

File No. BD/VET.CELL/10.2014
Directorate General of Health Services
Central Drugs Standard Control Organization
(O/o Drugs Controller General India)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: - 22-10-14

To

All State Drug Controllers

Subject: Strict regulatory control over the manufacture, sale and distribution of Oxytocin and measures required to be taken to curb the misuse of oxytocin by dairy owners for milking milch animals - regarding.

Sir,

The Government of India, Ministry of Health and Family Welfare, in exercise of powers conferred under Section 26A of the Drugs and Cosmetics Act, 1940 had issued a Gazette Notification GSR 29(E) dated 17.01.2014 under which it has been directed that the drug oxytocin shall be manufactured for sale or for distribution or sold in the manner specified below, in addition to the provisions contained in the said Act and Rules made thereunder, namely:-

1. The manufacturers of bulk oxytocin drug shall supply the active pharmaceutical drug only to the manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug.
2. The formulations meant for veterinary use shall be sold to the veterinary hospitals only.

A copy of the said Notification was earlier forwarded to you for your information and necessary action in the matter.

Under the above notification that manufacturers licenced to manufacture bulk oxytocin drug are required to supply the active pharmaceutical drug only to the manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug and the formulations meant for veterinary use shall be sold to the veterinary hospitals only.

Smt. Maneka Sanjay Gandhi, Hon'ble Minister of Women & Child Development has taken up the matter with the Secretary, Ministry of Health and Family Welfare that the misuse of Oxytocin, is leading to a substantial loss of livestock in the country. Not only does this drug made cows barren sooner, but also lowers the life span of the animal, thus causing economic loss to the owner in the long run. It is being widely used in the dairy industry despite there being a ban on its sale, except by a prescription from a registered medical practitioner.

In order to examine the issue of misuse of oxytocin injection and effectively check its misuse an Inter-Ministerial Committee has been constituted by the Ministry of Health and Family Welfare. The committee noted that there is a need to take stringent measures on all cases of misuse of oxytocin by the State Drug Control Authorities in their State / UT and a constant vigil needs to be kept on the illegal movement of the oxytocin. The State / UT Drugs Inspectors after picking of the samples from different places should investigate the source of the illegal supply of the oxytocin concoction sold to dairy owners. The help from the NGOs in the State / UT could be taken to locate the areas where such illegal sale is being done.

In this connection, the State Drugs Controllers are requested to provide the details of the manufacturers of bulk and formulations of oxytocin in their State along with the statistical information on the seizures conducted, quantity seized along with its value, persons arrested, prosecutions filed, samples taken, reports of sub-standard quality received during the last three years to the office of DCG(I) within 30 days of receipt of this letter.

This may kindly be taken on priority.

Yours faithfully,



(Dr. G. N. Singh)

Drugs Controller General (India)

Copy forwarded for information and necessary action to all Zonal /sub zonal offices of CDSCO for necessary follow up with the State Licensing Authorities under their jurisdiction.