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

LOK SABHA
UNSTARRED QUESTION NO.4972
TO BE ANSWERED ON 31ST MARCH, 2023

DEATHS DUE TO CONTAMINATED INJECTION

4972: SHRI DUSHYANT SINGH:

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

(a) whether the Government is aware of the eight adverse events leading to five deaths at PGI due to using a contaminated injection named Propofol manufactured by Nixi Laboratories Pvt. Ltd., if so, the details thereof;
(b) the steps taken/proposed to be taken by the Government in this regard;
(c) whether the Government is also aware that though the samples were taken by the CDSCO and the Himachal Drug Control Department from the same batch, they had a contradictory report concerning the safety of the drug;
(d) if so, the reasons for such variation in drug testing and the steps taken to remedy this variation; and
(e) the number of drugs recalled after failing quality tests due to impurities, stating year of manufacture, name of the manufacturer, number of units shipped pre-test for the last five years?

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

(a) to (e): There were 8 reports of suspected Adverse Drug Reaction (ADR) including 5 deaths allegedly due to use of Propofol Injection. The suspected ADRs included refractory hypotension, anuria, haematuria, tachycardia, hyperbilirubinemia, elevated AST and multiple deaths.

CDSCO in coordination with State Licensing Authority, sent sample of impugned batch No. (PNL-220316) manufactured by M/s Nixi Laboratories Pvt. Ltd. to Regional Drugs Testing Laboratory (RDTL), Chandigarh for test and analysis. As per report of the Government Analyst, the sample was declared Not of Standard Quality (NSQ).

State Drugs Controller, Himachal Pradesh issued order to stop manufacturing under Rule 85(2) of Drugs Rules, 1945 for the product "Propofol Emulsion for Injection" under generic or any brand name.

Another joint investigation was carried out by CDSCO in coordination with State Licensing Authority (SLA), Himachal Pradesh at M/s. Nixi Laboratories, Kalamb District Sirmour Himachal Pradesh. As the above Test Report of the impugned batch of product was challenged by the Firm under the Drugs & Cosmetics Act & Rules; Hon'ble Court of Chief Judicial Magistrate, Chandigarh sent the sample of same batch to Central Drug Laboratory (CDL), Kolkata for test and Analysis. The impugned sample was declared Standard Quality by CDL, Kolkata.

The manufacturing, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945. The regulatory control over the manufacture, sale and distribution of drug in the country is exercised through a system of licensing and inspection by the State Licensing Authorities (SLAs) appointed by the respective State Governments. The data regarding drugs recalled after failing quality tests is not maintained centrally by CDSCO.

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