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**Oxytocin Judgment – the Legal Issues**

***-S.Srinivasan[[1]](#footnote-1)***

**1. Oxytocin: A Brief History and Background to the Ban**

**The Issue**

The Delhi High Court bench of Justices Ravindra S. Bhat and A.K. Chawla pronounced on December 14, 2018 its final order[[2]](#endnote-1) on Oxytocin quashing the notification (hereafter the impugned notification)[[3]](#endnote-2) that had banned the manufacture and sale by private manufacturers of Oxytocin 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 manufacturing license for Oxytocin ampoules as late as April 2018. KAPL would directly supply, it was envisaged, by a countrywide cold chain, to only registered hospitals and clinics in the public and private sectors. 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.

Oxytocin is an essential and life saving drug frequently used for women during delivery, for induction and augmentation of labour, to make childbirth safe and prevent death from postpartum haemorrhage (PPH). In India PPH contributes to 38%, approximately a total of 32,000 maternal deaths, of all maternal deaths[[4]](#endnote-3) occurring every year in India. A recent report from the Registrar General of India (RGI) showed nearly 4 women die every hour in India from complications developed during childbirth, with heavy blood loss caused by haemorrhage being a major factor.[[5]](#endnote-4) 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 the practice of AMTSL should be performed universally in all women, i.e., every woman should get a shot of Oxytocin immediately after the birth of the baby in order to prevent PPH.[[6]](#endnote-5) The guidance note of the Maternal Health Division, Ministry of Health and Family Welfare on prevention and management of Postpartum Haemorrhage recommends AMTSL for prevention and PPH and states that: “Oxytocin remains the uterotonic of choice for AMTSL. Oxytocin (10 IU, IM) is the preferred uterotonic based on studies on the safety and effectiveness of uterotonics. It also is the recommended uterotonic drug for PPH prevention during caesarean sections.”

(A uterotonic, is an agent used to induce contraction or greater tonicity of the uterus.)

The immediate trigger for the series of orders leading up to the impugned notification was its purported misuse and dangers to the health and well-being of milch cattle. Cattle injected with Oxytocin was feared to have Oxytocin residues in the milk produced which was therefore feared to be harmful to human health.

Petitioner AIDAN cited studies by scientists from the Indian Council of Agricultural Research (ICAR) and National Dairy Research Institute (NDRI), that showed that there was no evidence for this apprehension. The studies show Oxytocin concentrations in milk after Oxytocin ingestions tend to be minimal and below the assay decision limit. Oxytocin was also known to rapidly degrade during intestinal digestion, ruling out its intestinal absorption and associated adverse health consequences, if any.[[7]](#endnote-6)

The AIDAN petition also argued that Oxytocin, an essential and life-saving medicine, needed for preventing deaths of mothers, during and immediately after delivery, and that was relatively easily available, would become scarce. In a country where more than half of all pregnant women are anaemic and with several states still unable to assure blood availability at all major delivery points, this would make women even more vulnerable and would lead to many more maternal deaths. The order was therefore entirely out of proportion to the alleged harms. Never before any essential drug included in WHO Essential Drug List and in National List of Essential Medicine (NLEM) has been meted such biased, adverse treatment and with such insouciance.

It is to be noted that the interests of the sole bulk drug producer of Oxytocin in India, Hemmo Pharma, were not disturbed who could, even if the impugned notification had gone through, still manufacture for export as could the licensed formulation manufacturers. Hemmo Pharma produced annually 22 kg out of which only 2 kg was used for annual domestic production of 6 crore ampoules while the rest 20 kg (equal to 66 crore ampoules) was exported. Therefore as the Hon’ble Court opined, “The arbitrary nature of the impugned prohibition is starkly apparent.” (Para 130 of the final order)

The other petitioners who were manufacturers – BGP Products Operations GMBH (a subsidiary of Mylan) and others – invoked Article 14 (right of equality before law) and Art 19 (1) (g) (right to practise any profession, or to carry on any occupation, trade or business) of the Constitution of India and submitted the impugned notifications were violative of these provisions, arguments essentially accepted by the Hon’ble Delhi High Court as we shall see.

