Marshall Islands & Federated States of Micronesia, CDSCO in coordination with State Drugs Authority, Punjab, conducted a joint investigation at M/s QP Pharmachem Ltd., Punjab. Drug samples drawn from the manufacturing premises under the provisions of Drugs & Cosmetics Act, 1940 for test and Analysis were declared as "Not of Standard Quality". The State Licensing Authority has directed the firm to stop all the manufacturing activities with immediate effect.

Following the suspension of manufacturing license, all the manufacturing and export activities of the said companies are halted.

(d): CDSCO and Ministry of Health and Family Welfare have taken following regulatory measures to ensure the quality of medicines in the country:-

(i). 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.

(ii). States/ UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.

(iii). The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been significantly increased in last 10 years.

(iv). 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 license of oral dosage form of some drugs.

(v). The Drugs and Cosmetics Rules, 1945 have been amended 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.

(vi). The Drugs and Cosmetics Rules, 1945 have been amended, making it mandatory that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of manufacturing license by the Authority.

Moreover, the Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce & Industry has issued a notification (No. 06/2023) dated 22.05.2023 for amendment in export policy of cough syrups, making it compulsory for cough syrup manufacturers to get certificate of analysis from a government-approved laboratory before exporting their products with effect from 01.06.2023.

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