

Oxytocin production by private companies

September 6, 2019

Source: *The Hindu*

Manifest pedagogy: In recent times the use of chemicals or natural products, which have ill-effects on human health are in discussion for their regulation and limited use. Be it marijuana or oxytocin. Hence these chemicals and their chemical composition are important for Prelims and the debate around their regulation is important for Mains.

In news: Recently a two judge bench of the Supreme Court referred the matter to a larger bench, to decide on whether it would be in the public interest to restrict the manufacture of Oxytocin for domestic use to a single public sector undertaking.

Placing it in syllabus: Science applications in everyday life.

Static Dimensions:

- What is oxytocin and its uses
- Ill-uses of it

Current dimensions: Recent executive and judicial pronouncements on Oxytocin

Content:

What is Oxytocin?

- Oxytocin is a hormone produced by the hypothalamus and secreted by the pituitary gland.
- It was discovered in 1906 and is on the World Health Organization (WHO)'s List of Essential Medicines.
- It is a peptide hormone approved for use in both humans

and animals for stretching the cervix and uterus to facilitate childbirth.

- It also stops maternal bleeding after childbirth.
- Oxytocin is the recommended first-choice uterotonic drug for the prevention of postpartum haemorrhage (PPH), a leading cause of maternal mortality in caesarean sections.
- Oxytocin is also important in a practice called **“active management of third stage labour” (AMTSL)**.
- Since it cannot be predicted with certainty beforehand which woman is going to develop PPH after delivery, all standard guidelines, both internationally (WHO) and in India (GOI) recommend that women should get a shot of Oxytocin immediately after the birth of the baby in order to prevent PPH.
- The hormone stimulates the uterine muscles to contract, so labor begins.
- It also increases the production of prostaglandins, which move labor along and increases the contractions even more.
- Because of this effect, synthetic oxytocin (pitocin) is sometimes used to induce a woman to start labor if she cannot start naturally, or it can be given to make contractions stronger if a woman’s labor is slowing.
- Once the baby is born, oxytocin promotes lactation in the mother.
- It also helps with male reproduction.

Ill-uses of Oxytocin:

- The use of oxytocin as a medication can result in excessive contraction of the uterus that can risk the health of the baby.
- Common side effects in the mother include nausea and a slow heart rate.
- Serious side effects include rupture of the uterus and with excessive dose, water intoxication.

- However, the hormone is also used controversially in milch cattle to enhance milk production.
- Most of the veterinary use comes from illegal import of oxytocin from neighbouring countries.
- This, in turn, has adverse effects on the health of cattle as well as humans who consume the milk.

Hence, in order to curb the misuse of oxytocin in milch animals, the Union Ministry of Health and Family Welfare made it compulsory for drug firms in 2001 to pack oxytocin in single unit blister packs.

Recent executive and judicial pronouncements on Oxytocin:

Oxytocin is listed as a prescription-drug in **Schedule H of the Drugs and Cosmetics Act, 1940**. It can only be sold with prescriptions from registered medical practitioners and records need to be maintained for at least three years. The advertisement of Schedule H drugs is also prohibited. The drug is also covered under the Prevention of Cruelty to Animals Act, 1960, which prohibits using oxytocin to extract milk from milch animals.

In March 2016, the Himachal Pradesh High Court observed that oxytocin was being manufactured on a large scale clandestinely and being sold, leading to its misuse. The court recommended that manufacture of the hormone should be done only by public sector companies.

Following the court's observations, the Union government has also regulated and restricted oxytocin supply to hospitals.

Delhi High court judgement:

The Delhi High Court bench pronounced on December 14, 2018, its final order on Oxytocin, quashing the central government notification that had banned the manufacture and sale by private manufacturers of Oxytocin. The ban also covered ampoules for domestic use and restricted manufacture to only

the public sector undertaking (PSU), Karnataka Antibiotics and Pharmaceuticals Ltd. (KAPL).

KAPL had no previous experience of producing Oxytocin. In fact, it was granted a manufacturing license for Oxytocin ampoules as late as April 2018. The company had said that the bulk production of the drug would take three-four years and this would put the lives of many pregnant women at risk as it would lead to acute shortages.

It was envisaged that KAPL could sell this only through registered hospitals under the **Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)** and the Affordable Medicines and Reliable Implants for Treatment (AMRIT). The related measures proposed by the government included not allowing retail or wholesale chemists to stock Oxytocin in their shops in any form or name.

SC judgement:

A two judge bench of Supreme Court on August 22, 2019 referred the matter to a larger bench, with a set of questions to decide on whether it would be in the public interest to restrict the manufacture of life-saving drug Oxytocin for domestic use to a single public sector undertaking. The bench directed the Apex Court's registry to place the matter before the Chief Justice of India for necessary directions.

Some of the questions raised by the bench include:

- Whether a drug included in the NLEM under Schedule 1 of the Drugs (Prices Control) Order, 2013, notified under Section 3 of the Essential Commodities Act, 1955 would be subject to the provisions of Section 26A of the Drugs and Cosmetics Act, 1940?
- Whether the impugned notification has resulted in creating a monopoly in favour of public sector companies, to the complete exclusion of private sector companies, and if so, whether it would be protected by

Article 19(6)(ii) read with Article 14 of the Constitution?

- Whether it would be in the public interest to restrict the manufacture of a lifesaving drug for domestic use, to a single public sector undertaking, to the complete exclusion of the private sector companies, particularly in view of the high maternal mortality rates in the country?
- Whether the exercise of power by the Central Government under Section 26A of the Drugs and Cosmetics Act, 1940 is legislative or executive in nature?

The case came up before the Supreme Court after the Central government challenged the Delhi High Court's verdict of December, 2018 that quashed the government's decision to ban private manufacturers from making and selling Oxytocin, calling it unreasonable and arbitrary.