The Union of India preferred to fall back upon Article 19(6) of the Constitution of India to justify its reservation of Oxytocin manufacture to the public sector even as it tried to highlight the supposed dangers to cattle and vegetables, and girl children in sex trafficking.

**Influential Lobbies and a Bad Decision**

The several minutes of the Drug Technical Advisory Board (DTAB) - for instance the minutes of the 65th, 67th, 69th, 70th, 78th and 80th meetings; and the 40th, 43rd, 44th, 46th and 49th meetings of the Drugs Consultative Committee (DCC) - nowhere recommend the ban of private manufacture and sale of Oxytocin nor suggest confining it to PSUs or for that matter a single PSU. Neither could the Union of India produce satisfactory evidence of ‘widespread misuse’ of Oxytocin.

The decision to ask KAPL to be the sole manufacturer of Oxytocin in India was despite several notings in the Government files requisitioned by the Delhi High Court to be produced – these notings doubted the capability and viability of KAPL to execute the role of the sole manufacturer of oxytocin formulations.

Smt. Maneka Gandhi, the Minister for Women and Child Development Ministry of the NDA Government, used her political clout in the matter to influence various levels of decision making. On 16.10.2015, the 49th meeting of the DCC was addressed by Smt. Maneka Gandhi highlighting the negative consequences of misuse of oxytocin for milch cattle. The files requisitioned by the Hon’ble Court (and not shared with the petitioners) show inter alia that:

“… a meeting convened on 05.11.2014 by the Women and Child Development Ministry (MWCD) Cabinet Minister (Ms. Maneka Gandhi) attended by other Secretaries of various Ministries, suggested that there was rampant misuse of Oxytocin which led to cows and animals contracting diseases and that such illegal use for increasing milk production can be effectively controlled if *“Government of India owned company may be allowed for production of this drug in the country and the private companies may be prohibited for the same.*”

… Thus, the issue of banning (oxytocin) drug manufacture appears to have been mooted at least on the file, on 05.11.2014 by the Ministry of Women and Child Development - *despite the expert group finding that there was no data to support such allegation of misuse*.

(Para 53- 54, itals in the original)

All the statutory body meetings “recommended against the ban of sale of Oxytocin having regard to its beneficial medical effects….” The 67th and 70th meetings of the DTAB; the 49th and 69th meetings “consistently and clearly stated that Oxytocin could not be banned or prohibited as it has a defined use for therapeutic purposes.” (Para 123 (iv) and (v)).

The Union Cabinet Minister replying to questions on the floor of the Parliament quoted the studies[[8]](#endnote-7) from Government institutions NDRI and ICAR and asserted as much on the floor of the Parliament on August 2014 and December 2015. On the latter date he said in the Parliament that “The National Dairy Research institute (NDRI) has informed that there is no scientific evidence that artificial use of Oxytocin has adversely affected progeny of cattle and buffaloes resulting in dwindling of livestock. However, continuous Oxytocin use could lead to progressive addiction and normal lack of response to normal let down of milk.” (Para 123 (vii) and (viii)).

Such studies did not convince Maneka Gandhi, Minister for Women and Child Development, nor did it convince apparently sympathisers of her cause in the PMO and Niti Aayog.[[9]](#endnote-8) They decided to bash on and press for severe restrictions on the manufacture and availability of oxytocin in order to prevent the so-called ill-effects on cattle and in human health. The active involvement of the PMO, with a couple of meetings on the issue held in the PMO, sent its own message. The minutes of the 78th meeting of the DTAB held on February 12, 2018 recommended sale of Oxytocin to hospitals in the public and private sector but not total ban on private manufacture. By February 28, 2018 the decision to ban was taken and a public notice of the Government’s intentions was issued. (In fact a High Level Group meeting of 8th February 2018 had already taken the decision to ban private manufacture of Oxytocin once production of Oxytocin ampoules by KAPL was in full swing. (Para 123 (xxiii))

This shows if anything the decision to ban was taken in spite of research evidence and expert opinion to the contrary. Also, it is ironical that in the run up to the ban, the Minister whose primary remit was, and is, Women and Child Development, did not show as much concern for deaths of women in childbirth as it did for cattle and vegetables. A sense of balance in a Union Minister would have been desirable.

