* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

**Reserved on: 25.10.2018**
**Pronounced on: 14.12.2018**

\+ **W.P.(C) 6084/2018, C.M. APPL.23517/2018**

BGP PRODUCTS OPERATIONS GMBH AND ANR..... Petitioners

versus

UNION OF INDIA AND ORS. ..... Respondents

\+ **W.P.(C) 8555/2018, C.M. APPL.32864/2018 & 34112/2018**

ALL INDIA DRUG ACTION NETWORK ..... Petitioner

versus

UNION OF INDIA AND ANR. ..... Respondents

\+ **W.P.(C) 8666/2018, C.M. APPL.33281/2018**

NEON LABORATORIES LTD. ..... Petitioner

versus

UNION OF INDIA AND ORS. ..... Respondents

\+ **W.P.(C) 9601/2018, C.M. APPL.37387/2018 & 37388/2018**

CIRON DRUGS AND PHARMACEUTICALS PVT. LTD. AND ANR. ..... Petitioner

versus

UNION OF INDIA AND ORS. ..... Respondents

Through : Sh. C.S. Vaidianathan, Sr. Advocate with Sh. Jayant Bhushan, Sr. Advocate, Ms. Gayatri Roy, Ms. Soumili Das, Sh. Anirudh and Sh. Amit Panigrahi, Advocates, for petitioners, in W.P.(C) 6084/2018.

Sh. Colin Gonsalves, Sr. Advocate with Ms. Olivia A.I. Bay, Sh. Deepak Kumar Singh and Ms. Harini Raghupathy, Advocates, for petitioner, in W.P.(C) 8555/2018.

Sh. Sandeep Sethi, Sr. Advocate with Sh. Ravikesh Kumar Sinha, Advocate, for petitioner, in W.P.(C) 8666/2018.

Sh. Tushar Mehta, SG with Mrs. Maninder Acharya, ASG; Sh. Kirtiman Singh, CGSC; Sh.

Ripu Daman Bhardwaj, CGSC; Sh. Rishikant Singh, Sh. Waize Ali Noor, Sh. Sahil Sood, Sh. Harshul Choudhary, Ms. Shruti Dutt, Sh. Vikramaditya Singh and Sh. Viplav Acharya, Advocates for UOI.

Sh. Varun Singh, Sh. Gaurav Nair and Ms. Pranati Bhatnagar, Advocates, for petitioner, in W.P.(C) 9601/2018.

Sh. Ashish Prasad, Ms. Mukta Dutta and Sh. Rohan Roy, Advocates.

**CORAM:**
**HON'BLE MR. JUSTICE S. RAVINDRA BHAT**
**HON'BLE MR. JUSTICE A.K. CHAWLA**

**MR. JUSTICE S. RAVINDRA BHAT**

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*"Youth fades; love droops; the leaves of friendship fall. A mother's secret hope outlives them all."—Oliver Wendell Holmes.*

1. This common judgment disposes of a batch of writ petitions challenging the validity of a notification; the writ petitioners complain that the impugned notification endangers the lives of pregnant women and young mothers. The said notification [GSR 411(E) dated 27.04.2018 (hereafter "impugned notification"]was issued by the Union of India and the Ministry of Health & Family Welfare (the first two Respondents, referred to variously as "MHA" and "UOI" respectively), acting through the third respondent in exercise of the powers under Section 26Aof the Drugs and Cosmetics Act, 1940 (hereafter the "Act").The notification prohibited the manufacture and distribution for domestic use, of the essential drug OXYTOCIN injection for human use, by private sector companies, including the Petitioners. The Petitioners also challenge the validity of an Office Memorandum dated 21.05.2018 in File No. X-11026/103/2018-BD (Annexure P-31-hereafter "impugned OM") issued by the fourth Respondent (hereafter "DCI").

2. The facts of the case are that the BGP Products Operations Gmbh (hereafter "BGP") is the petitioner in W.P.(C) 6084/2018; the petitioner in W.P.(C) 8555/2018 is an association, All India Drug Action Network ("AIDAN"); that in W.P.(C) 8666/2018 is the Neon Laboratories Ltd. ("Neon"); and in W.P.(C) 9601/2018 is the Ciron Drugs and Pharmaceuticals (P) Ltd (hereafter "Ciron"). BGP is the subsidiary of Mylan Inc, a leading generic pharmaceutical manufacturer; Neon and Ciron, likewise are drug manufacturers; all of them hold licenses to manufacture Oxytocin, which is termed as an essential medicine in terms of the 20th World Health Organization (WHO) Model List of Essential Medicines, March, 2017. Oxytocin injection is also included as an essential medicine under National List of Essential Medicines, 2015 (NLEM) published under the First Schedule to the Drugs (Prices) Control Order, 2013. According to the petitioners, Oxytocin is recommended by WHO as the first line drug for prevention and treatment of postpartum haemorrhage (excess bleeding immediately after childbirth). Oxytocin is also drug of choice used for pregnant woman for induction or reinforcement of labor. It is also used in state of incomplete or threatened abortion. Postpartum Haemorrhage (PPH) occurs when a woman bleeds excessively after she gives birth. As she bleeds, she become anemic and goes into shock and may eventually die of the condition if the bleeding does not stop or she does not receive blood transfusion. Worldwide, every year 8 million of 136 million women who give birth develop PPH. PPH is a leading cause of maternal mortality and causes a quarter of all 2,79,000 maternal deaths that occur yearly worldwide or approximately 69,000 deaths. Stemming postpartum bleeding among animals, prominently cattle, during childbirth, is also a known veterinary and approved use of the drug. The World Health Organization (WH) describes the post-partum period as the most critical *"yet the most neglected phase in the lives of mothers and babies"* and that most maternal and/or new born deaths occur during this period (Ref. "WHO Recommendations on postnatal care of

mothers and newborns" WHO Publication, 2014 http://www.who.int/maternal_child_adolescent/documents/postnatal-care-recommendations/en/ accessed at 09:31 hours, 28.11.2018).

3. It is stated that Oxytocin is capable of misuse by its administration in cattle to induce easier lactation; it can also be injected in fruits and vegetables to artificially induce their ripening. It is alleged that such the respondents' failure to check the misuse of the life-saving drug results in its abuse in cattle. The petitioners allege that State and Central Authorities are tasked with preventing Oxytocin misuse but failed to check and curb such misuse. It is contended that this failure has resulted in the impugned notification, which completely prohibited the manufacture and distribution of the product by licensees, who had no history of abuse of the licenses issued to them. All the petitioners cite a notification, E.S.R. 29 (E) dated 17.01.2014 issued under Section 26 A of the Drugs Act, which directed that the manufacture of the Oxytocin formulations can only be by the manufacturers who are licensed under the Drugs and Cosmetics Rules, 1945 (hereafter "the Rules") and further that oxytocin formulations meant for veterinary use shall be sold to the veterinary hospitals only. Further curbs with respect to Oxytocin, were in the form of regulation that pharmacists had to maintain a record with respect to sale of each Oxytocin drug or injection/ampoule.

4. It is argued on behalf of the petitioners, by learned senior counsel, M/s C.S. Vaidyanathan, Jayant Bhushan and Colin Gonzales, that the predominant or sole *rationale* for the impugned notification is the direction contained in a judgment dated 15.03.2016 passed by the Himachal Pradesh High Court (in CWPIL No. 16/2014)which, *inter alia*, directed the State of Himachal Pradesh ("HP") and Central Government bring about an efficient Drug Regulatory System both at the Centre and the State for better coordination and handling of entire problem as to regulate the manufacture, import and distribution, especially, drugs like Oxytocin; and that HP was in particular directed to examine the licenses of all the existing

manufacturers of such drugs to ensure that the same have been issued strictly in accordance with the Drugs and Cosmetics Act and Rules. It was submitted that of the twelve directions, given by the High Court only two were for the Central Government and rest were for the State. The directions to the Central Government are in para 21(i) and (ii). That judgment, did not in any manner call upon the Central Government to prohibit the manufacture of Oxytocin by Indian manufacturers. The entire emphasis of the judgment in the directions passed demonstrates that the High Court recognized problems relating to misuse of Oxytocin were not because Oxytocin was being manufactured in India but because, it was either being illegally diverted / smuggled / imported and sold and that there was not enough that the Central or State machinery was doing to prevent it.

5. It is urged that Oxytocin is an active ingredient in the pharmaceutical product, and is sold under various brands; BGP sells it under the brand name SYNTOCINON. It is available in India for the last 40 years and is used to induce labour; enhancement of labour in certain cases of uterine inertia; early stages of pregnancy as adjunctive for management of incomplete, inevitable and imposed abortion; during caesarean section but after delivery of child and lastly, prevention of post-partum uterine atony and haemorrhage. It is submitted that owing to its assured safety and quality, Oxytocin is a preferred product for human use. BGP says that it acquired all rights, including goodwill and reputation from its erstwhile owner - Novartis AG through an asset purchase agreement dated 17.08.2017. The second petitioner in BGP's writ petition is the distributor/wholesale licensee of the drug license issued in that regard. Learned counsel points to the fact that Oxytocin is a peptide hormone comprising of nine amino acids, produced in the human brain and released by the posterior pituitary. It was discovered in 1906 by Henry Dale. Its molecular structure was determined in 1952 as a uterine stimulant hormone. It is indicated for human consumption to induce labour and also primarily used to

prevent post-partum haemorrhage and excessive bleeding from the uterus following child birth.

6. The petitioner cited published figures, to say that 50% pregnancies in India are post-term, i.e. those which reach 42 weeks and premature rupture of membranes occurs in 5-10 %. It is claimed that pregnancy induced hypertension leads to mortality deaths between 52,000 and 77,000 annually. These conditions could be effectively managed by induction or augmentation of Oxytocin. It is contended that UN Population Fund and its partners have identified Oxytocin as one of the four priority medications to save mother's life during pregnancy and child birth. WHO has also cited to say that Oxytocin is to be regarded as the first option for induction of labour in cases where prelabour rupture of membrane occurs. It is also recommended for post-partum and post abortion haemorrhage as it is more stable than *Ergometrine*.

7. Learned counsel urged that Oxytocin injection for human use was included in the National list of Essential Medicines (NLEM) in 2011 and continues to be listed in the latest version published in 2015. According to the National Pharmaceutical Pricing Policy of 2012, the essential criteria for drugs is determined by considering the listed medicines specified in the NLEM as revised from time to time. NLEM is prepared by an expert core committee constituted by the DGHS out of the world model list of essential medicines. Learned counsel highlighted that according to the drug pricing policy, NLEM contains medicines "*that satisfy the primary health needs of the country's population*."

