

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION NO. 575
TO BE ANSWERED ON THE 25th June, 2019

OXYTOCIN DRUGS

575 SHRIMATI RAKSHA NIKHIL KHADSE:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

- (a) whether the Government proposes to ban private companies for producing and selling Oxytocin drug which is used for inducing labour contraction and controlling bleeding on account of misuse of this drug by the dairy sector for increasing milk production; and
(b) if so, the details thereof?

ANSWER

**MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)**

(a) & (b) 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 in the following mann

- i. The manufacture of Oxytocin formulations for domestic use shall be by public sector undertakings or companies only and the label of the product shall bear barcodes.
- ii. The manufacture of Oxytocin formulations for export purposes shall be open to both public and private sector companies and the packs of such manufacture for exports shall bear barcodes.
- iii. The manufacturers of Active Pharmaceutical Ingredient (API) of Oxytocin shall supply the API only to the public sector manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug for domestic use.
- iv. The manufacturers of active pharmaceutical ingredient of Oxytocin shall supply the said active pharmaceutical ingredient to the manufacturers in public and private sector licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug for export purpose.

- v. The Oxytocin formulations manufactured by the public sector companies or undertakings licensed under the Drugs and Cosmetics Rules, 1945 shall be distributed or sold in accordance with such rules.

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 had pronounced the final judgment on dated 14.12.2018 and 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.