**HP High Court Judgment and its Detritus**

The judgment of the HP High Court dated 15.03.2016 [CWP (PWL), No 16 of 2014] – Court on its own motion v. State of Himachal Pradesh] proved to be “*the tipping point or the catalyst for the eventual decision to impose the prohibition which is under challenge in these cases*.” (Para 109, itals in original)

The judgment was a result of the HP High Court taking suo moto cognisance of a report of Oxytocin misuse in animals in the Hindi newspaper *Amar Ujala* dated Nov 9, 2014. The HP Court even appointed an amicus curiae. The HP High Court judgment notes that Oxytocin misuse was acknowledged in all the statutory committee/board minutes of meetings leading up to the first notification dated 17.01.2014. The crucial part is the direction issued in Para 21 (ix) of the HP High Court judgment wherein it directed “to consider the feasibility of restricting the manufacture of Oxytocin only in public sector companies and also restricting and limiting the manufacture of Oxytocin by companies to whom licenses have already been granted,” a suggestion made by the amicus curiae and one that was conveniently interpreted as a mandate for confining Oxytocin manufacture to public sector.

The HP bench in issuing directions “did not consider the therapeutic uses of Oxytocin in human beings and its critical role in pregnant women, particularly at the post- partum stage to stem haemorrhage.” [Para 123 (xvi)]

Instead the HP High Court chose to focus on the alleged misuse and harmful impacts of Oxytocin on milch cattle, milk and vegetables.

**2. Legal Issues in the Delhi HC Final Order**

Considering the various issues narrated above, the bench of Justices Bhat and Chawla decided in its wisdom the following questions worthy for determination in the batch of writ petitions challenging the Oxytocin ban and related restrictions:

1. Does the impugned notification, namely, GSR 411(E) dated 27.04.2018[[10]](#endnote-9), fall within the scope of Article 19(6) of the Constitution of India?

2. Is the impugned notification *ultra vires* the provisions of the Drugs (and Cosmetics) Act?

3. Whether the impugned notification is arbitrary and therefore, unsustainable?

**Impugned Notification and Scope of Article 19(6) of the Constitution of India**

Art 19 outlines six freedoms. And specifically Art 19 (1) (g)[[11]](#endnote-10) asserts the right to trade/any profession/business. The proposed ban would have shut down domestic Oxytocin production and sales of all licensed private sector manufacturers. And with it the right enshrined in Art 19 (1) (g) would have been infringed. An exception is however made through Art 19 (6) (ii) which asserts the right of the State to reserve, in public interest, certain products/business/trade for the public sector as part of ‘reasonable restrictions’ on the right to trade, etc. Art 19 (6) (ii) basically legitimises State Monopoly and seemingly puts its beyond judicial review. Government counsel cited several related cases in support of the restrictions/ban on the manufacture/sale of Oxytocin which de facto led to State monopoly over manufacture and sale of Oxytocin formulations. While the judgment interrogates the logic and relevance of these cases cited by the Government and its appropriateness to the argument, it does not question in anyway the right of the Government to create such a monopoly. The judgment also appears to quote in approval certain case laws[[12]](#endnote-11) that argue that public interest is to be assumed, unless the contrary is shown, if the action of the State results in monopoly.

Probably if the Central Government had cited Art 19 (6) (ii) to prohibit Oxytocin for private manufacture while reserving the same for public sector, the Central Government may have ‘got away’ after a fashion except that the reasonableness of this restriction on Art 19 (1) (g) and whether the restriction is in public interest (read mothers in childbirth) may have been difficult for the State to prove.