8. It is submitted furthermore, that approval for inclusion of any drug in the NLEM is given only after the Expert Committee appointed by the second respondent – the Union Health Ministry is satisfied with respect to the safety and efficacy of the concerned drug. Furthermore, for inclusion in the NLEM, the Core Committee's report of 2015 provides *inter alia* 5 parameters, i.e. that the medicine should be approved and licensed in India; that it should be useful in disease which

is a public health problem in India; it should have proven efficacy and safety approval based on valid scientific evidence and should be aligned with current treatment guidelines and it should be stable in storage conditions in India.

9. Learned counsel also point out that Oxytocin for human use was included in the 6th edition of India Pharmacopeia [hereafter "IP"] and rely upon the IP 2014 and IP 2018 which continued to provide Oxytocin injections for human use. It is submitted that IP is the book of standards which can be relied upon for quality of products of the Central and State drug control organizations.

10. The petitioners urge that the Union Government recognized the critical role of the private sector in the pharmaceutical industry since 1995 and the UN also recognized in 1996 that reservation of bulk Oxytocin exclusively for public sector was neither necessary nor expedient in public interest. They submit that the 1994 drugs policy abolished industrial licensing, also allowed foreign investment in the country and largely dispensed with reservation of drugs exclusively for public sector. In 1956, 15 bulk drugs not excluding Oxytocin were exclusively reserved for public sector and the 1994 policy reduced its exclusivity to 4 bulk drugs – Vitamin B1, Vitamin B2, Tetracycline and Oxy Tetracycline. These too were done away in 1999 through Press Note No.3 which recognized that reservation was no longer necessary in public interest. It is underlined that even in 1986, with the previous restrictive drug licensing regime, all companies, including under the FERA, were eligible for licenses for Oxytocin bulk drug. It is, therefore, highlighted that this means that the bulk drug Oxytocin or the active pharmaceutical ingredient has never been reserved for public sector nor is it so even after the impugned notification.

11. The petitioner partly rely upon the draft pharmaceutical policy of 2017 which recognized the role played by the public sector and the negligible contribution of public sector in the pharmaceutical industry. The following extracts of the report are highlighted:

> *"1.1 The Pharmaceutical Industry in India is robust and thriving. The annual turnover of the Industry in 2015-16 was Rs.2,04,627.15 Crores. Of these the exports constituted Rs. 110,5,342.20 Crores (Data source – CMIE – Economic Outlook) and the domestic consumption according to 'Pharma trac' data was Rs.98,414.4 Crores [Pharma trac is the database of All India Organization of Chemists and Druggists & Advanced Working, Action and Correction System (AWACS)]. The Indian Pharmaceutical sector is largely fuelled by exports and is the 3rd largest foreign exchange earner for India. According to the CMIE data, the industry has been growing at a Compound Annual Growth Rate (CAGR) of approximately 10% for the period 2010-11 to 2014-15. However, the growth rate is coming down from 14.36% in 2010-11 to 8.68% in 2014-15 (based on sales data of CMIE Industry Outlook). It employs about 2 Million work force across the value chain. 1.2 It is a private enterprise driven industry and the contribution of the Public Sector Undertakings (PSU) are negligible."*

12. Learned counsel submitted that the Drugs Consultative Committee (DCC) is an advisory Committee set up under Section 7 of the Drugs Act to advise the State Governments, Drug Tariff Advisory Board and the Union government on any matter tending to secure uniformity throughout India. The petitioner referred to the DCC's minutes of the 44th meeting (dated 20.07.2012); 46th meeting (dated 12/13.11.2013) and the 49th meeting, stating that none of these advised the Central Government or the respondent on the need to take action of such magnitude as to prohibit the manufacture and sale of Oxytocin by private licensees altogether for national purposes. It was submitted that a careful and plain reading of its minutes would show that several sections of medical experts undoubtedly flagged concerns with respect to alleged misuse of Oxytocin in the dairy sector but never did the DCC recommend or approve complete prohibition of drug manufacture by private licensees, and preferred monopoly by the Public Sector. Likewise, the recommendations and meetings of the Drug Technical Advisory Board (DTAB), particularly the minutes of the 65th, 67th, 69th, 70th and 78th meeting are relied upon. Learned counsel submitted that the recommendations of the expert bodies under

the Drugs Act led to the Central Government increasing the regulatory control, especially with respect to marketing of Oxytocin. It is submitted that secondly, on 17.01.2014, the respondent issued a notification restricting bulk drug supply to manufacturers licensed to produce Oxytocin; furthermore, formulations made for veterinary use could be sold only to veterinary hospitals. It is submitted that this was the direct result of the recommendations of the 65th meeting of the DTAB. Learned counsel also relied upon the minutes of the 76th DTAB meeting (dated 18.08.2015) which had recorded that Oxytocin manufacture in accordance with law has the highest costs and is not used in dairy sector to extract milk and further that the raw material or bulk drug is clandestinely smuggled into the country and manufactured clandestinely and sold to dairy owners. It is submitted that likewise in reply to a query in the Parliament on 01.08.2014, the Union Minister of Health and Family Welfare admitted that there was some reports in media about the misuse of Oxytocin injection and further "scientific data on the extent of such practice is not available". It was stated that that the Minister clearly stated that according to the expert body Indian Council for Agricultural Research (ICAR), "no ill effects have been observed in the animals in the experiments carried out on the use of Oxytocin"

13. All counsel highlighted that the available materials with the Central Government clearly indicated that there was no widespread misuse of Oxytocin by manufacturers licensed in accordance with law and rather that the formulation was clandestinely and illegally smuggled into the country from border States and crudely mixed with other substances for sale to the dairy sector. It was urged that this assumption of widespread misuse is the basis for the impugned notification which comprehensively bans manufacture for the purpose of domestic sale of Oxytocin in India. Learned counsel highlight that this material as indeed any other material with respect to alleged "widespread" misuse of Oxytocin on the part of the licensed manufacturers is so scanty and appears to have no proximity with the

response by the Central Government in issuing the impugned notification as to render it manifestly arbitrary and, therefore, violative of Article 14. It is also submitted that there is no scientific data or reliable material to show that Oxytocin has deleterious effect on cattle, as to be injurious to their health.

14. Learned counsel argued that the impugned notification is *ultra vires* and contrary to the powers granted to the Central Government under Section 26A. It is argued that the provision plainly enacts that the power can be exercised based upon satisfaction and availability of objective scientific material that a drug for human use poses risk to human life and/or is lacking in therapeutic value claimed or therapeutic justification. Further, the exercise of power under Section 26A presupposes that the Central Government is satisfied that a drug for human use poses risk to human health and is lacking therapeutic value claimed or therapeutic justification. Such satisfaction is to be based on objective material regulation or restriction, sufficient to control, manufacture or use.

15. It is submitted that in the present case, all the material on record, including the minutes of the DCC, DTAB, the replies to the queries posed in Parliament and the figures of alleged widespread misuse of Oxytocin in the dairy sector do not state that Oxytocin *per se* pose risk or danger of any kind to human life or that it does not have therapeutic value claimed or that it contains ingredients in such quantity for which there is no therapeutic justification. It is submitted that unless there is substantive material in the form of scientific data and objective justification, to so conclude, the ban of drugs manufactured by valid licensees, whose drugs have consistently met with safety standards besides all other technical and therapeutic stipulations cannot be denied market entry. Learned counsel relied upon the decision of the Supreme Court in *Union of India v. Pfizer Limited* 2018 (2) SCC 39 which held that the Central Government should be satisfied that a drug or cosmetic is likely to involve risks to human use or family or that the drug does not have therapeutic value claimed or contains ingredients in such quantities for

which there is no therapeutic justification. It is stated that the Court recognized the role of the expert bodies, i.e. the DTAB constituted under Section 5 and the DCC constituted under Section 7 of the Drugs Act. It was urged that even though the Court held that the power under Section 26A cannot be premised upon previous consultations with the DTAB nevertheless if there is overwhelming material by expert bodies, such as deliberations and Committee reports of DCC and DTAB, they are to be taken into account and cannot be brushed aside. Learned counsel submitted that in the facts of this case, the decision making by the Central Government through the impugned notification, enabling only the public sector entities, reserving manufacturing of Oxytocin for domestic use to the public sector, is based on utterly inadequate and scanty material given the severity of the restriction - it amounts to prohibition altogether from the legitimate exercise of the right to carry on trade. The material has no proximity to the nature of the measure, i.e. complete ban on manufacture.

16. Learned senior counsel pointed out that significantly the bulk drug manufacturer of Oxytocin formulation has not been prohibited from producing it or selling it nor has it been monopolised by the public sector. It continues to be manufactured by one single producer, who would continue (as it hitherto did in the past, to supply the Active Pharmaceutical Ingredient (API) Oxytocin for production of the drug formulations that can be retailed in injectable forms. Learned counsel also underlined that nor has manufacture for the purpose of export sale by the private licensees, including several petitioners been banned. These indicate clearly that Oxytocin – both the bulk drug as well as one retailed for ultimate consumption neither pose risk or danger to human life nor lack therapeutic value or justification. On the contrary, Oxytocin continues to be in the list of essential medicines. The complete ban on manufacture by private entitles who continue to hold valid license in this regard, is therefore, arbitrary and unreasonable and violate of Articles 19(1)(g) and 14 of the Constitution of India.

17. It is highlighted that the UOI cannot fall back upon the public interest element in Article 19(6) of the Constitution of India that enables it to enact a measure, completely taking over the manufacture or trade in one activity. In this regard, it is submitted that the exception under Article 19(6), enabling State monopoly is visualized in a situation where one of the predominant aspects of law is to provide for taking over of the business- whatever be its nature or nomenclature. It was submitted that Section 26A cannot be, by any stretch of the imagination, or on a plain interpretation, be construed as indicative by Parliament as a law through which the State *"has enabled the carrying on by State or by Corporation owned or controlled by the State, of any trade, business, industry or service, whether to the exclusion - complete or partial - of the citizens or otherwise."* It was argued that Article 19(6) aids or protects any law relating to creation of monopoly and handle those provisions of law integrally connected to the creation of the monopoly. The learned senior counsel submitted that Section 26A was not concerned with the creation of monopoly at all but rather with the regulation of manufacture of drugs, having regard to the prescribed factors, i.e. satisfaction of the Central Government that a drug posed a risk to life or health of human beings or animals or did not possess therapeutic values claimed or decision provided. The continued use of Oxytocin in the present case is an express indication of the conditions under Section 26A do not apply. Therefore, the reservation to the public sector, for the purpose of domestic manufacture clearly is a statutory override and cannot be supported by Section 26 A of the Drugs Act.

