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

LOK SABHA
UNSTARRED QUESTION NO.1807
TO BE ANSWERED ON 16th DECEMBER, 2022

CONTAMINATED COUGH SYRUP

1807: SHRI ANUBHAV MOHANTY:

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

(a) whether the Government is aware that many children/infants have lost their lives after consuming contaminated cough syrup;
(b) whether the Government has taken/proposed to be taken steps to ensure that Indian pharmaceutical products are not of sub-standard quality or contaminated, if so, the details thereof;
(c) the details of the action taken by the Government against pharmaceutical companies that are habitual offenders;
(d) whether there is a lack of coordination between State and Central drug regulators, if so, the details thereof;
(e) whether the Government has any plans to centralise all licensing functions with the Central regulator, if not, the reasons therefor;
(f) whether the Government has any plans to establish a statutory regulator for pharmaceuticals and medical devices thereby revamping the Central Drugs Standard Organisation (CDSO); and
(g) if so, the details thereof and if not, the reasons therefor?

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

(a) to (g): There is a regulatory framework under the provisions of Drugs and Cosmetics Act and Rules to regulate drugs, medical devices and cosmetics. Manufacture, sale and distribution of Drugs is primarily regulated by the State Licensing Authorities (appointed by respective State Governments) through a system of licensing and inspection while the Central Licensing Authority is responsible for approval of New Drugs, Clinical Trials in the country, laying down the standards for Drugs, control over the quality of imported Drugs etc. Isolated cases of allegedly contaminated cough syrup leading to death in Children have been reported in the past.

For regulation of Medical Device, comprehensive Medical Device Rules 2017 have been published which came into force with effect from 1st day of January, 2018.

The cases concerning quality or safety of drugs when reported, the matter is taken up with the concerned State Licensing Authority (SLA) in order to take necessary action under the provisions of Drugs and Cosmetics Act 1940 and its Rules. The State Licensing Authorities are empowered to take action on violation of any conditions of such licenses including prosecution in appropriate Court of law.

Central regulator coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee (DCC) meetings held with State Drugs Controllers for uniformity in administration of the Drugs and Cosmetics Act.

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