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

**LOK SABHA**
**UNSTARRED QUESTION NO.397**
**TO BE ANSWERED ON 21ST JULY, 2023**

# HARMFUL EFFECTS OF DRUGS MANUFACTURED BY INDIAN COMPANIES

**397: SHRI E.T. MOHAMMED BASHEER:**

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

(a) whether the Government is aware that the drugs manufactured by Indian manufacturers has caused severe harm and deaths of dozens of patients across the world like Sri Lanka, Gambia, Uzbekistan, etc.;
(b) if so, the details thereof along with the steps taken/proposed to be taken by the Government to address this issue; and
(c) the details of the manufacturers of such medicines alongwith the findings of the regulatory body in this regard?

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

(a) to (c): Subsequent to reports from Srilanka, Gambia, Uzbekistan etc., Central Drugs Standard Control Organisation (CDSCO) in coordination with State Drug Controllers has carried out joint investigations at the following manufacturing units:

(1) (i) Subsequent to reports of deaths of children in Gambia, CDSCO in coordination with State Drug Controller, Haryana carried out investigation at the manufacturing unit of M/s Maiden Pharmaceuticals Limited, to ascertain the facts. Control samples of the aforementioned drugs from the manufacturing unit were drawn and sent for test and analysis to Regional Drug Testing Laboratory, (RDTL) of CDSCO by the investigating team. The said samples were found to be negative for both Diethylene Glycol (DEG) and Ethylene Glycol (EG).

(ii) 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.

(2) (i) In case of Uzbekistan, CDSCO in coordination with State Drugs Controller, Uttar Pradesh conducted a joint investigation at M/s. Marion Biotech Pvt. Ltd., Gautam Budh Nagar, Noida-201301 (U.P.), India to ascertain the facts that allegedly led to the death of children in Uzbekistan. Drug samples were drawn from the manufacturing premises under the provisions of Drugs & Cosmetics Act, 1940 for test & analysis.

(ii) 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 under Section 17A and 17B of the Drugs and Cosmetics Act, 1940. An FIR has been lodged on 02.03.2023 in the concerned police station and three persons have been arrested.

(3) (i) In the matter of complaint received regarding Prednisolone Eye Drops, drugs samples were drawn from the premises of M/s Indiana Opthalmics LLP, Gujarat for test and analysis as per the provisions under the Drugs and Cosmetic Act, 1940. Further, State Drugs Controller, Gujarat has issued show cause notice to the firm on 02.06.2023.

(ii) In the matter of complaint received regarding Propofol Injection, drug samples were drawn from the premises of M/s SP Accure Lab Pvt. Ltd. Hyderabad. Further, State Drugs Controller, Telangana has cancelled the product permission of Propofol Injection.

Further, 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 manufactures to get certificate of analysis from a government-approved laboratory before exporting their products with effect from 01.06.2023.

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