18. Learned counsel submitted that the licenses issued to drug manufacturers – who are over 100 in number, have neither been cancelled nor suspended. This means that such of the manufacturers who have authorisations or permissions to export Oxytocin can continue to produce the drug. The statistics on record in this regard were relied upon to say that for producing 600,00,000 (6 crore) ampoules- which is needed for human and veterinary use in India, 2 kg. of Oxytocin API is

necessary, to meet the annual overall national needs. It is highlighted in this context, that Oxytocin production for export sale accounts for 10 times that number, or 20 kgs, annually. Thus the bulk of such manufacture – of the ultimate product, is permitted. It was urged that in the absence of any widespread documentation of lapse or wrongdoing by licensed manufacturers, (very few of whose licenses have been suspended or cancelled), the allegations of "widespread misuse" which form the essential premise for the impugned notification, cannot support the ban.

19. It is argued, lastly, that the Union Government's attempt to bolster its case by relying on facts and figures collected *post* the issue of impugned notification is arbitrary. It is submitted that the notifications are to be judged, for their legality on the basis of materials which were *taken into consideration at the time of decision making.* Reliance is placed on *Mohinder Singh Gill and Anr. v. The Chief Election Commissioner and Ors* [1978] 2SCR 272 and *Commissioner of Police v Gordandas Bhanji* AIR 1952 SC 16 that *"public orders, publicly made, in exercise of a statutory authority cannot be construed in the light of explanations subsequently given"* of what was intended to be done and that *"Public orders made by public authorities are meant to have public effect and are intended to affect the acting and conduct of those to hum they are addressed and must be construed objectively with reference to the language used in the order itself"*.

20. It is contended that even if the material, brought on the record, after August, 2018 is taken into account, it does not support the picture that there was any widespread or significant misuse of oxytocin API by licensed manufacturers; the facts and figures relating to enforcement quoted were the same cited earlier. It was argued, further that the attempt to *statistically* link excess production of the pharmaceutical, by deducing that given the bulk drug supplied, if a 30% production loss were factored, less final products would be manufactured, is inherently flawed. It is submitted that without concrete cases of seizures or cancellation of licenses, the inferences drawn to

justify the impugned notification is dangerous, because it ignores efficiencies in production and is premised on a flawed assumption that with 2 kg API annually supplied to licensees, somehow more than the capacity available, can be achieved, in drug production.

21. The Central Government had filed a brief affidavit on 23.08.2018, resisting all these writ proceedings and contending that the misuse of Oxytocin in the dairy sector, was serious and required appropriate response which was the basis for the impugned measure. It was highlighted that the sole public sector unit – Karnataka Antibiotics Limited (KAPL) has the capacity to produce 1.8 lakhs ampoules per day with an output of 1.7 lakh ampoules. This, it is submitted, would adequately cover the national requirement of approximately 1.6 lakh ampoules per day given the birth rate of 7.8 lakhs per annum. It was submitted that KAPL has Pan-India presence with 20 branches, over 700 distributors who cover all 29 States and UTs. Later, on 19.09.2018, the Union of India filed a comprehensive and detailed affidavit. It states that misuse of Oxytocin had been engaging the attention of the various stakeholders since 1997. It submits that widespread misuse of Oxytocin impelled the HP High Court by its judgment of 15.03.2016, to issue directions for regulation of manufacture, distribution and sale of the drug and consider feasibility of manufacturing, only to public sector units. It is submitted that Oxytocin has two primary uses, i.e. preventing uterus bleeding during child birth and stimulating of milk secretion. It is submitted that Oxytocin has proved to be a potent artificial hormone used for labour pain in human beings; it induces active labour; increases force of contraction in labour as well as stimulates milk secretion. Realising that Oxytocin has potential use for milk secretion, certain unscrupulous elements have – in the past indulged in its widespread misuse illegally, in the dairy sector.

22. It is submitted that the first misuse of Oxytocin was noticed in the 31st meeting of the DCC (21/22.08.1997) for veterinary purposes; the body recommended raising of more information. Likewise, in the 36$^{th}$ meeting (dated

23/24.06.2005) of the DCC, misuse of Oxytocin in the veterinary sector was discussed and it was gone into in the 40th meeting. This meeting acknowledged that the drug was manufactured in a clandestine manner and used by the dairy owners in the veterinary sector. At the same time, the DCC also observed that Oxytocin has defined place in the medical treatment. Likewise, several meetings – the 43rd meeting (dated 14.11.2011); 44th meeting (dated 20.07.2012); 46th meeting (dated 12-13.11.2013), all flagged concerns with respect to misuse of Oxytocin in the veterinary and dairy sector. In fact, the last 46th meeting recommended that manufacturers of the bulk drug Oxytocin should supply the API only to licensed manufactures of Oxytocin and that injections should be banned for veterinary use. Similarly, the DCC minutes of meeting of the 49th and 50th meeting (on 16.10.2015 and 04/05.11.2016 respectively) discussed the issue of veterinary misuse of the Oxytocin. Likewise, the fact that DCC was apprised of misuse of Oxytocin and its recommendation to keep strong vigil, in the 50th meeting was relied upon. Lastly, the minutes of meeting of the 53rd and 54th meeting (dated 18.09.2017 and 09.04.2018) were relied upon. The Central Government also relied upon the minutes of the DTAB meeting, i.e. 64th, 65th, 67th, 69th, 70th, 78th and 80th meetings in support of the arguments that widespread and misuse of Oxytocin which was noticed and effective measures were insisted upon.

23. It is urged by the learned Solicitor General (SG) Mr. Tushar Mehta and the Additional Solicitor General (ASG) Ms. Maninder Acharya, that the recommendations of the minutes of DCC and the DTAB were taken into account by the Central Government at the time when the impugned notification was issued. They also highlight that the Drugs and Cosmetics Rules, 1945 ("Drug Rules") was amended on 03.04.2001.These state that Oxytocin injection had to be packed in a single unit blister pack to avoid its bulk sale. The learned ASG highlighted that on 17.01.2014, acting upon the recommendations of the DCC, a notification was issued, amending the rules, restricting the sale of bulk Oxytocin to only

manufacturers licensed by law and further completely restricting the sale of the drug for veterinary use to veterinary hospitals. It is submitted that this notification – of 17.01.2014 was challenged before the Punjab and Haryana High Court in *Narang Medical Store v. Union of India* [ W.P. (C) 7135/2014]; by judgment dated 28.01.2016, the restriction was upheld and the ban on sale by anyone other than veterinary hospital was held to be legal. It is submitted that hence restrictions that can be prescribed cannot be in any manner artificially curtailed by literal interpretation.

24. The SG and ASG also submitted that an inter-Ministerial Committee under the chairmanship of DGHS was held on 25.09.2014 to consider the issue of regulating Oxytocin drug in the country. Pursuant to this, a letter was issued on 22.10.2014, to consider for strict control over manufacture, distribution and sale of the product to curb misuse. Likewise, reminders were issued on 04.12.2014 and 18.02.2015 in this regard. The letter dated 15.04.2015 by the Drug Controller General to all State Drug Controllers to curb misuse of Oxytocin by dairy owners for milk production was relied on. It is submitted that a surprise raid was conducted on 16.10.2014 by the officers of North Zone of the Drugs Control Department of Delhi. The other letters emphasized the need to keep strong watch and vigil over model practices was brought to the notice of the Court. The Central Government in its affidavit relies upon the judgment of the Himachal Pradesh High Court, particularly, the direction issued to it *"to consider the feasibility of restricting the manufacture of Oxytocin only to public sector company"*. The Central Government then outlined its decision as follows: *" Answering respondent made its endeavour to comply with the various directions as passed by the Hon'ble Court in the judgment. The Answering Respondent also apprised other Ministries to comply with the directions as ordered by the High Court. The Answering Respondent also took various steps relating to Ministry of Health and Family Welfare in so far as to comply with the Hon'ble Court."*

25. It is stated that between 29th and 30.08.2018, data was collected from all manufacturers of Oxytocin as also from API manufacturers by deputing drug inspectors. It is submitted by learned the SG that a notification, under Section 26Ais pursuant to exercise of power that is legislative in character. He relied upon the order of the Supreme Court in *UOI v. Cynamide India Pvt. Ltd* 1987 (2) SCC 720; *E Merck (India) Limited v. UOI* 2001 (90) DLT 16; *Macleods Pharmaceuticals Limited v. UOI* 2012 SCC online Mad 1735 and *Franklin Laboratories India v. Drugs Controller (India) Limited* AIR 1993 P&H 107.

25. It was contended that the jurisdiction to exercise power under Section 26A by the Central Government, to issue the impugned notification is justified and valid. In this regard, the observations in *Pfizer (supra)* was relied upon. It is stated that sufficient material under Section 26A existed by way of abundant material, collected over a period of time of several years. Particularly, learned SG relied upon the following observations in *Pfizer (supra)*:

> *"16.…It is clear that the additional power that is given to the Central Government under Section 26A does not refer to and, therefore, mandate any previous consultation with the DTAB. On the contrary, the Central Government may be "satisfied" on any relevant material that a drug is likely to involve any risk to human beings etc. as a result of which it is necessary in public interest to regulate, restrict or prohibit manufacture, sale or distribution thereof. So long as the Central Government's satisfaction can be said to be based on relevant material, it is not possible to say that not having consulted the DTAB, the power exercised under the said Section would be non-est. Take the case of an FDC that is banned in 50 countries of the world owing to the fact that the said FDC involved significant risk to human beings. Assuming that the Central Government is satisfied based on this fact alone, which in turn is based on expert committee reports in various nations which pointed out the deleterious effects of the said drug, can it be said that without consulting the DTAB set up under Section 5, the exercise of the power under Section 26A to prohibit the manufacture or sale or distribution of a drug that is banned in 50 countries would be bad only because the DTAB has not been consulted? The obvious answer*