The impugned notification cites Section 26 A of the Drugs and Cosmetics Act[[13]](#endnote-12) to promulgate the prohibition of private manufacture. However as the judgment points out after detailed examination, "no provision in the enactment (Drugs and Cosmetics Act) *per se* authorizes the taking over of the drug business or an entire line of business for monopoly production by one licensee – even if it were a State monopoly.” (Para 79)

And further:

“…. Any provision or law which does not enable the creation of a monopoly either directly or authorize the creation of State monopoly, therefore, does not fall within the productive ambit of Article 19(6)(ii). In the present case, this Court is of the opinion that Section 26A does not and cannot be considered by any standard or interpretation as a law that creates State monopolies or enables the creation of State monopolies. Consequently, the Union’s arguments on this score are unsustainable and have to fail.”

(Para 82 of the order)

So the instant case the State cannot – per the order – claim immunity under Art 19 (6).

**A Fine Distinction**

But here is a fine, if confusing, distinction that the judgment seeks to make. What if we ask the question: is the ban order per se beyond the powers (ultra vires) of Section 26A of the Drugs and Cosmetics Act? Their Lordships after an extensive discussion (see Paras 83 to 90) on the implied meanings of decisions that are regulatory, restrictive and prohibitive, conclude that “in a given, or suitable case, the power to “restrict” or “prohibit” can be used by the Central Government, under Section 26A to *partially ban* the manufacture of a drug, i.e. prohibit its production by private manufacturers, and reserve it, so to speak for the public sector. The measure - i.e. the impugned notification cannot therefore, be said to be *ultra vires* the power under the statute.” (itals in original)

But again we have not completely examined Section 26 A. Section 26 A talks of prohibiting (that is banning), restricting or regulating a drug only if it has unacceptable safety (risk to human beings or animals), or efficacy (does not have the therapeutic value claimed/purported to be claimed), or the content of the drug has no therapeutic justification. And it needs to use relevant material in determining so, and such actions have to be in public interest.

From relevant material examined by the Court (see Paras 100-102) including several minutes of DTAB/DCI, and after noting that it is part of the NLEM and the WHO Essential Medicine List, as also WHO recommendations for prevention and treatment of postpartum haemorrhage,[[14]](#endnote-13) and after taking into account Oxytocin’s vital role on saving lives of pregnant women in PPH, the Hon’ble Court observed:

“… it is apparent, that the materials on record, as well as the materials produced in the form of official files, do not point to any known or established risk to human or animal life, on account of Oxytocin use. On the other hand, its use for medicinal and therapeutic purposes is known and recognized …. As to the beneficial use – even necessity of Oxytocin, the (maternal mortality) figures, in a sense speak for themselves …... The Central Government stated, in Parliament, that the largest cause of maternal deaths is haemorrhaging which accounts for 38% of all maternal deaths. According to UN data, India is estimated to account for 15% of the total global maternal deaths. It would be a fair, or reasonable assumption that ease of access to Oxytocin was one of the reasons for the significant decline in maternal deaths due to haemorrhaging.” (Paras 103-105)

The impugned notification therefore cannot be seen to be valid in the light of the provisions of Section 26 A and powers exercisable thereof.

**Shoddy Data**

Their Lordships also noted that none of the data produced by the Government in the Court warranted a conclusion by the Central Government that Oxytocin was misused in such a manner that necessitated a ban on domestic manufacture and sale by the private sector (Paras 106-108).[[15]](#endnote-14)

If anything, in this writer’s opinion, the data submitted to the Court was skimpy, shoddy and non-sequitur and bespoke of a half-hearted attempt, probably a consequence of rational and conscientious officials (at least a majority of them) forced to defend, on political imprimatur, the indefensible. The Court’s opinion (see Paras 124-127) of the indifferent quality of the data presented by the Union of India is exemplified with observations like:

124. The action banning licensed manufacturers must be premised on data showing that licensed manufactures are misusing their licences and engaging in illegal import, manufacture, distribution or sale of the drug. In the entire counter affidavit there is not a single instance established, of such misuse by any licensed manufacturer… These facts do not show that the action of a complete prohibition for domestic manufacture of Oxytocin, an essential drug, by indigenous valid license holding manufacturers, was called for….

125. Furthermore, the UOI did not consider the fact that not all manufacturing units would have the same manufacturing loss factor; some may be more efficient….

