

File No. X-11026/103/2018-BD
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla road, New Delhi
(Veterinary Cell)

FDA Bhawan, Kotla Road,
New Delhi-110011, India,
Dated- 02 AUG 2018

Office Memorandum

Subject: Strict regulatory actions to prevent illegal manufacturing, sale and distribution and import of Oxytocin in India- regarding.

In order to prevent the misuse of Oxytocin, the Ministry of Health and Family Welfare has issued the Gazette notification vides GSR No.390 (E) dated 24.04.2018 prohibiting import of Oxytocin with immediate effect.

The Ministry has also issued Gazette notification vides GSR No.411 (E) dated 27.04.2018, which will come into effect from 01.09.2018, to regulate and restrict the manufacture, sale and distribution of Oxytocin in following manner:

1. 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.
2. 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.
3. The manufactures 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
4. 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.
5. The Oxytocin formulations manufactured by the public sector companies or undertakings licensed under the Drugs and Cosmetics Rules, 1945 for domestic use shall supply the formulations meant for human and veterinary use only,-

- a) To the registered hospitals and clinics in public and private sector directly; or
- b) To the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and Affordable Medicines and Reliable Implants for Treatment (AMRIT) outlets or any other Government entity which may be specified by the Central Government for this purpose in the country which shall further supply the drug to the registered hospitals and clinics in public and private sector.

6. The Oxytocin in any form or name shall not be allowed to be sold through retail Chemist.

The issue is being discussed and monitored at highest level of Government from time to time for proper implementation of the above measures taken to prevent misuse of the drug in the Country.

In view of the above, all Zonal/sub zonal offices are hereby directed to give special emphasis in the matter and keep strict vigil so as to ensure that Oxytocin in any form/name is not imported into the country in violation of the notification issued by Government vide GSR No.390 (E) dated 24.04.2018. It is also directed to keep strict vigil in coordination with the State/UT Drugs Controllers, to unearth illegal manufacture/sale/distribution of Oxytocin so as to prevent its misuse in dairy and Agriculture.

The Zonal/Sub zonal offices shall submit the action taken report in this regard to CDSCO (HQ) on quarterly basis for further necessary action.

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

1. All Zonal Offices /Sub Zonal offices of CDSCO

Copy to-

PS to JS (R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi-110011.