File No: X-11026/40/2018-BD
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla road, New Delhi
(O/o DCG (I))

PUBLIC NOTICE

28th February, 2018.

Sub: Restriction on import, manufacture, sale and distribution of Oxytocin to curb its misuse – regarding

Reports have appeared from 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.

2. Central Drugs Standard Control Organisation (CDSCO) and Ministry of Health and Family Welfare have taken various measures to prevent the misuse of the drug.

3. Oxytocin is included in Schedule H to the Drugs & Cosmetics Rules, 1945, requiring that the drug should be sold by retail under the prescription of a Registered Medical Practitioner only.

4. To avoid bulk sale of Oxytocin injection, a provision was made under the said Rules in April 2001 that the Oxytocin Injection shall be packed in single unit blister pack only.

5. The manufacture for sale, sale or for distribution of the drug have also been restricted on 17-01-2014 under Section 26A of the Drugs and Cosmetics Act, 1940 providing that;

i. The manufacturers of bulk Oxytocin drug shall supply the active pharmaceutical ingredient only to the manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug.

ii. The formulations meant for veterinary use shall be sold to the veterinary hospitals only.

6. Hon'ble High Court of Himachal Pradesh in its order dated 15-03-2016 in CWPIL No. 16 of 2014 has directed to consider the feasibility of restricting the manufacture of Oxytocin only in public sector companies.

7. Accordingly, Ministry of Health and Family Welfare has taken up the matter with the Department of Pharmaceuticals for restricting the manufacture of Oxytocin in Karnataka Antibiotics and Pharmaceuticals Limited (KAPL) Bangalore.

8. As the whole issue of Oxytocin is of paramount importance for protection of human and animal health, following proposals are under consideration to curb its misuse.

i. To prohibit the import of the Oxytocin and its formulations for human use as well as animal use under section 10A of the Drugs and Cosmetics Act, 1940.

ii. To regulate and restrict the Oxytocin formulations for human use under Section 26A of the Drugs and Cosmetics Act, 1940 so that the drug is supplied only to registered hospitals and clinics in public and private sector.

iii. To adopt bar-coding system for manufacture of Oxytocin formulations so as to ensure track and traceability of the product to avoid its misuse.

iv. Manufacturing of Oxytocin (formulation) shall be restricted in public sector units only.

However, above proposals shall not be applicable for Oxytocin meant for export purpose.

9. All the stakeholders are requested to forward their comments / suggestions on the above proposals through email at dci@nic.in or in hard copies to the O/o DCG(I), CDSCO, FDA Bhawan, Kotla Road, New Delhi-110002, within 15 days of issue of this notice, so as to consider the matter further.

28/2/2018

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