*is no inasmuch as the Central Government's satisfaction is based upon relevant material, namely, the fact that 50 nations have banned the aforesaid drug, which in turn is based on expert committee reports taken in each of those nations. Take another example. Suppose the Central Government were to ban an FDC on the ground that, in the recent past, it has been apprised of the fact that the FDCs taken over a short period of time would lead to loss of life, which has come to the notice of the Central Government through reports from various district authorities, in let us say, a majority of districts in which the said FDC has been consumed. Could not the Central Government then base its ban order on material collected from district authorities which state that this particular drug leads to human mortality and ought, therefore, to be prohibited? The obvious answer again is yes for the reason that the Central Government has been satisfied on relevant material that it is necessary in public interest to ban such drug. Examples of this nature can be multiplied to show that the width of the power granted under Section 26A cannot be cut down by artificially cutting down the language of Section 26A ……."*

26. The SG relied upon the observations of the Supreme Court in *Akadasi Pradhan v. State of Orissa and Ors.* AIR 1963 SC 1047 and submitted that by virtue of Article 19(6), any law, and in this case, the subordinate legislation, through the impugned notification, (which falls within the description of law) creating State monopoly, should be presumed to be in the interest of general public. The observations that there are no limits on the power of the State with regard to creation of State monopoly emphasizing the width of such powers were relied upon. It is submitted that the decisions of the Supreme Court with respect to the presumption of public interest in the case of any law or measure which creates a public monopoly was reiterated in several other decisions such as *Orient Paper Industries Pvt. Ltd. v. State of Orissa* 1991 (1) SCC Suppl.81; *State of Tamil Nadu v. L. Abu Kavur Bai and Ors.* 1984 (1) SCC 516; *Tinsukhia Electric Supply Co. Ltd. v. State of Assam and Ors.* 1989 (3) SCC 709 and *Uday Singh Dagar and Ors. v. UOI and Ors.* 2007 (10) SCC 306.

27. The learned ASG submitted that in regard to issues and matters, including complex assumptions that even otherwise in regard to decisions that concern issues affecting the public at large, especially public health, the Courts have declined to interfere in judicial review. In support, learned ASG relied upon the *Directorate of Film Festivals v. Gaurav Ashwin Jain and Ors.* 2007 (4) SCC 737; *Systopic Laboratories Pvt. Ltd. v. Dr.Prem Gupta* 1994 Suppl (1) SCC 160 and *Macleods Pharmaceuticals Limited v. UOI* 2012 SCC online Mad 1735.

28. It is also urged by the ASG that between 29th and 31st August, 2018, data was collected from all the licensed manufacturers of Oxytocin formulation and also from the API manufacturer (M/s Haemmo Pharma) by deputing Drug Inspectors. Based on the collected data, analysis was made to match the quantity of oxytocin formulation produced with the quantity of API procured, most of the cases, discrepancies were observed. The details of the statistics collected and analyzed were relied on to say that the Central Government was justified in issuing the impugned notification. It is further submitted that the Trafficking of Persons (Prevention, Protection and Rehabilitation) Bill, 2018 stipulates and recognizes the rampant and systemic abuse of the chemical substances by administering them on a person for the purposes of early sexual maturity. The ASG referred to Clause 31 of Bill, to say that this is additional justification for the impugned notification and creation of monopoly in favour of a State enterprise, which would then eliminate the possibility of any misuse. The notes for Clause 31 reads as follows:

> *"Clause 31 of the Bill seeks to provide for the offence of aggravated forms of trafficking, such as trafficking for the purpose of forced labour or bonded labour by using violence, intimidation, inducement, promise of payment of money, deception or coercion or by subtle means including, allegations of accumulated debt by the person, retention of any identity paper, threats of denunciation to authorities, or for the purpose of bearing child, either naturally or through assisted reproductive techniques, or by administering any narcotic drug or psychotropic substance or alcohol on a person for the purpose of trafficking or forcing him to remain in exploitative*

*condition, by administering any chemical substance or hormones on a person for the purpose of early sexual maturity, or for the purpose of marriage or under the pretext of marriage trafficks a woman or child after marriage, or by causing serious injury resulting in grievous hurt or death of any person, including death as a result of suicide as a consequence of trafficking of person, or who is a pregnant woman or the offence results in pregnancy of the person, or by causing or exposing the person to a life threatening illness including acquired immune-deficiency syndrome or human immunodeficiency virus, or for the purpose of begging, or who is a mentally ill person as defined in clause (I) of section 2 of the Mental Health Act, 1987 or a person with disability as defined in clause(s) of section 2 of the Rights of Persons with Disabilities Act, 2016, or as a consequence of trafficking, the person becomes mentally ill or disabled, or by encouraging or abetting any person to migrate illegally into India or Indians in to some other country."*

29. It was submitted that the statistic and data collected shows that 6 seizures were made between 2015-16 and 2017-July 2018 in Andhra Pradesh; 12 cases were instituted for Oxytocin injection misuse in the dairy sector and vegetables, for violation of the Drugs and Cosmetics Act and Rules, resulting in 12 FIRs, in the State of Bihar. This included seizures of drugs worth ₹ 35 lakhs, resulting in two arrests, 3 prosecutions and cancellation of two licenses. The detailed chart in respect of Telangana, relied on by the respondents, is extracted below:

| *S.No* | *Date* | *Name of firm* | *Seized quantity of Oxytocin* | *Remarks* |
|---|---|---|---|---|
| *1.* | *30-8-2014* | *Tawakkal Medical & Gen Stores, Telengana* | *170x100 ml vials* | *Complaint was filed against accused in court; case pending* |
| *2.* | *2-9-2015* | *Rahul Kumar Mukhta, Hyderabad* | *410x100 ml vials* | *Complaint was filed against accused in court; case* |

| | | | | |
|---|---|---|---|---|
| | | | | *pending* |
| *3.* | *12-9-2014* | *Banwarilal Bansal and Suresh Kumar Gupta, Hyderabad* | *300x100 ml vials* | *Complaint was filed against accused in court; case pending* |
| *4.* | *12-9-2014* | *Dharanand Agarwal and Sub hash Agarwal, Hyderabad* | *351x100 ml vials* | *Complaint was filed against accused in court; case pending* |
| *5.* | *25-9-2014* | *Chittibonia Damodar* | *47x100 ml* | *Complaint was filed against accused in court; case pending* |
| *6.* | *28-8-2014* | *Appanapalli Anjaiah and M/s Shanta Pharma* | *50x100 ml* | *Complaint was filed against accused in court; case pending* |
| *7.* | *31-8-2015* | *Sanjeevini Medicals* | *23x60 ml* | *Under investigation* |
| *8.* | *1-3-2015* | *Mohd. Arif* | *130x60 ml* | *Under investigation* |
| *9.* | *5-3-2015* | *Lachu Rai* | *400x60 ml* | *Under investigation* |
| *10.* | *5-3-2015* | *Mohd. Khaled* | *300x60 ml* | *Under investigation* |
| *11.* | *5-3-2015* | *Mukesh Agarwal* | *200x60 ml* | *Under investigation* |
| *12.* | *10-7-2018* | *B. Suresh Kumar Gupta* | *230x200 ml* | *Illegal sale and stocking; value of stock was Rs. 2300/- ; it was seized and kept in safe custody.* |
| *13.* | *10.07.2018* | *Mr. Abdul Khaled* | *400 x 200 ml 600 x180 ml* | *Illegal manufacturing* |

| | | | | |
|---|---|---|---|---|
| | | | *and 200 x 140 ml* | *and sale. Value of seized property is Rs.1,20, 000/-; it was deposited in court for safe custody. Investigation is under progress.* |

30. The ASG relied on data showing that in Karnataka, during the period 2012-2018 one seizure of 293x100 ml in the residence of one individual took place, which has resulted in an FIR and further investigation; no reported case was discerned in Madhya Pradesh; in Rajasthan, 73 plastic bottles were seized in Jaipur and 264 bottles of Oxytocin, injection as well as 76 bottles in Jodhpur and 17 bottles of Oxytocin were found in M/s Manish Provision store; in Tamil Nadu, 4 cases were initiated against animal feed traders for stocking and sale of Oxytocin contrary to provisions of the Drugs Act. It was submitted that in UP, 11 FIRs were lodged against misuse of Oxytocin injections. In Delhi, in the last 3 years; a case where two accused were apprehended on 22nd September, 2015 in the Railway Station and complaint registered against them, is mentioned. In Jharkhand, 9 FIRs and prosecutions were launched in the last 3 years. It is submitted that on two days in June, 2018, raids were conducted in Bihar of 35 facilities, were irregularities were detected in 11 units; this accounted for seizure of 2,58,750 Ampoules for non-compliance with requirement of the schedule to the Drugs Rules.

31. The ASG submitted that given these materials and the fact that the data gathered by the enforcement wing of the authorities, i.e. the Drug Controller of India, only are like the tip of the iceberg, indicating samples of the larger malaise reinforcing the Union's decision based on objective materials, that the existing

*status quo* with regard to domestic manufacture and sale of Oxytocin was responsible for its serious misuse in the dairy sector as well as potential use in the offense of human trafficking, speeding sexual maturity of young girls, the public interest in the impugned measure is undeniable. It was also submitted that whether the material on the record is adequate or otherwise cannot be a subject matter of judicial review; as long as there is material to justify an executive decision, the courts cannot justly conclude that there was no material, or that extraneous material were taken into account.