126. … Now, the origin of this data is not explained; further-more the table talks of 45 licenses being suspended. However the chart preceding this one, says that over 100 licensees are permitted to manufacture Oxytocin. Therefore, whether the 45 licenses suspended is of the manufacturers, or pharmacists or dairies is unknown. Also, even if the seizures of 1.5 kg of API is correct, the culprits are known. The UOI does not say who is or are those culprits. …. Moreover, the fact that of those figures 1.5 kg was seized in one year (2015-16); in the preceding two years, the seizures were far less, thus showing lack of any emergent necessity for the prohibition.

127. This court has discussed the charts, particularly the last one, despite the fact that the UOI did not offer any explanation regarding the source of it. Statistics, unless explained, can be highly misleading. Therefore, unless the details of raids and other connecting materials are disclosed, the bare statistics (without explanation) proves little.

(Extracts from Paras 124-127, emphasis ours)

**Subordinate Legislation and Judicial Scrutiny**

Duty bound to defend a weak case, the Government counsel opened a third legal window, a red herring that demands a nuanced response as the courts have opined variously. The Union of India argued that the notification under Section 26 A was a subordinate legislation, an exercise of legislative power, and the therefore courts need to exercise judicial restraint. The Hon’ble Justices demurred: “This court is of opinion that there is no *per se* bar to reviewing regulatory provisions, even if they are made in the exercise of subordinate legislative power. Such rules or regulations do not *per se* carry a threshold of immunity greater than what any other instrument, either statutory or non-statutory would. The relevant public law standards applicable would be no different, to adjudge their validity.” (Para 91)

Among the reasons for rejecting the claim of immunity from judicial scrutiny of the impugned notification under Section 26 A is that the notification smacked of being manifestly unreasonable, a line of thinking bolstered by case laws[[16]](#endnote-15) like *Shri Sitaram Sugar Mills Company v Union of India* (1990) 3 SCC 223: “… A repository of power acts ultra vires either when he acts in excess of his power in the narrow sense or when he abuses his power by acting in bad faith or for an inadmissible purpose or on irrelevant grounds or without regard to relevant considerations or with gross unreasonableness."

The impugned notification would be inadmissible because of its gross unreasonableness and bad faith if one considers the disastrous public health impact on women giving birth that it would have had, a irrefutable fact that the discourse of the Union of India repeatedly sought to elide despite advice to the contrary of its own committees and experts. The learned judges cite *Cellular Operators Association v Telecom Regulatory Authority of India* (2016) 7 SCC 703, wherein the Supreme Court ruled that a subordinate regulatory legislation, can be set aside in judicial review, if they show no *rationale* or are arbitrary. On both counts the impugned notification is guilty. A thirdcriteria spelt out in *Cellular Operators Association* is whether the subordinate legislative measure is an unreasonable restriction. All change in Government policy “must be in conformity with Wednesbury reasonableness and free from arbitrariness, irrationality, bias and malice.”[[17]](#endnote-16)

A major part of the order from Para 98 (page 66 of 100) onwards, the Hon’ble Court has taken care to justify as it were for future legal scrutiny by higher courts, to explain the circumstances it would exercise its powers of judicial review, that is when the legality of a subordinate legislation such as the impugned notification involves arbitrariness and infringement of rights. Whether the infringement is excessive or not is for the Courts to decide. (Para 131)

“The judicial review standard to be applied when a measure is attacked for arbitrariness is that of Wednesbury reasonableness.”[[18]](#endnote-17) (Para 132)

“If an action taken by any authority is contrary to law, improper, irrational or otherwise unreasonable, a court of law can interfere with such action by exercising power of judicial review. One of such modes of exercising power, known to law is the "doctrine of proportionality".[[19]](#endnote-18)

The judgment sweeps, in masterly fashion, a welter of details - some of which we have already mentioned above and much of which we have to regrettably skip for reasons of space - leading up to the impugned notification and shows how it suffers from arbitrariness, impropriety, irrationality and is otherwise unreasonable and hence deserves to be rejected.

