

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

FDA Bhawan, Kotla Road
New Delhi-110011

Dated- 21 MAY 2018

To

The All State Drugs Controllers,

Subject: Special operations to prevent and detect illegal manufacturing of (API, formulations) and import of Oxytocin in India - regarding.

Sir / Madam,

As you are aware, reports have appeared time to time in various fora about misuse of Oxytocin in the country by the farmers and dairy owners to extract milk from milch animals.

Cases of illegal manufacture, import and sale of the drug and its misuse by the farmers or dairy owners have also been unearthed from time to time in different parts of the country.

The issue has been discussed in several meetings at highest level of government and it has been decided to conduct special operations to prevent and detect illegal manufacturing of (API, formulations) and import of Oxytocin in India with the cooperation of Police wherever required.

The Ministry of Health and Family Welfare has issued the Gazette notifications vide GSR No.390 (E) dated 24.04.2018 to prohibit the import of Oxytocin in public interest.

The Ministry of Health and Family Welfare has also issued Gazette notifications vide GSR No.411 (E) dated 27.04.2018 to regulate and restrict the manufacture, sale and distribution of Oxytocin in the country to prevent its misuse by unauthorized persons or otherwise. The Central Government has regulated the manufacture for sale or for distribution of Oxytocin under section 26A of the said Act in the following manner:

- 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 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.

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

The regulations with regard manufacture of Oxytocin for domestic use will come into force on 1st July 2018 as per GSR 411(E). However, the ban on import takes immediate effect as per GSR 390 (E) dated 24.04.2018.

As decided at the highest level of government, you are requested to conduct special operations to prevent and detect illegal manufacturing, sale and distribution of Oxytocin with the cooperation of Police wherever required.

Details of action taken in the matter may please be forwarded to this office for further action.

Yours faithfully,



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

Copy to-

1. PPS to JS (R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi-110011.
2. Chief Commissioners of customs of all port offices.
3. The Director NITI Aayog (Health division) Government of India Sansad Marg, New Delhi-110001
4. IT cell of CDSCO (HQ) for uploading in CDSCO website.