*The impugned notification, relevant provisions of law and statutory committee reports*

32. The impugned notification in this case, reads as follows:

> *"G.S.R. 411(E).—Whereas the Hon'ble High Court of Himachal Pradesh, Shimla, has, in its judgment dated 15.3.2016 in CWPIL No. 16 of 2014 titled 'Court on its own motion' versus State of Himachal Pradesh and others, observed that there is large scale clandestine manufacture and sale of the drug Oxytocin leading to its grave misuse, which is harmful to animals and humans;*
>
> *And whereas, the said Hon'ble High Court also observed that 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 should be considered;*
>
> *And whereas, the Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) considered the said issue in its meeting held on the 12th February 2048 and recommended that Oxytocin formulations for human use be regulated and restricted to be supplied only to registered hospitals and clinics in public and private sector to prevent misuse of the said drug;*
>
> *And whereas, the Central Government, on the basis of the recommendations of the said Board and after examination of the matter, is satisfied that unregulated and illegal use of the drug Oxytocin is likely to involve risk to human beings or animals and that in the public interest it is necessary and expedient to regulate and restrict the manufacture, sale and distribution of the drug Oxytocin in the country to prevent its misuse by unauthorised persons or otherwise;*

*Now, therefore, in exercise of the powers conferred by section 26A of the said Act, and in supersession of the notification number G.S.R. 29(E) dated 17th January, 2014, the Central Government hereby directs that the drug Oxytocin shall be manufactured for sale or for distribution or sold in the manner specified below, namely:-*

*(i) The manufacture of Oxytocin formulations for domestic use shall be by public sector undertakings or companies only and the label of the product shall bear barcodes.*

*(ii) The manufacture of Oxytocin formulations for export purposes shall be open to both public and private sector companies and the packs of such manufacture for exports shall bear barcodes.*

*(iii) The- manufacturers of active pharmaceutical ingredient of Oxytocin shall supply the active pharmaceutical ingredient only to the public sector manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug for domestic use.*

*(iv) The manufacturers of active pharmaceutical ingredient of Oxytocin shall supply the said active pharmaceutical ingredient to the manufacturers in public and private sector licensed under the Drugs and Cosmetics Rules, 1945for manufacture of formulations of the said drug for export purpose.*

*(v) The Oxytocin formulations manufactured by the public sector companies or undertakings licensed under the Drugs and Cosmetics Rules, 1945 for domestic use shall supply the formulations meant for human and veterinary use only-*

*(a) to the registered hospitals and clinics in public and private sector directly; or*

*(b) to the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and Affordable Medicines and Reliable Implants for Treatment (AMRIT) outlets or any other Government entity which may be specified by the Central Government for this purpose in the country which shall further supply the drug to the registered hospitals and clinics in public and private sector.*

*(vi) The Oxytocin in any form or name shall not be allowed to be sold through retail Chemist.*

*2. This notification shall come into force on the first day of July 2018."*

34. Section 26A of the Drugs Act reads as follows:

*"26A 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."*

35. Since both parties referred to reports of the DCC and DTAB, it would be useful to notice them. The minutes of the 44th meeting *inter alia,* read as follows:

*"The drug oxytocin has medical use for induction and augmentation of labour, to control post partum bleeding and uterine hypo tonicity and is included under Schedule H. The oxytocin injection is required to be packed in single unit blister pack only for sale and is required to be dispensed on the prescription of a Registered Medical Practitioner only. The reports of manufacture and sale of the drug in clandestine way in large quantities and its misuse by the farmers or dairy owners is a matter of great concern and is required to be checked on priority basis. The office DCG(I) had earlier written to the State Drugs Controllers to check and unearth the clandestine manufacture and sale of drug to the farmers or dairy owners in violation of the provision of the Drug and Cosmetic Rules through surveillance and raids conducted on the possible hide outs where such activities are being undertaken.*

*The manufacture and sale of the drug with or without a licence for such clandestine activity is an offence under the Drugs and Cosmetics Act, and the violators are required to be handled with a heavy hand. The amended penal provisions of the Drugs and Cosmetics Act, 1940 make such offences cognizable and non-bailable. This clandestine activity of manufacture and sale of the drug to the farmers or dairy owner require constant surveillance and interstate coordination. The intelligence inputs should be passed on to the concerned State Regulatory Authorities for taking timely action. Deterrent and determined steps in this direction will help in minimizing the use of the drug for purposes other than for which it is*

*permitted to be marketed. Handouts and publicity in the print or electronic media about the hazards of the use of the drug by the farmers or cattle owners can go a long way in educating the public and curbing the misuse of the drug.*

*Recommendations*

*The members felt that the misuse of oxytocin is rampant in many of the States and reports of its clandestine manufacture and sale appear now and then in the press. The Drug is available as unlabelled or wrongly labeled packs. Many of the States like UP, Delhi have taken action in seizures of stocks on the basis of intelligence gathered. As the manufacture and sale of these products is through clandestine channels, it becomes difficult to stop their misuse except through continuous surveillance. After deliberations it was opined that as the bulk drug (oxytocin) is being manufactured in a few States only, the diversion of the bulk drug to the illegal channels could be curtailed to a large extent if it is ensured that the bulk drug is sold to the licensed manufacturer only."*

36. The minutes of the 45th Minutes of meeting (of the DCC) dated 4/5th February 2013 took note of the letter by Smt. Maneka Gandhi, (then MP, Lok Sabha) to the Secretary, MHFW about continued Oxytocin injection misuse by dairy owners for milk production and its harmful effects on the health of cows and buffaloes as well as on the consumers. The letter stated that though the drug is an essential drug in medical practice for certain conditions in human as well as veterinary use, the alleged abundant availability and use of the drug, in a clandestine way is a matter of great concern for public health. In the light of the deliberations, the following recommendation was recorded:

*"The members felt that the illicit manufacture of oxytocin injection for the use of extracting milk from milch animals by the dairy owners is a clandestine activity. The manufacture of the drug for dairy owners etc takes places in the regions where drug control administration is lax and then the drug is transported to other States clandestinely. It is available in unlabelled or wrongly labeled packs.*

*Even though many of the State have taken action on the basis of intelligence gathered through surveillance. However, strong measures are required to restrict the supply of oxytocin injection for veterinary use and also ensured that diversion of the bulk drug to illegal channels is curtailed.*
*The DCC after deliberations recommended that the manufacture and sale of the oxytocin injections should be banned for veterinary use under section 26A of the Drugs and Cosmetics Act, 1940 along with the condition that the manufacturers of bulk drug oxytocin should supply the active pharmaceutical drug only to the manufacturers licensed for manufacture of Oxytocin formulation for human use."*

37. Likewise, the 46th DCC meeting (dated 12.11.2013) recommended that:

*"The members felt that the illicit manufacture of oxytocin injection for the use of extracting milk from milch animals by the dairy owners is a clandestine activity. The manufacture of the drug for dairy owners etc takes places in the regions where drug control administration is lax and then the drug is transported to other States clandestinely. It is available inun-labelled or wrongly labeled packs. Even though many of the State have taken action on the basis of intelligence gathered through surveillance. However, strong measures are required to restrict the supply of oxytocin injection for veterinary use and also ensured that diversion of the bulk drug to illegal channels is curtailed.*
*The DCC after deliberations recommended that the manufacture and sale of the Oxytocin injections should be banned for veterinary use under section 26A of the Drugs, and Cosmetics Act, 1940 along with the condition that the manufacturers of bulk drug, oxytocin should/supply the active pharmaceutical drug only to the manufacturers licensed for manufacture of Oxytocin formulation for human use."*

38. The 65th meeting of the DTAB (dated 25.11.2013) considered the use and misuse of Oxytocin; it recommended *inter alia* that:

*"The DTAB after deliberations agreed that as the drug has a definite use for therapeutic purposes it need not to be prohibited. It however, agreed to the suggestion that the manufacturers of bulk*

*drug should supply active pharmaceutical drug only to the manufacturers licensed for manufacture of formulations and the formulations meant for veterinary use are sold to the veterinary hospitals only.*

*It was further recommended that the State Drugs Controllers may be asked to curb the misuse of the drug through increased surveillance and raids conducted on the possible hideouts of clandestine manufacture and sale of this drug and take strict action against the offenders."*

39. Pursuant to these recommendations, a statutory notification was issued on 17th January, 2014 placing restrictions on the sale of Oxytocin and stating that:

*"manufacturers of bulk oxytocin drug shall supply the active pharmaceutical drug only to the manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug"*
and further-more that

*"The formulations meant for veterinary use be sold to the veterinary hospitals only."*

40. This meant that the API could be supplied <u>*only to licensed manufacturers.*</u> Furthermore, it also required sale of veterinary use pharmaceuticals only to veterinary hospitals.

41. The 67th meeting of the DTAB (dated 1st April, 2014) took note of the letter of Ms. Maneka Gandhi (then Hon'ble Member of Parliament) highlighting concerns of Oxytocin misuse and requiring effective measures. The Secretary to the Union Government desired action, in the light of the letter. The DTAB resolved, on the issue, *inter alia*, as follows:

*"So far as the manufacture and sale of the drug through illegal channels is concerned, it cannot be simply stopped by banning the drug as the bulk drug is liable to be smuggled from the neighbouring countries for illegal use. Misuse can only be contained by enhanced surveillance by the regulatory authorities followed by strict action against the violators. The public at large is also required to be*

*sensitized. Campaigns could be launched by the public spirited organizations in the areas prone to such misuse through print and audio visual media to educate the public about the harmful effects of misuse of Oxytocin. The help of the local police could also be enlisted to book cases under Prevention of Cruelty to Animals Act, 1960, the Drugs and Cosmetics Act, 1940 does not permit the sale of the drug except under proper prescription.*

*The committee after deliberations recommended that in order to curb the illegitimate sale by the chemists, a new clause may be added to the already issued notification stating that the supply of the oxytocin shall be recorded by the retail chemist at the time of supply giving the name and address of the prescriber, the name of the patient and the quantity supplied. Such records shall be maintained for three years and be open for inspection. This would help in not only maintaining the legitimate supply of the drug but also to curb misuse of the drug through the legitimate sale channels."*

42. The 49th Meeting of the DCC (on 16th October 2015) was attended by the Hon'ble Minister of Women and Child Development, who mentioned that Oxytocin was misused in the dairy sector and it had long term adverse effect on cattle health and life; she also highlighted the channels of misuse:

*"....24. She stated that even though oxytocin is well regulated, under the provisions of the Drugs and Cosmetics Rules, 1945, it is being illegally manufactured and clandestinely sold to the dairy owners. She highlighted that the bulk drug in the country is being manufactured by only one manufacturer i.e. Hemmo pharma, Mumbai but the formulations are manufactured, by largenumber of manufacturers with or without valid licence. Because of large, demand in the country, the bulk drug is also imported clandestinely into the country.*

*25. Oxytocin is also being imported clandestinely from China and a Company under the name of Xio Qiang Changzhou, China is sending it as Custom Peptide to many individuals. As the product is not considered a drug, no license/permission is required for its import. It is supplied through courier agencies such as Fedex.*

*26. The drug is smuggled into the country at a much cheaper rate and is then filled crudely in plastic bottles which may or may not have labels. The labels even, if these are there, are fake labels. The*

*major areas where such material enter into India are Bihar and West Bengal across the borders. Reports are there that other channels are also used for smuggling of bulk oxytocin into the country.*

*27. The Hon'ble Minister informed the regulatory authorities that this clandestine manufacture and sale can only be curbed by continuous surveillance and raids at the hideouts and sales outlets from where it is sold clandestinely. Repeated raids will act as a deterrent to stop this activity."*

43. The DCC noted the DTAB's 70th meeting (dated 18.08.2015) had commented that the high cost of Oxytocin manufactured in accordance with the law could not be used by the dairy sector and that misuse was because of clandestine manufacture and import. The DCC, in its meeting, therefore, recommended strong enforcement measures:

*"Discussions and Recommendations*

*(i) During deliberations, it was noticed that Telengana, Delhi, Rajasthan, Gujarat and Andhra Pradesh have been able to seize stocks of clandestinely manufactured oxytocin in their States. The investigations revealed that major places from where clandestine manufacture has been reported are Gaya and Barauni in Bihar and 26 Parganas in West Bengal. The bulk drug illegally enters into India via West Bengal from the porous borders of Bangladesh, through boats or other such illegal channels.*

*(ii) the States must provide information in respect of manufacturers of oxytocin formulations licenced in their State to the DCG (I) office at the earliest so that concerted efforts are made to monitor the manufacture and sale of the drug in the country.*

*(iii) Director, Central Drugs Laboratory, Kolkata was requested to develop rapid test for detection of oxytocin as the drug is filled in unlabeled plastic bottles and transported through rail or other ordinary mode of transport. For this purpose, the services of the scientists or Universities could be undertaken. This will help in detection of clandestine consignments, which otherwise do not come under the ambit of the Drugs & Cosmetics Act.*

*(iv) States however, lamented that even though investigations are done, by, the drug regulatory officials, police do not actively cooperate and is reluctant in registering FIR or apprehending the*

*culprits. The investigations, in respect, of channels of supply come to a dead end. The Central Govt. may instruct the State Police Deptt. to take due notice of offences relating to misuse of oxytocin:*
*(v) It was also suggested that FSSAI which controls production of milk may be asked to find ways and means to make use of oxytocin for production of milk as an offence under their Act as milk is regulated under the FSSAI Act.*
*(vi) In nutshell, following recommendations were made to, fight the misuse of oxytocin in the country:*
- *State Drug Regulatory officials must conduct raids with the assistance of Police Authorities at the suspected outlets of such drugs near the dairy farms after due surveillance to apprehend culprits red handed.*
- *The manufacture and sale of oxytocin. formulations by the licenced manufacturers in the State should be monitored regularly.*
- *States should share information about the raids conducted and results of investigations with other concerned State Drug Control Authorities and Zonal offices for interstate coordination.*
- *Samples of milk may be drawn to assess the presence of oxytocin in milk.*
- *Rapid test for detection of oxytocin may be developed.*
- *The Port offices of CDSCO shall inform custom authorities that import all peptide formulations be monitored for their use.*
- *The Central Government may request Police authorities of States to take cognizance of offences related to misuse of oxytocin.*
- *FSSAI may be asked to explore the possibility of declaring the use of Oxytocin on animals for production of milk as an offence under the FSSAI Act.*
- *Each State and Central regulatory system must develop an intelligence wing for keeping close watch, sharing of information and prompt action for checking/eradicating the misuse of Oxytocin in the country."*

44. The 69th meeting of the DCC (held on 22.05.2015), likewise was of the opinion that prohibition of Oxytocin manufacture was not needed and that stringent enforcement of the laws was necessary. The Minutes of meeting were recorded; the relevant extract thereof reads as follows:

*"The members felt that the problem of misuse of oxytocin is more related to stricter control over the manufacture and sale of the drug especially through clandestine channels. The dairy owners get the drug manufactured at dubious premises from unscrupulous suppliers. The members noted that the raid conducted at Ghazipur Dairy in Delhi by the officer of the North Zone of CDSCG have revealed that the drug was clandestinely manufactured and packed in plastic bottles and not as per provisions of the Drugs and Cosmetics Rules. Constant surveillance by the State Drug Regulatory Authorities and other such regulatory agencies can only, curb the misuse of the drug. The dairy owners are needed to be educated by the Department of animal, husbandry about the harmful effects of the use of oxytocin for milking the milch animals.*

*The members after deliberations recommended that the issue requires detailed examination with more experts from outside- before we can give any decision. The matter was therefore deferred for next DTAB meeting."*

45. The minutes of the 70th meeting of the DTAB (held on 18th August 2015) are significant; in the light of the previous (69th meeting of the DTAB) experts from the animal husbandry and food sector – including statutory technical authorities were invited to attend and give their opinions. After considering their views, the DTAB resolved as follows:

*"The Chairman briefed the members that the issue of continued misuse of oxytocin injections by the dairy owners for extracting milk from milch animals and its harmful effects on the health of cows and buffaloes was deliberated by the DTAB from time to time. In the 69th meeting held on 22.04.2015 DTAB reiterated its earlier recommendations that the drug need not be prohibiting (sic prohibited) as it has definite, use for therapeutic, purposes. The problem of misuse of oxytocin is more related to stricter control over the manufacture and sale of the drug especially through clandestine channels. The dairy owners get the drug manufactured at dubious premises from unscrupulous suppliers. Constant surveillance by the State Drug Regulatory Authorities and other such regulatory agencies can only curb the misuse of the drug. It was however, further decided that the issue may be further examine with experts from, outside especially related to the Animal Husbandry for recommendations.*

*Accordingly, Dr. B. S. Prakash, Assistant Director General (ANP), Ministry of Agriculture, Krishi Bhawan, New Delhi, Dr. Ajay Kumar Dang, Principal Scientist, Dairy Cattle Physiology Division, NDRl, Kamal, Haryana and 3. Dr. Mihiar Sarkar, Principal Scientist, Division of Physiology &Climatology, IVRI, Izatnagar were invited to the meeting. Dr. Mihiar Sarkar however, could not attend the meeting because of his pre-occupation.*

*Shri. O.S. Sadhwani, Joint Commissioner, FDA. Maharashtra stated that the drug manufactured in accordance to the Drugs and Cosmetics Rules, 1945 has high costs and Is not used by milkmen for extracting milk from the cows. The raw material or the bulk drug is clandestinely smuggled into the country from the border States which is than crudely manufactured clandestinely and sold to dairy owners at very cheap rate. It only needs sustained efforts through constant surveillance to curb the menace.*

*Dr. B. S. Prakash informed that extensive work has been done on the use of oxytocin in milch animals and a Status Report of ICMR -ICAR Technical, Working Group was compiled by him on the extent of use of oxytocin in milch animals. As per European agency for evaluation of medicinal products, there are no, data on mutagenicity, carcinogenicity and teratogenicity Oxytocin is inactivated by the reduction of disulfide chain in the kidney, liver and lactating mammary gland. The drug oxytocin is used by medical practitioner's world over for medical purposes and has a place in veterinary medicine.*

*Some members pointed out that the cheap crude drug used for clandestine manufacture might belong to some surreptitiously smuggled material from the neighboring countries.*

*After deliberations the members agreed that the drug legitimately manufactured in the country is required for medical purposes and as such cannot be, prohibited. The misuse of the drug in a crude form, can only be curbed through constant surveillance by the Regulatory authorities."*

46. The minutes of the 78th meeting of the DTAB (dated 12th February 2018) interestingly saw the body recommend sale of Oxytocin to hospitals in the public and private sector. The relevant minutes are as follows:

*"CONSIDERATION OF PROPOSAL TO PROHIBIT IMPORT OF OXYTOCIN UNDER THE DRUGS AND COSMETICS ACT, 1940*

*TO PREVENT MISUSE OF THE DRUG AS ALL BONAFIDE REQUIREMENTS OF OXYTOCIN WOULD BE MET BY INDIGENOUS PRODUCTION*

*The members of DTAB deliberated the matter and agreed to prohibit the import of the Oxytocin and its formulations for human use as well as animal use under section 10A of the Drugs and Cosmetics Act, 1940.*

*ADDITIONAL AGENDA - S2*

*CONSIDERATION OF PROPOSAL TO RESTRICT SUPPLY OF OXYTOCIN FORMULATION FOR HUMAN USE ONLY TO REGISTERED HOSPITALS AND CLINICS IN PUBLIC AND PRIVATE SECTOR TO PREVENT MISUE OF THE DRUG*

*The members deliberated the matter and agreed on a draft notification for regulating, restricting the Oxytocin formulations for human use to be supplied only to registered hospitals and clinics in public and private sector."*

47. It appears that after the decision to prohibit domestic manufacture and supply of Oxytocin except by the public sector was taken, by the Central Government, a Public notice was issued, on 28 February, 2018, eliciting comments. It *inter alia*, reads as follows:

*"8. As the whole issue of Oxytocin is of paramount importance for protection of human and animal health, following proposals are under consideration to curb its misuse.*

*i. To prohibit the import of the Oxytocin and its formulations for human use as well as animal use under section lOA of the Drugs and Cosmetics Act, 1940.*

*ii. To repulate and restrict the Oxytocin formulations for human use under Section 26A of the Drugs and Cosmetics Act, 1940 so that the drug is supplied only to registered hospitals and clinics in public and private sector.*

*iii. To adopt bar-coding system for manufacture of Oxytocin formulations so as to ensure track and traceability of the product to avoid its misuse.*

*iv. Manufacturing of Oxytocin (formulation) shall be restricted in public sector units only.*

*However, above proposals shall not be applicable for Oxytocin meant for export purpose*

*9. All the stakeholders are requested to forward their comments /suggestions on the above proposals through email at dci@nic.in or in hard copies to the O/o DCG(l), CDSCO, FDA Bhawan, Kotla Road, New Delhi- 110002, within 15 days of issue of this notice, so as to consider the matter further."*

*Material placed in the form of files and documents, of the Central Government, by the Department of Health and Family Welfare and the DGCI*

48. The relevant consideration by the Central Government with regard to the Expert bodies views (i.e. DTAB and DTG) were made available to the Court. The notings and minutes of meeting and other relevant documents culminating in the decision to issue the impugned notification also were furnished to the Court. They are briefly discussed hereafter.

49. The notings of the Government in its file (i.e. of the DCI dated 11.12.2013 and of the Ministry (i.e. of the Department H&FW) right up to 17.01.2014, leading to the issue of the notification of 17.01.2014, discuss the question of restricting the manufacture and distribution of the bulk drug Oxytocin only to licensed manufacturers under the law and that veterinary formulation should be sold only to hospitals. Thereafter, the Secretary, Department of Health and Family Welfare forwarded a letter of Ms. Maneka Gandhi (dated 07.02.2014). That letter had requested the Central Government to take steps to *"ensure that the supply of Oxytocin (veterinary or human) is withdrawn from the market except in registered hospitals".* Thereafter, the minutes of the 67$^{th}$ DTAB meeting had been placed on the file. The relevant note highlights the need for effective regulation and also records that the Oxytocin is a prescription drug which can be sold under the prescription of an RMP and has a defined role in medical field for humans and animals and that *"it cannot be simply subject to banning the drug as the bulk drug is liable to be smuggled from the neighbouring countries for illegal use"*.

