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**The Committee**

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Dear Prime Minister,

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**Subject :**

Oxytocin and related scientific information.

The International Society of Drug Bulletins (<https://www.isdbweb.org/>) is a worldwide network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of the pharmaceutical industry. It was founded in 1986, with the support of the World Health Organization Regional Office for Europe. The aim of the Society is to support the analyses and dissemination of scientific drug information to promote access and the appropriate use of pharmaceuticals.

ISDB learned that Ministry of Health and Family Welfare of India in its circular dated 1st August 2018, “has restricted the manufacture of oxytocin formulations for domestic use to public sector only from 1st September, 2018, due to complaints of misuse.”<sup>1</sup>

As per a media report, this particular restriction is based on a complaint of “misuse” of oxytocin and is as quoted below:

“Reacting to Maneka’s concerns, the Health Ministry, through the director general (health services), has asked state drug controllers for details of the manufacturers of oxytocin along with detailed information about the seizures conducted for the illegally produced hormone, the number of persons arrested in connection with these seizures, prosecutions filed and reports, if any, of sub-standard quality seized.”<sup>2</sup>

We believe that If the results of this investigation prove that the pharmaceutical is being misused, then the Minister of Health should use its power to resolve the problems identified and avoid overreacting and causing undesirable harm.

ISDB is of the opinion that such restricted manufacturing will create a shortage of the availability of a life-saving drug. It is estimated that 44,000 women die due to preventable pregnancy-related causes in India (<http://unicef.in/whatwedo/1/maternal-health>). Though these deaths have declined it is well known that the single major medical cause of maternal death is postpartum haemorrhage (PPH). Nearly three quarters of deaths from hemorrhage were classified as postpartum hemorrhage.<sup>3</sup> The medicine of choice to prevent PPH is oxytocin which is classified as an Essential Medicine according to the World Health Organization. It is included in the National List of Essential Medicines for India and the vast majority of countries.

So the availability of affordable and good quality oxytocin is extremely important. Oxytocin is also used to induce unobstructed labour, which needs monitoring by health experts. We fear that any such restriction of the manufacture of oxytocin to a single manufacturer may ultimately result in shortage of this life-saving medicine.

ISDB would like to clarify that Ms Maneka Gandhi in the article cited below contains some serious unscientific statements that need to be challenged. For example, she claims that in order to get milk, dairy owners inject cows “with an illegal drug called oxytocin twice a day. Oxytocin sends the animal into labour, so for two hours a day the animal is writhing in labour pains till the milk is squeezed out of her inflamed diseased teats. Oxytocin comes into the milk and results in hormonal imbalances in humans, who get diseases like tuberculosis, cancer, blindness in children etc.”<sup>3</sup>

Firstly, oxytocin as mentioned above is not illegal, it is a WHO classified Essential Medicine which is used by both medical doctors and veterinarians to stop or prevent PPH. Of course, if the drug is substandard or illegally manufactured then proper legal action needs to be taken against the manufacturers, a fact that applies to any drug found in the Indian marketplace.

Secondly, oxytocin acts on the uterus only when there is a pregnancy and not otherwise. Labour pain is induced when the uterus has a foetus and not otherwise and so it is simply not true that an animal writhes in pain for two hours every time oxytocin is injected, as stated above by Ms Gandhi. Oxytocin acts on the muscles (called myoepithelial cells) in breast tissue and can aid in squeezing out milk, but it does not increase milk secretion.

Thirdly, oxytocin is administered either intramuscularly or intravenously and never orally. The drug does not act or does not get absorbed when administered orally. So even if consumed orally by humans as mentioned, it has absolutely no action at all, as it is inactivated in the digestive system.

Fourthly, oxytocin, as mentioned, does not in any way cause hormonal imbalances.

And finally, there is no scientific evidence that oxytocin will cause tuberculosis, cancer or blindness in children and all these are assertions that aren't supported by scientific facts.

These facts stated here about oxytocin would be easily supported by any standard pharmacology textbook.<sup>4</sup>

ISDB learned from the media reports that the issue is currently pending in the Supreme Court of India and may soon appear before a three judge panel.<sup>5</sup> Unfortunately, we have no expertise in the Indian legal system but are mostly concerned about any oxytocin shortages that might arise from manufacturer's restrictions due to court judgements.

ISDB would like to emphasize that oxytocin is a drug that is absolutely essential to the appropriate management of pregnant women, and that prior to taking any action that might limit its access the Indian Minister of Health should have a full and scientific appraisal of this drug. We believe that Ms. Makena's concerns, though well-meaning, are inconsistent with the science of oxytocin and such court intervention may be unnecessary.

In the light of these scientific facts and also the essential nature of oxytocin, we request and urge you to write to the Ministry of Health & Family Welfare, Government of India to withdraw the restriction on manufacturing oxytocin. This action is absolutely vital to save the lives of mothers who may owe their lives to this important medicine.

As the President of ISDB, I want to assure you that our organization is totally independent from any industrial support and our only intention is to provide unbiased and scientific information regarding oxytocin and its important role in childbirth.

If you need more information on this issue we would be happy to provide it. We hope you will examine this action seriously and we look forward to hearing from you.

Yours Respectfully,

dr Dick Bijl, President ISDB



Copy to;

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