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Health Ministry addresses regulatory issues related to Oxytocin

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In the meeting, Manoj Jhalani clarified that Oxytocin has not been banned in the country, only its manufacture for domestic market has been restricted in the public sector through Karnataka Antibiotics and Pharmaceuticals Ltd. (KAPL) with effect from 1st September, 2018.



The Health Ministry recently held a video conference with the States/UTs on various issues relating to regulation of Oxytocin including the status of preparedness of the State Governments for implementing the amended rules in regard to manufacture, distribution and sale of Oxytocin. The video conference also assessed the stock of Oxytocin in the States to ensure that there is no shortage after the restriction order on its manufacture for domestic use comes into effect from 1st September, 2018.

R K Vats, Additional Secretary and DG (CGHS) and Manoj Jhalani (Ayushman Bharat Scheme Mission Director) chaired the video conference meeting. Vandana Gurnani, JS and Sudhir Kumar, JS, along with Dr Ishwar Reddy, DGCI and the other senior officers of the Ministry also attended the meeting. Principal Secretaries and Mission Directors from States/UTs and the KAPL team participated in the video conference.

In the meeting, Manoj Jhalani clarified that Oxytocin has not been banned in the country, only its manufacture for domestic market has been restricted in the public sector through Karnataka Antibiotics and Pharmaceuticals Ltd. (KAPL) with effect from 1st September, 2018. He further said that the private manufacturers of oxytocin can very well manufacture the drug for export purpose. Jhalani also emphasized that the government will ensure that there is no shortage of Oxytocin when the changed dispensation comes into effect.

The States were requested to ensure availability of Oxytocin Injection in all Government hospitals/clinics by placing purchase order to KAPL Ltd. As Oxytocin Injection is a lifesaving drug and now with its restricted manufacture and sale through KAPL, all procurement agencies of State Governments shall ensure sufficient stocks are available at any given point of time.

Jhalani emphasized that all States shall keep a vigil on any artificial shortage of Oxytocin Injection in their States. The States Authorities were also asked to ensure availability of Oxytocin Injection in all government hospitals by placing orders to KAPL and also have meeting with all stakeholders like FOGSI, IMA, PMBJP, etc., to ensure its availability in all private clinics also.

The States have been advised to assess their requirement of the drug and to place the orders with KAPL in time. Most states indicated that they have sufficient stock, and would also be placing orders to meet the requirement of Government sector hospitals.

KAPL requested the states to place their orders in advance for bulk procurement. KAPL assured that they have the required manufacturing capacity. KAPL also assured to maintain the adequate quality of the drugs. It has started a 24 hour Helpline number: 080- 23577595. It also assured that it shall be revising its bulk purchase pricing.

The Government also asked the States to mount an awareness campaigns about the government notification on restricting the manufacture and sale of Oxytocin restricting to KAPL and asked KAPL Ltd to ensure a robust supply chain to prevent any stock outs.

The Ministry shall be reviewing the production and distribution of Oxytocin drug on a regular basis.