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

RAJYA SABHA UNSTARRED QUESTION NO. 1859 TO BE ANSWERED ON 05TH AUGUST, 2025

REGULATION OF OXYTOCIN MISUSE AND ITS HEALTH IMPLICATIONS

1859: MS. SWATI MALIWAL:

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

- (a) the total number and details of inspections, raids, and seizures conducted by Central and State authorities against illegal manufacture, sale, and use of oxytocin since the ban on private manufacture and import, year-wise and State/UT-wise;
- (b) the number of cases registered, prosecutions initiated, and convictions secured related to oxytocin violations during this period, year-wise and State/UT-wise;
- (c) the quantity of oxytocin seized annually under these enforcement actions, year-wise and State/UT-wise; and
- (d) whether Government has undertaken any study on the impact of consuming dairy products from animals treated with oxytocin, if so, the details thereof and results of such study?

ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. ANUPRIYA PATEL)

- (a) to (d): As informed by Indian Council of Agricultural Research (ICAR), Indian Veterinary Research Institute (IVRI) in collaboration with Indian Council of Medical Research (ICMR) conducted one research entitled, "Assessing the thermal stability of oxytocin in milk and digestive stability of oxytocin *in vitro* and *in vivo*". It was launched under "ICMR-ICAR-FSSAI Joint Committee for Research on Food Safety" in December 2011. The key findings of the research outcome are as below: -
 - The oxytocin is a native component of dairy milk
 - Exogenous injections of oxytocin do not change the milk oxytocin content.
 - Oxytocin present in the milk is stable during milk boiling
 - Oxytocin is stable to gastric pepsin digestion.
 - However, Oxytocin is rapidly digested in the intestine by serine proteases

"These studies strongly suggest that exogenous oxytocin injections do not influence its content in milk. Further, oxytocin present in milk is rapidly degraded during intestinal digestion, ruling out its intestinal absorption and associated adverse health consequences if any"

The manufacture, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take stringent action against violation of any provision of the Act and Rules. Manufacturing and marketing of banned drugs is a punishable offence.

The Ministry of Health & Family Welfare had published notification vide GSR No.411 (E) dated 27.04.2018, which was subsequently amended vide G.S.R. No. 794 (E) dated 21.08.2018, initially with effect from 01.07.2018 and which was later postponed vide GSR No. 602 (E) dated 29.06.2018 with effect from 01.09.2018, for restricting the manufacture of Oxytocin formulations for domestic use to public sector only, under Section 26A of the Drugs and Cosmetics Act.

However, some of the affected parties had filed petitions before the Hon'ble High Court of Delhi challenging the notification G.S.R. No. 411(E) dated 27.04.2018. After hearing both sides, the Hon'ble High Court vide dated 14.12.2018 quashed and set aside the notification. Subsequently, the Government has filed Special Leave Petition (Civil) No.(S). 3296-3299/2019 in the Supreme Court of India on 04.01.2019 which is sub-judice.
