GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 3059
TO BE ANSWERED ON THE 28TH MARCH, 2023

Export of substandard medicines

3059 Dr. John Brittas:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) whether it is a fact that WHO has issued in the recent past alerts and warnings against substandard/contaminated medicines and cough syrups manufactured in India which were exported to Gambia and Uzbekistan;
(b) if so, the details thereof and the actions taken by Government thereon;
(c) whether it is a fact that there are loopholes in the extant regulations governing the quality of medicines manufactured in the country solely for the purpose of export to foreign countries vis-a-vis domestic supply;
(d) if so, the details of extant statues and rules dealing with this; and
(e) the actions proposed to be taken to curb these appalling lapses?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) & (b)**:** The subject matter pertains to Central Drugs Standard Control Organization (CDSCO) under the Department of Health and Family Welfare**.** As per the information received from CDSCO**,** WHO has issued following two Medical Products Alerts w.r.t. cough syrups manufactured in India which were exported to Gambia and Uzbekistan: -

i. WHO Alert dated 05-10-2022 on four products namely Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup and Magrip N Cold Syrup, manufactured by Maiden Pharmaceuticals Limited (Haryana, India), identified in The Gambia.
ii. WHO Alert dated 11-01-2023 on two products namely DOK 1 Max syrup (Paracetamol, Guaiphenesin and Phenylephrine Hydrochloride Cough syrup) and Ambronol Syrup (Ambroxol Syrup), manufactured by M/s. Marion Biotech Pvt. Ltd. Uttar Pradesh, identified in Uzbekistan.

Details of investigation in case of The Gambia and Uzbekistan are mentioned as under:

In the matter of deaths reported in Gambia, a joint investigation was carried out by CDSCO in coordination with State Drug Controller, Haryana at M/s Maiden Pharmaceuticals Limited 81, HSIDC Industrial Area, Kundli 131028, Dist. Sonepat (Haryana) and control samples of the drugs were drawn and sent for test and analysis to Regional Drug Testing

Laboratory, (RDTL) Chandigarh. As per report of the Government Analyst of RDTL Chandigarh, the samples were declared to be of standard quality. The said samples were also found negative for both Diethylene Glycol (DEG) and Ethylene Glycol (EG).

However, based on violations observed in Good Manufacturing Practices, State Drugs Controller, Haryana issued show cause notice to M/s Maiden Pharma on 7.10.2022. Further, an order has been issued to M/s Maiden Pharmaceuticals Limited, Sonepat, Haryana on 11.10.2022 stopping all the manufacturing activities of M/s Maiden Pharmaceuticals at Sonepat with immediate effect in public interest.

Similarly, in case of Uzbekistan, CDSCO in coordination with State Drugs Controller, Uttar Pradesh conducted a joint investigation at M/s. Marion Biotech Pvt. Ltd. B-49, Sector 67, Gautam Budh Nagar, Noida-201301 (U.P.) and during the investigation, drug samples were drawn from the manufacturing premises and sent to Regional Drug Testing Laboratory (RDTL) Chandigarh for test and Analysis. Further, manufacturing license of the firm has been suspended by State Licensing Authority, Uttar Pradesh on 09.01.2023. RDTL, Chandigarh has forwarded the test reports of 30 drug samples so far, wherein 24 samples of drugs/raw material were declared as "Not of Standard Quality". Out of these 24 samples declared as "Not of Standard Quality", 22 samples fall under the category of adulterated/spurious, which can cause grievous hurt to patients. An FIR has been lodged on 02.03.2023 in the concerned police station and three persons have been arrested.

(c) to (e)**:** So far as manufacture of drugs for export is concerned, the manufacturers are required to obtained license for such manufacturing of drugs for export from the concerned State Licensing Authority (SLA) under the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder. Further, the manufacturer is required to meet the requirements of importing country.

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