DCGI directs state drug controllers to strictly control manufacture, sale & distribution of oxytocin

The Drugs Controller General of India (DCGI) has directed the state drug controllers to maintain strict regulatory control over manufacture, sale and distribution of oxytocin and to curb its misuse by the manufacturers, especially where stoppage of production of oxytocin has been ordered for various reasons including non-compliance to GMP, GLP and GDP.

The DCGI directive comes following a meeting in this regard convened by the secretary, Union Health Ministry on March 14, 2017 to take stock of the 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 DCGI.

The DCGI, in his directive, has asked the state drug controllers to submit the details of such cases where manufacturers have been directed by them to stop manufacturing of oxytocin bulk/injection in their state due to above mentioned reasons and the action taken thereon.

The DCGI asked the state drug controllers to conduct inspection of all the units manufacturing oxytocin in their 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”, the DCGI in his directive said.

Earlier, there was a proposal by the Union Health Ministry to ban oxytocin injection in the country because of its misuse by dairy owners to extract milk from milch animals. The issue of restricting or prohibiting the oxytocin injection was again discussed in the DTAB's 70th meeting held on August 18, 2015. In the 69th meeting held on April 22, 2015, the DTAB had reiterated its earlier recommendations that the drug need not be prohibited as it has definite use for therapeutic purposes.

The members in the 70th meeting felt that the problem of misuse of oxytocin is more related to stricter control over the manufacture and sale of the drug especially through clandestine channels. The dairy owners get the drug manufactured at dubious premises from unscrupulous suppliers. Constant surveillance by the state drug regulatory authorities and other such regulatory agencies can only curb the misuse of the drug.