FOGSI Position statement on the Oxytocin Issue - 09 August 2018

The Government of India through the Central Drugs Standard Control Organization division of the Ministry of Health and Family Welfare has issued two Gazette notifications regarding Oxytocin on 24 April 2018 [1] and 27 April 2018 [2]. There has been a further notice on this matter by the Ministry of Health and Family Welfare issued on 01 August 2018 [3].

The practical effects of the above notifications are as under:

· The import of Oxytocin is banned.

• The manufacture / distribution of Oxytocin for the entire country will be done by only one public sector unit (PSU). This is Karnataka Antibiotics and Pharmaceuticals Ltd. (KAPL).

• Public and private health care units can obtain Oxytocin directly from KAPL only or through Jan Aushadhi and AMRIT stores. Oxytocin will not be available through the other and more accessible chemist or retail shops.

The above notifications have been made because Oxytocin was found to have been misused in farming, dairy and child trafficking. The regulation and restriction of manufacture is being brought into force to prevent these misuses of the drug.

Though the motives behind the above steps taken by the Government and Ministry of Health and Family Welfare are appreciable, there are important and potentially dangerous implications of the restriction and regulation of manufacture of Oxytocin on maternal health. The primary concern of care providers particularly from the grass roots level upwards is the shortage or non-availability of Oxytocin since there will be only a single source of manufacture.

KAPL has yet to prove that they are capable of manufacturing and distributing an adequate quantity of Oxytocin efficiently. From what is known so far, the pricing of the KAPL supply is more than three times the cost of the Oxytocin available now (strange in this time of cutting down on other medicines), and they will supply only in batches of 1000 ampoules to any one source. This has profound economic implications on small nursing homes (which provide the bulk of healthcare). For a large majority of these healthcare units 1000 ampoules of oxytocin represents a stock of almost a year and above. In areas where electricity is uncertain even if the small nursing home or even public sector hospitals can bring themselves to order the entire amount at once (a considerable investment), what of the cold chain which is essential to Oxytocin. It would amount to using Oxytocin with a compromised efficacy.

As per the Notice [3], there are offices in 17 states and union territories. There is no information as to how health units in other states and union territories may obtain the drug. Also, prominently missing is the coverage to the North Eastern states which have a high maternal mortality rate. There is a serious concern that the supply outside metro cities and especially in rural and less accessible areas will be hampered or it may be suboptimal due to lack of cold chain transport (Oxytocin needs to be transported and stored between 2 and 8 degrees C).

The other concerns are increasing difficulty of obtaining the drug, need for complex systems to track usage in healthcare units and the possibility of harassment by authorities. The fact that Oxytocin is a vital drug is amply demonstrated by the fact that it was included in the National List of Essential Medicines 2015 issued by the Ministry of Health and Family Welfare itself.[4] A number of references can be cited to demonstrate its value in maternal health and its role in reducing maternal mortality. One of these authoritative statements has been put forth by the World Health Organization (WHO) stating that the drug of first choice in preventing postpartum hemorrhage is Oxytocin. [5] The WHO also recommends an enabling environment to widen the availability of Oxytocin.

The effects of the current regulations are anticipated to bring about an exact opposite of these recommendations. Postpartum hemorrhage is a large contributor to maternal mortality and the availability of Oxytocin is an important element in keeping this menace in check. It should be available widely and at every possible birth scenario. Curbing its availability could result in the incidence of postpartum hemorrhage increasing and consequently mothers dying.

The use of oxytocin in the augmentation of the labour process also needs to be highlighted. It is the safest drug that can be used for this purpose. Without augmentation, labour is likely to stall and progress in an abnormal manner. This could have an impact of increased interventions in labour and higher cesarean section rates.

FOGSI reiterates its deep commitment to reducing maternal mortality and serving women in our country. FOGSI and other professional bodies including the Indian Medical Association (IMA) strongly condemn this unilateral step and decision on the part of the Government on this extremely important issue. We express our deep reservations on the restriction of manufacture of this lifesaving drug in maternity care. FOGSI urges the Government to seriously reconsider the implications of these steps and remove the newly placed restrictions. If there are concerns about the misuse of this lifesaving drug, better mechanisms to curb its unauthorized use need to be put in place rather than restricting its legitimate uses in pregnant and delivering women.