**Lack of Balance**

Although reluctant to do a ‘merits review’ as part of a judicial review of a notification claimed to be a subordinate legislation, if we go by the above discussion, the Hon’ble Court consciously seems to have crossed the lines; and pronounced its opinion on the impugned notification considering the crucial public interests involved, above all the public interest of women and preventing their needless deaths due to post-partum haemorrhage. In the context of drawing and crossing lines, we find their Lordships inter alia quoting Oliver W Holmes, “All distinctions of law -- even Constitutional law are in the ultimate analyses, "matters of degree". At what line the 'white' fades into the 'black' is essentially a legislatively perceived demarcation.”[[20]](#endnote-19)

Tragically in contrast, the learned judges observe in their final order that the “predominant consideration which runs like a common thread through the government’s decision making process is that Oxytocin had been misused in the past, resulting in adverse impact on the health of animals. In a case like this assuming the respondents had a good case to conclude Oxytocin was a risk to cattle health nevertheless in the nature of things its therapeutic benefit to humans could not have been overlooked or given less importance.”

In the end, the Court quashed the notification as both unreasonable and arbitrary as the Union of India did not “ adequately weigh” on inter alia what banning private manufacture, and restricting manufacture and supply of a life saving drug, could do to “increase in maternal fatalities, during childbirth, impairing lives of thousands of innocent young mothers. …

…. For these reasons, this court is of the opinion that the conclusions recorded by this court – to quote the Supreme Court – do not transgress the arena of permissible judicial review, but rather “*enough for us to say that the present case is on the right side of any line that could reasonably be drawn.”* [[21]](#endnote-20) (itals in original)

We need to celebrate the judgment both for its qualities of heart and mind.

***Endnotes***

1. *Author is affiliated with All-India Drug Action Network (AIDAN) and LOCOST, Vadodara. AIDAN was a petitioner in the Oxytocin matter in the Delhi High Court and gratefully acknowledges role of AIDAN legal counsel Colin Consalves. An experienced senior community obstetrician/gynaecologist, who does not want to be named, along with AIDAN colleagues Mira Shiva, Malini Aisola and the author were involved in the drafting of the petition and follow up. Anant Phadke and Mira Shiva improved this essay with comments on an earlier draft. Other acts of omission and commission are the author’s.*  [↑](#footnote-ref-1)
2. See <http://lobis.nic.in/ddir/dhc/SRB/judgement/14-12-2018/SRB14122018CW60842018.pdf> [↑](#endnote-ref-1)
3. Notification G.S.R. 411(E) dated April 27, 2018 at <http://www.cdsco.nic.in/writereaddata/GSR%20411(E).pdf>

   [↑](#endnote-ref-2)
4. RGI (2006) Maternal Mortality in India. 1997–2003: Trends, Causes and Risk Factors, Office of the Registrar General & Census Commissioner, India, New Delhi.

   Sample Registration System: Special bulletin on maternal mortality in India, 2014-16. New Delhi: Registrar General, India; 2018. [↑](#endnote-ref-3)
5. op.cit. endnote 3 [↑](#endnote-ref-4)
6. World Health Organization. WHO recommendations for the prevention and treatment of postpartum haemorrhage. World Health Organization, 2012; Maternal Health Division, Ministry of Heath and Family Welfare. Guidance note on use of uterotonics during labour, Government of India, 2015; Maternal Health Division, Ministry of Heath and Family Welfare. Guidelines for Antenatal Care and Skilled Attendance at Birth by ANMs/LHVs/SNs Government of India, 2010. [↑](#endnote-ref-5)
7. Results paraphrased from:

   Pullakhandam R, Palika R, Vemula SR, Polasa K, Boindala S. Effect of Oxytocin injection to milching buffaloes on its content & stability in milk. The Indian Journal of Medical Research. 2014;139(6):933-939).

