(Dr. G. N. Singh)
DRUGS CONTROLLER GENERAL (INDIA)

Central Drugs Standard Control Organization

Directorate General of Health Services
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FDA Bhawan, Kotla Road, New Delhi –110002.
F.No. BD/VET/ CELL./04-2017
Dated the, 30th March, 2017

To,

All State Drug Controllers,

Subject: Strict regulatory control over manufacture, sale and distribution of oxytocin and to curb its misuse -reg.

Sir,

The Secretary, Health and Family Welfare, Ministry of Health and Family Welfare took a meeting on 14.03.2017 to take stock of situation relating to restrict and regulate manufacturing of oxytocin and to permit its manufacturing in PSU in compliance to the judgement of the High Court of Himachal Pradesh.

In regard to control over manufacture, sale and distributions of oxytocin, it was decided in the meeting that cases where stoppage of production of oxytocin has been ordered for various reasons including non compliance to GMP, GLP and GDP etc should be monitored by the DCG (I).

In view of the above, you are requested to submit the details of such cases where manufacturers have been directed by you to stop manufacturing of oxytocin bulk/injection in your State due to above mentioned reasons and the action taken thereon.

You are also requested to conduct inspection of all the units manufacturing oxytocin in your State within a period of one month to verify the compliance to the requirements of the Drugs and Cosmetics Act, 1940 and Rules 1945 made thereunder by these units. During the inspection, if any non compliance is observed, the manufacturing unit should be directed to comply with the deficiencies with in a period of three months followed by compliance verification within a period of one month.

In case, a manufacturer fails to comply with the regulatory requirements even after giving opportunity as above, the manufacturer should be directed to stop the manufacture, sale and distribution of oxytocin bulk/injection with immediate effect.

The progress in the above cases may please be intimated to the undersigned on monthly basis so as to ensure that the drug is manufactured in the country for human and animals in compliance to the regulatory provisions of the Drugs and Cosmetics Act, 1940 and Rules 1945 made thereunder and its misuse is curbed.

This may be treated on priority.

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (India)

Copy to: JS (R), Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi.