

Cir.No.04/Admn/2018.Dated:07.08.2018.**C I R C U L A R**

Sub: Drugs and Cosmetics Act, 1940 and Rules made there under - Certain Instructions issued on Sale of Oxytocin - Regarding.

Ref: 1. G.S.R. 411(E) Notification dated. 27<sup>th</sup> April, 2018.  
2. G.S.R. 602(E) Notification dated. 29<sup>th</sup> June, 2018.

\* \* \*

Vide reference 1<sup>st</sup> and 2<sup>nd</sup> cited, The Ministry of Health and Family Welfare, Government of India has issued notification directing that the drug Oxytocin shall be manufactured for Sale or for distribution or sold in the manner specified below, namely,

- (i) The manufacture of Oxytocin formulations for domestic use shall be by public sector undertakings or companies only and the label of the product shall bear barcodes.
- (ii) The manufacture of Oxytocin formulations for export purposes shall be open to both public and private sector companies and the packs of such manufacture for exports shall bear barcodes.
- (iii) The manufacturers of active pharmaceutical ingredient of Oxytocin shall supply the active pharmaceutical ingredient only to the public sector manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug for domestic use.
- (iv) The manufacturers of active pharmaceutical ingredient of Oxytocin shall supply the said active pharmaceutical ingredient to the manufacturers in public and private sector licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug for export purpose.
- (v) The Oxytocin formulations manufactured by the public sector companies or undertakings licensed under the Drugs and Cosmetics Rules, 1945 for domestic use shall supply the formulations meant for human and veterinary use only,-
  - (a) to the registered hospitals and clinics in public and private sector directly; or
  - (b) to the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and Affordable Medicines and Reliable Implants for Treatment (AMRIT) outlets or any other Government entity which may be specified by the Central Government for this purpose in the country which shall further supply the drug to the registered hospitals and clinics in public and private sector.
- (vi) The Oxytocin in any form or name shall not be allowed to be sold through retail \ Chemist.

The above said notification shall be w.e.f 01.09.2018.

The Karnataka Antibiotics and Pharmaceuticals Ltd, (KAPL) a PSU, would be manufacturing this drug for human and Veterinary Use.

In view of the above, all the Enforcement Officers are instructed to implement above orders strictly and submit compliance from time to time.

*Preeti Meena*  
**DR. PREETI MEENA, I.A.S**  
**DIRECTOR**

To,  
All the Drugs Inspectors in the State.  
All the Assistant Directors in the State.

Copy to:  
The Joint Director, DCA, HQ  
The Deputy Directors in the State.