   Prakash, Bhukya & Paul, Vijay & Kliem, Heike & Kulozik, Ulrich & H D Meyer, Heinrich. 2009. Determination of Oxytocin in milk of cows administered Oxytocin. Analytica chimica acta. 636. 111-5. 10.1016/j.aca.2009.01.050). [↑](#endnote-ref-6)
8. op.cit., end note 6. [↑](#endnote-ref-7)
9. See also: Menaka Rao. “Maneka Gandhi’s 19-year-long quest to ban oxytocin, a life-saving drug, without scientific basis” at <https://caravanmagazine.in/government-policy/maneka-gandhis-19-year-long-quest-to-ban-oxytocin-a-life-saving-drug-without-scientific-basis> [↑](#endnote-ref-8)
10. See endnote 2. [↑](#endnote-ref-9)
11. Art 19 (1) (g) says: “All citizens shall have the right to practice any profession, or to carry on any occupation, trade or business.”

    This right is subject to Art 19 (6):

    “Nothing in sub-clause (g) of the said clause shall affect the operation of any existing law in so far as it imposes, or prevent the State from making any law imposing, in the interests of the general public, reasonable restrictions on the exercise of the right conferred by the said sub-clause, and, in particular, nothing in the said clause shall affect the operation of any existing law in so far as it relates to, or prevent the State from making any law relating to:

    (i) the professional or technical qualifications necessary for practicing any profession or carrying on any occupation, trade or business, or

    (ii) the carrying on by the State, or by a corporation owned or controlled by the State, of any trade, business, industry or service, whether to the exclusion, complete or partial of citizens or otherwise.

    [↑](#endnote-ref-10)
12. For instance *M/s. Daruka & Co. v. UOI and Ors.* (1973AIR SC 2711) [↑](#endnote-ref-11)
13. Section 26A in the Drugs and Cosmetics Act, 1940 is about Powers of Central Government to prohibit manufacture, etc., of drug and cosmetic in public interest:

    Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette,[regulate, restrict or prohibit] the manufacture, sale or distribution of such drug or cosmetic.] [↑](#endnote-ref-12)
14. “Recommendations for prevention and treatment of postpartum haemorrhage‖ (available on its website http://apps.who.int/iris/bitstream/handle/10665/75411/9789241548502\_eng.pdf;jsessionid=2C60A698255DA85442B838185F6E4DF4?sequence=1) [↑](#endnote-ref-13)
15. As this essay is more on the legal aspects we are not elaborating on the extent of the poverty of the data submitted by the Government in justification of misuse of Oxytocin by milch cattle owners, the purported smuggling across national borders and the putative raids conducted by the authorities all over the country. But the referenced Paras in the judgment is a good start. [↑](#endnote-ref-14)
16. Other case laws cited in this part of the judgement are:  *Khoday Distilleries v State of Karnataka* 1996 (10) SCC 304; *Cellular Operators Association v Telecom Regulatory Authority of India* (2016) 7 SCC 703. [↑](#endnote-ref-15)
17. As held by the Supreme Court in *Shimnit Utsch India (P) Ltd v West Bengal Transport Infrastructure Development Corporation Ltd &Ors*2010 (6) SCC 303. On Wednesbury reasonableness, see the discussion of Justices Bhat and Chawla in the judgement.

    Wednesbury unreasonableness is “ A standard of unreasonableness used in assessing an application for judicial review of a public authority's decision. A reasoning or decision is Wednesbury unreasonable (or irrational) if it is so unreasonable that no reasonable person acting reasonably could have made it (Associated Provincial Picture Houses Ltd v Wednesbury Corporation (1948) 1 KB 223). The test is a different (and stricter) test than merely showing that the decision was unreasonable.” Source: https://uk.practicallaw.thomsonreuters.com/6-200-9152?transitionType=Default&contextData=(sc.Default)&firstPage=true&comp=pluk&bhcp=1 [↑](#endnote-ref-16)
18. Quoted in *Om Kumar v. Union of India* (2001) 2 SCC 386 [↑](#endnote-ref-17)
19. *Coimbatore District Central Coop. Bank v. Employees Association* (2007) 4 SCC 669 [↑](#endnote-ref-18)
20. Requoted from *Shri Kihota Hollohon v. Mr. Zachilhu* AIR 1993 SC 412 [↑](#endnote-ref-19)
21. As quoted in *Collector of Central Excise, New Delhi v. Ballarpur Industries Ltd. 1989 (4) SCC 566* [↑](#endnote-ref-20)