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

LOK SABHA
UNSTARRED QUESTION NO.2984
TO BE ANSWERED ON 17TH MARCH, 2023

QUALITY OF DRUGS

2984: SHRI GAURAV GOGOI:

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

(a) whether WHO has raised an alert over any products of any Indian firm, since 2014;
(b) if so, details of those products and the producer;
(c) whether India's apex drug regulator had undertaken any inspection based on such alert by WHO; and
(d) if so, the details of the result of such inspection?

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

(a) & (b): World Health Organisation (WHO) from time to time issues various Medical products alert with reference to products being manufactured in various countries. Recent such Alerts on Indian products are:-

(i) 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.

(ii) Two products namely DOK 1 Max syrup and Ambronol Syrup manufactured by M/s. Marion Biotech Pvt. Ltd. Uttar Pradesh.

(iii) Tetracycline Hydrochloride Ophthalmic Ointment USP 1%, manufactured by Galentic Pharma (India) Pvt. Ltd., Maharashtra.

(iv) Methotrex (methotrexate) 50mg, manufactured by Celon Laboratories, Pvt. Ltd., Telangana.

(c) & (d): Details of investigation are mentioned as under:

A joint investigation was carried out by Central Drugs Standard Control Organisation (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.

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.). 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.

In cases of other drugs, the matters are referred to concerned Zonal/subzonal office of CDSCO and investigated in coordination with the State Licensing Authorities (SLAs). Based on the investigations, SLAs take suitable action under the provisions of the Drugs and Cosmetics Act, 1940.

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