GOVERNMENT OF INDIA MINISTRY OF CHEMICALS AND FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

LOK SABHA

UNSTARRED QUESTION No. 3900

TO BE ANSWERED ON THE 22nd December, 2015

Sale of Oxytocin

3900. SHRI T. RADHAKRISHNAN: SHRI SATAV RAJEEV: SHRIMATI SUPRIYA SULE: DR. HEENA VIJAYKUMAR GAVIT: SHRI DHANANJAY MAHADIK: DR. J. JAYAVARDHAN:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether the retail sale of Oxytocin which was banned last year by the Government has been illegally continuing in the market, if so, the details thereof;
- (b) whether Drug Controller General of India (DCGI) has conducted countrywide raid in this regard, if so, the quantum of Oxytocin confiscated by DCG;
- (c) whether the DCGI has asked State Drug Controllers to provide information regarding licences issued for the manufacture of bulk oxytocin formulation, if so, the details thereof along with the objective behind the move; and
- (d) whether oxytocin is also smuggled from China which is available at cheaper rate, if so, the corrective steps taken/being taken by the Government for implementation of ban on the use of Oxytocin in the country?

<u>ANSWER</u>

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a): There is no ban on the sale of oxytocin in the country for permitted use of the drug. However to prevent misuse of oxytocin the measures have been taken by government:

- Drug is permitted to be manufactured and sold in single unit blister pack only.
- Government of India under section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), has issued a notification vide

GSR no. 29 (E) dated 17/01/2014, to regulate and restrict the manufacture, sale and distribution of Oxytocin in the country and to prevent its misuse, directing that the drug Oxytocin shall be manufactured for sale or for distribution or sold in the manner specified below:-

- 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.

(b) to (d): Various Zonal Sub Zonal offices under DCG (I) conduct investigation/raids from time to time based on complaint/surveillance etc. relating to manufacture, sale, distribution of drugs including Oxytocin. However, DCG (I) on 06 October 2015 deputed 8 teams of CDSCO officers including independent experts to conduct investigation at various ports to undertake investigation of the import, export, domestic supplies, raw material and finished bulk of oxytocin supplied to formulation manufacturers etc. While the teams have conducted the investigation no raid/seizure have been done.

Further based on information that Oxytocin was allegedly being imported under the name of Custom Peptide through courier company, different teams comprising senior officers of CDSCO were constituted by DCG (I) recently in October 2015 to further investigate the matter. The teams had conducted raids in Delhi, Kolkata, Ludhiana & Patna and seized 1.7 Kg of oxytocin being illegally imported from China under the name of custom peptide.

To keep vigil on illegal movement of oxytocin and take action thereof, DCG (I) on 22/10/2014 had written to the State Drugs controllers to provide information of manufacturers of bulk & formulation of oxytocin in their states along with details of seizures, raids conducted etc..

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