GOVERNMENT OF INDIA MINISTRY OF HEALTH AND FAMILY WELFARE DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA UNSTARRED QUESTION NO. 2989 TO BE ANSWERED ON 3rd AUGUST, 2018

OXYTOCIN BAN

2989. SHRI RAJAN VICHARE:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether the Government has issued instructions to restrict the sale of excessive quantity of oxytocin drug in the country and the drug would be sold on prescription, if so, the details thereof;
- (b) whether any guidelines have been issued in regard to complete ban on the sale of the drug;
- (c) whether the orders of the Union Government are not being adhered to in several States;
- (d) whether any task force was set up to monitor the sale of oxytocin in every State; and
- (e) if so, whether it was successful and if not, the reasons therefor?

ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY)

(a): Oxytocin is a Schedule 'H' drug under the Drugs & Cosmetics Rules, 1945 which is requires its retail sale to be on the prescription of a registered medical practitioner only.

Government has, vide GSR No.411 (E) dated 27.04.2018, which will be effective from 1st September, 2018, restricted the manufacture of Oxytocin formulations for domestic use to public sector only. It has also been stipulated in the said notification that Oxytocin formulations meant for domestic consumption will be supplied by the manufacturers to the registered hospitals and clinics in public and private sector directly. Further, Oxytocin in any form or name shall not be sold through retail Chemist.

- (b): The drug has not been banned in the country.
- (c): Misuse of Oxytocin has been reported from time to time in various forums including print and electronic media.

The manufacture, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take stringent action against violation of any provision of the Act and Rules.

(d) & (e): As per direction of Hon'ble High Court of Himachal Pradesh, Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare vide letter dated 22.09.2017 had requested all State Drugs Controllers to constitute Special task force in each District of each State to ensure that no prohibited/regulated drug including Oxytocin is freely available in each district in open market.