50. The noting of the DCG – on 21.04.2014 recommended that in amendment to the notification of 17.01.2014 restricting sale of Oxytocin injections by incorporating the additional clause advised by DTAB. Consequently, an order was issued by the Central Government stating that the supply of Oxytocin formulations for human use by retail chemists shall be recorded at the time of supply giving full particulars of the patients and the quantity sold. The Minister of Agriculture on 15.07.2014 requested for consideration of a total ban of the drug as it was causing harm to the cattle population.

51. On 16.07.2014, a multi-disciplinary committee to consider these measures were constituted. The minutes of meeting of that committee – 25.09.2014 interestingly recorded as follows:

> *"8. The Chairman summarized the deliberations as below:*
> *(i) there is no data on the scale of the alleged misuse of oxytocin and it would be necessary to gather more information in this regard to ensure that meaningful action is taken;*
> *(ii) the misuse of oxytocin has to be mentioned by the State Drug Controllers and the Animal Husbandry Departments in the States. He added the existing mechanism is unable to meet the expectations amongst others due to the shortage of Inspectors in several States;*
> *(iii) specific details of the misuse of Oxytocin or any other formulations containing oxytocin could be collected by the Department of Animal Husbandry, Dairy and Fisheries and CDSCO including through the State Drug Controllers and State Animal Husbandry Departments.*
> *(iv) the CDSCO will obtain information from all the States Drug Controllers on the details of the manufacturers of bulk and formulations of oxytocin, statistical information on the seizures conducted, quantity seized along with its value, persons arrested, prosecutions filed, samples taken, reports of sub-standard quality received and any other detail to gauge the scale of misuse"*

52. On 20.10.2014, the Central Government wrote to the Department of Animal Husbandry asking it to follow up action with respect to the decision – to collect data, draw samples etc. In response on 22.10.2014, the Ministry of Animal

Husbandry mentioned in its letter that the misuse of Oxytocin has to be monitored by the State Drug Controller and Animal Husbandry Department in the States and requested that a close liaisoning of all authorities was necessary. It also stated that several representations were received with regard to Oxytocin misuse in the dairy sector. On 22.10.2014, a letter was written to by the DGCI to all States Drug Controller about the need to collect data and take enforcement measures.

53. The file shows that on 07.11.2014, 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"*.

54. Thus, the issue of banning 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*. The notings then go on to record need to see feedback from State level enforcement authorities with respect to data etc.

55. The file then contains an undated, 12 page comprehensive note on the medical use of Oxytocin including that its used to induce labour and to control Post-partum uterine haemorrhage. The note then discusses the past measures taken including (a) the inter-ministerial committee recommendations as well as the Ministry of Women and Child Development view with respect to prohibiting manufacture by private entities (b) the 69$^{th}$ and 70$^{th}$ meeting of the DTAB which highlighted that constant surveillance by State Drug Regulatory Authorities can curb misuse of the drug and that *"the drug need not be proscribed as it as definite*

*use for therapeutic purposes."* This is at Pages 340-362 of the file given to the Court.

56. Again on 15.04.2015 the DGCI addressed a letter to all State Controllers of Drugs; a press release was also issued by the Central Government with respect to the information dated 13.04.2015 that raids were conducted on 15.04.2015 at hideouts by five officers of the North Zone of the Drug Controlling Authority in the Government of NCT of Delhi with regard to Oxytocin misuse by a dairy at Gazipur. The tabular statement of this indicated that 390 bottles of Oxytocin injections (100 ml) manufactured by M/s. Priya Pharmaceuticals and 160 bottles of milk suspected to contain Oxytocin allegedly manufactured by M/s. Durga Chemicals of Gaya were seized. That apart 58 bottles of Oxytocin injections were also seized.

57. The file then contains the report of investigations dated 15.04.2015, with respect to raids and profits, the details of the team that posted the various place followed by a detailed tabular chart (undated) with respect to action taken across the country in the form of seizures. This detailed tabular chart spans the period 2012 to 03.07.2015 and describes 25 instances which accounted for seizure of various quantities of Oxytocin across the country. Out of the 25 inspections/action reports listed in the tabular chart, 10 did not relate to Oxytocin as no ampoule or material was found or seized. In respect of two cases of seizures (both dated 13.05.2015), small quantities *of suspected Oxytocin injections were seized in one case* (relating to Gaya, Bihar); the other seizure was in respect of sealing and filling machine- not Oxytocin. The three year period covered one action from Himachal (254 injections seized); one in Odisha (97 ampoules seized); Tamil Nadu (3 seizures, 53 x 100, 54 x 100 & 126 x 100 ml of unlabelled Oxytocin injections were seized); Jammu ( 1 ml Oxytocin BP was sized); Andhra Pradesh ( 6 seizures resulting in 4 samples and 1 prosecution filled); Jharkhand 12 samples and prosecutions); Madhya Pradesh (2,38,195 Ampoules); Karnataka (7001 ml

ampoules); Delhi (quantities mentioned previously); Chhattisgarh (seized quantity unknown); Jalandhar, Punjab (case of suspected Oxytocin injections 46x100 ml). With regard to the Jharkhand, an investigation report of 2922 ampoules Oxytocin, I.P. 2 ml for human use and 339 for ampoules of Oxytocin Injections veterinary 2 ml were seized from different unlicensed premises and three persons were arrested.

58. The file then contains a letter disclosing the case pending in the HP High Court and also the opinion of the *amicus curiae* that

> *"Oxytocin misuse can be effectively checked and controlled only in one situation i.e., if manufacture of this drug is undertaken only in Public Sector. It can be easily presumed that the unauthorized and illegal inflow of such huge quantity of drug oxytocin in the market proved that the steps, if any, so far taken by the Government, have remained totally in efficient".*

59. The file notings also deals in some details with respect to measures to be taken in respect of a drug manufactured by one M/s. Durga Chemicals, towards enforcement of the Drugs and Cosmetics Act. The Central Government file contains the note of the DCC – approved by the Drug Controller General (DGCI) dated 01.09.2015 stating that there is only one drug bulk manufacturer. The note also states that according to the 40$^{th}$ DCC there is medical use of Oxytocin for induction and augmentation of labour, to control postpartum bleeding and Uterine hypo tonicity. This was repeated in the 65$^{th}$ meeting of the DTAB. The note further stated that the Department of Animal Husbandry, Dairy and Fisheries, Ministry of Agriculture whose opinion was sought, had stated *"in respect of production and use of oxytocin for veterinary use is not recommended. The drug has therapeutic application in case of expulsion of fetus, retention of placenta".*

60. The proposal – ultimately accepted was that the affidavit to be filed in the Court in the HP High Court was only to provide information without indicating the intention to discontinue manufacture of Oxytocin or its manufacture only by Public Sector companies.

61. The Central Government file contains a detailed note running into 8 sub-paragraphs – largely describing the directions containing in the HP High Court judgment (i.e. note dated 19.04.2016). The note then suggests the setting up of a cell to monitor action and also to impart training to the concerned officials. Apparently, pursuant to the judgment of the Court discussions took place between the MHFW and Department of Industrial Policy and Planning (DIPP) –the noting dated 21.07.2016 stated that according to the DIPP to reserve any item for exclusive manufacture in Public Sector Undertaking, amendment in the Notification of 25.07.1991 (issued by DIPP) was necessary and for which prior Cabinet approval was also sought to be required. It was also stated that the administrative Ministry needed to *"justify the same with detailed facts and figures and reasons for not bringing similar commodities under compulsory licensing along with Oxytocin". Therefore, DIPP suggest that this Ministry may consult Department of Pharmaceuticals, being the concerned administrative Ministry in the subject issue".*

62. The Joint Secretary in the Union Ministry (Health and Family Welfare) on 29.12.2016 quoted that the Department could not take any action to reserve exclusive manufacture of Oxytocin by the Public Sector as involvement of other Ministries and clearance by them was necessary. The file then talks about the KAPL and its future plan for it with respect to exclusive manufacture, volume-wise and whether it was producing it as of then or not. This note is dated 15.02.2017. A further note (dated 21.02.2017) proposed that according to the Department of Pharmaceuticals – OM dated 02.02.2017, KAPL could be considered for exclusive manufacture for <u>*veterinary use*</u>.

63. The file noting (BD/VET.CELL/13.2014(Pt.-1), of the Drug Regulation Section of the Department of H&FW contains a detailed note are in para 3(iv) recounts interesting facts i.e. the only PSU i.e. KAPL has competition and that "<u>its viability is uncertain</u>". The note also stated *inter alia* as follows:

*"3(iv) Manufacturing facilities for Oxytocin in the company is non-existent today, and as per Department of Pharmaceuticals, this needs to be created.*
*(v) As per the submission of KAPL, the earliest production of Oxytocin can be possible only after 3 years, that too for bulk (API) production and one more year for manufacturing of formulation of Oxytocin.*
*(v) As per the submission of KAPL, the earliest production of Oxytocin can be possible only after 3 years, that too for bulk (API) production and one more year for manufacturing of formulation of Oxytocin.*
*4. Department of Pharma has also stated that the real issue is not about controlled production, but of the controlled end use of the product. According to them the objective is to control the end use of Oxytocin, so that it is not diverted to non-authorized users by wholesalers and retailers. It is further explained that if this is the objective, the same can be achieved better by bringing an efficient drug regulatory system, scrupulously enforcing the same, monitoring the controlling the sale and use of the product and sensitizing the general public about the ill effects of misuse and abuse of Oxytocin."*

64. The noting dated 18.04.2017 expressed lack of support by the Department of Pharmaceuticals. On 15.05.2017, sanction to place firm orders for exclusive manufacture (by KAPL) for ₹ 7.95 crores were sought. Thenceforth, the notings relate to the figures and manufacture of the private licence manufactures in the country.

