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

RAJYA SABHA
UNSTARRED QUESTION NO. 1388
TO BE ANSWERED ON 01ST AUGUST, 2023

SUBSTANDARD QUALITY OF COUGH SYRUPS

1388: Dr. AMEE YAJNIK:

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

a) whether it is a fact that Government has banned 14 cough syrups citing risk to humans; if so, whether the quality of such medicine was not checked by Government;
b) whether these cough syrups were of substandard quality due to which nearly 300 people died worldwide as stated by WHO in its investigation;
c) whether recently WHO has banned 7 Indian cough syrups which contain diethylene glycol and unacceptable amounts of ethylene glycol as a contaminant and whether Government has taken strict action against the manufacturer; and
d) the details of the plan made by Government to avoid such incidents in future?

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

(a) & (b): Government has prohibited the manufacture for sale, sale or distribution for human use of 14 Fixed Dose Combinations (FDCs) including various cough syrup formulations vide gazette notification dated 02.06.2023 vide S.O No. 2394(E) to 2407(E) on the basis of recommendation of expert committee, that there is no therapeutic justification for such FDCs and the FDCs may involve risk to human beings and hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of such FDCs which were agreed by Drugs Technical Advisory Board.

(c) & (d): WHO has issued alerts and asked various information in four 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) In case of Gambia, joint investigation was undertaken by CDSCO and State Drug Controller, Haryana. 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 , Haryana with immediate effect for violation of GMP.

2) In the case of Uzbekistan, 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.

4) In case of Cameroon, a joint inspection was conducted by CDSCO, Sub-Zone Indore with SLA, Madhya Pradesh at M/s. Riemann Labs., Indore and based on the findings the State Drugs Controller M.P. has directed the firm to stop the manufacturing activities.

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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