65. The file contains an office memorandum of 21.09.2015 indicating that a meeting was to be held in the office of the Principal Secretary to the PM regarding harmful effects of Oxytocin that was accompanied by the detailed 12 page note (described previously). The minutes of that meeting, recorded that dealers of import, export, domestic supplies, raw material furnished by drugs etc had to be reviewed to ensure that drugs was not illegally available to clandestine manufacturers. The series of actions suggested were

a) advisory to send to ports to examine of imports of oxytocin;

b) regulation of crude bulk material (pre-API) for non-medical purposes at all entry points;

c) detailed study by ICMR and ICR in consultation with the Department of Animal Husbandry, Dairy and Fisheries to consider the effect of Oxytocin on milch cattle and its impact on humans;

d) details of international regulatory practices e.g. in EU, USA to curb misuse of Oxytocin;

e) advisory to Department of Animal Husbandry, Dairy and Fisheries in States to educate farmers;

f) review of information collected from local manufacturers about quantity of bulk Oxytocin purchased, formulations manufactured and sold;

g) Inspection of chemists and retailers and issue instructions for strict observance;

h) harmonization of Indian Standards;

i) enhanced surveillance and follow up of clandestine manufacturing/import/sale of oxytocin/sale of oxytocin by unlicensed manufacturers.

66. A meeting of 29.06.2015 was held by the Joint Secretary to the PMO; its participants included Secretaries of Agriculture, Revenue, Animal Husbandry, Pharmaceuticals, MHFW, Director General (Health Services) and the DGCI. The note on the file (No #37) dated 20.09.2017 reads as follows:

> *"DoP vide OM dated 02.05.2017 has further informed that the production of Oxytocin in the public sector was discussed with Managing Director, Karnataka Antibiotics & Pharmaceuticals Limited (KAPL) on 25th April, 2017 in the chambers of Secretary (Pharmaceuticals). In response thereto, the company has furnished details of equipments/instructions requires along with the budgetary cost thereof amounting to Rs.7.95 crores. In this regard, DoP has requested this Ministry to indicate the quantity of Oxytocin required*

*and placed firm orders for Oxytocin manufacture along with necessary sanction of Rs.7.95 crores at the earliest.*

*9. In this regard, an OM dated 01.08.2017 was sent to DoP informing that this Department as of now does not have any budgetary provision/object/head/scheme from which the funds could be released to KAPL. As KAPL comes under the domain of Department of Pharmaceuticals, it would be appropriate, if Department of Pharmaceuticals provides requisite funds so that order of the Court could be implemented. However, in principle, there is no objection to provision of funds to KAPL by this Department and efforts would be made to locate an appropriate object head and obtain the approval of Competent authority for the purpose.*

*10. D/o Pharmaceuticals was further informed that the details of production and sale of Oxytocin (both domestic and export) for the year 2015 to 2016 & 2016 to 2017 received from M/s Hemmo Pharmaceuticals Pvt. Ltd Mumbai has been sent to DoP. The Drugs Controller General (India) has informed that M/s Hemmo Pharmaceuticals is the only Bulk Drug (Active pharmaceuticals Ingredients) manufacturer of oxytocin in India. Till date, no importer has applied for grant of Import License to DCG(I). Therefore, it can be concluded that the domestic sale from M/s Hemmo Pharmaceuticals is the approximate total consumption quantity in India, which is 959 Million International Units for year April 2015 – March 2016; and 1289 Million International Units for year 2016.*

*11. D/o Pharmaceuticals was also requested to ensure that the production of oxytocin by KAPL is initiated at the earliest. Only after the production is initiated, which can meet the legitimate demand will be question of restricting its manufacture to public sector arise, else it may create an unavoidable situation of shortage of oxytocin.*

*12. After not receiving any information from D/o Pharmaceuticals with reference to OM dated 01.08.2017, a reminder dated 04.09.207 has been sent requesting to provide information about updated status regarding initiation of production of oxytocin by KAPL.*

*13. D/o Pharmaceuticals vide OM dated 07.09.2017 has informed that KAPL has already initiated requisite actions for manufacture of Oxytocin. The company has obtained Test Licence from the Drugs Controller, Government of Karnataka for procurement of the raw*

*material, manufactured the prototype batches of the product and is in process of manufacturing development and stability batches. DoP has further informed that it is expected that manufacturing of commercial batches of the drug can be started from May, 2018 onwards".*

67. The minutes of the meeting held on 08.02.2018, which was attended by all the Secretaries of the concerned departments, including Health and Family Welfare, DGCI as well as other officers of the is on the file. This contains the decision that led to the impugned notification. The minutes read as follows:

*"2. A presentation was made by Secretary, D/o Health and Family Welfare (DHoFW) on the subject. The following decisions were taken after detailed deliberations:*

*i) As all bonafide requirements of Oxytocin would be met by indigenous production, all the imports of Oxytocin/API in any name should be banned with immediate effect;*

*ii) DCGI and Department of Revenue (DoR) to step up vigilance mechanism to check smuggling of Oxytocin after the ban, in any form.*

*(iii) In view of the directives of the High Court of Himachal Pradesh, DoHFW and DoP to ensure that production of Oxytocin is started in public sector, as the earliest. Accordingly, the Karnataka Antibiotic & Pharmaceutical Ltd. (KAPL) should complete all the statutory requirements and start manufacturing Oxytocin from April, 2018. DCGI to facilitate the necessary permissions to KAPL in collaboration with Govt. of Karnataka.*

*(iv) Till the time KAPL is able to produce Oxytocin to meet the entire requirement in the country for humans and veterinary purpose, the existing licensed manufacturers of Oxytocin formulation may be allowed to continue with the production. The list of all such licensed manufacturers should be displayed on the website by DCGI.*

*However, all the existing licensed manufacturers of Oxytocin and the KAPL should ensure that the Oxytocin is supplied only to the registered hospitals and clinics in public & private sector and is not made available to any chemist, agency or any individual.*

*v) DCGI to give the data to Oxytocin formulations required for human and veterinary purpose to KAPL.*

*vi) The API for Oxytocin is being manufactured by one indigenous manufacturer. DoP to put up a vigilance mechanism to ensure that the API being manufactured is either sold to KAPL and licensed*

*manufacturers of Oxytocin in the country or is exported. In any case, API should not be made available by the indigenous manufacturer to any other entity or individual in the country.*
*vii) HLL, a PSU under DoHFW to take up the task of working as the distributor of Oxytocin across the country. Further, oxytocin should also be made available through all the PMBJP and AMRIT outlets in the country, for usage by registered hospitals and clinics in public and private sector.*
*viii) DoHFW in collaboration with KAPL, HLL, DoP and DARE to design a comprehensive MIS to track production, distribution and end-use of Oxytocin produced by KAPL and other licensed manufacturers and collate the data with the bonafide requirements/usage for human and veterinary purposes so as to avoid any misuse of Oxytocin produced. JS, DoHFW to lead the process.*
*ix) DARE should immediately issue circular to all agricultural universities to regulate the misuse of Oxytocin.*
*x) DoHFW and DoP to ensure that bar coding practice is adopted in manufacturing of Oxytocin formulation, within three months.*
*x) An intensive education and awareness campaign be undertaken highlighting the adverse effects of misuse off Oxytocin and the punishments for illegal production, distribution or use.*
*xi) DCGI to give the data on Oxytocin formulations required for human and veterinary purpose to KAPL".*

68. It was pursuant to this meeting that a public notice on 28.02.2018 was issued on the proposal to impart manufacture sale and distribution of Oxytocin. Thus, public notice – after setting out the history of Oxytocin licensing; the restriction imposed on 29.07.2014 etc. stated as follows:

*"6. Hon'ble High Court of Himachal Pradesh in its order dated 15.03.2016 in CWPIL No.16 of 2014 has directed to consider the feasibility of restricting the manufacture of Oxytocin only in public sector companies.*
*7. Accordingly, Ministry of Health and Family Welfare has taken up the matter with the Department of Pharmaceuticals for restricting the manufacture of Oxytocin in Karnataka Antibiotics and Pharmaceuticals Limited (KAPL) Bangalore.*

*8. As the whole issue of Oxytocin is of the paramount importance for protection of human and animal health, following proposals are under consideration to curb its misuse.*

*i. To prohibit the import of the Oxytocin and its formulations for human use as well as animal use under Section 10A of the Drugs and Cosmetics Act, 1940.*

*ii. To regulate and restrict the Oxytocin formulations for human use under Section 26A of the Drugs and Cosmetics Act, 1940 so that the drug is supplied only to registered hospital and clinics in public and private sector.*

*iii. To adopt bar-coding system the manufacture of Oxytocin formulations so as to ensure track and tradability of the product to avoid its misuse.*

*iv. Manufacturing of Oxytocin (formulation) shall be restricted in public sector units only.*

*However, above proposals shall not be applicable for Oxytocin meant for export purpose.*

*9. All the stakeholders are requested to forward their comments/suggestions on the above proposals through email at* dci@nic.in *or in hard copies to the O/o DCG(I), CDSCO, FDA Bhawan, Kotla Road, New Delhi-110002 within 15 days of issue of this notice, so as to consider the matter further.*

69. The papers provided to the Court, thereafter, include the minutes of review meeting held under the Chairmanship of the Vice Chairman, NITI Aayog on 11.04.2018 in regard to action points of the decisions taken in the meeting of 08.02.2018. It stated that inclusion binding import of Oxytocin would be issued on 18.04.2018 and that the inclusion would also restrict manufacture of Oxytocin formulations to public sector only from 01.07.2018.

*Points to be decided*

70. From the above discussion, this court is of the opinion that the following questions arose for determination in this batch of writ petitions:

1. Does the impugned notification fall within the scope of Article 19(6) of the Constitution of India?

2. Is the impugned notification *ultra vires* provisions of the Drugs Act?

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

*The impugned notification*

71. The impugned notification (dated 26th April, 2015) *inter alia*, reads as follows:

> *Now, therefore, in exercise of the powers conferred by section 26A of the said Act, and in supersession of the notification number G.S.R. 29(E) dated l?"" January, 2014, the Central Government hereby directs that the drug Oxytocin shall be manufactured for sale or for distribution or sold in the manner specified below, namely:-*
> *(i) The manufacture of Oxytocin formulations for domestic use shall be by public sector undertakings or companies only and the label of the product shall bear barcodes.*
> *(ii) The manufacture of Oxytocin formulations for export purposes shall be open to both public and private sector companies and the packs of such manufacture for exports shall bear barcodes.*
> *(iii) The manufacturers of active pharmaceutical ingredient of Oxytocin shall supply the active pharmaceutical ingredient only to the public sector manufacturers licensed under the Drugs and Cosmetics Rules 1945 for manufacture of formulations of the said drug for domestic use.*
> *(iv) The manufacturers of active pharmaceutical ingredient of Oxytocin shall supply the said active pharmaceutical ingredient to the manufacturers in public and private sector licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug for export purpose.*
> *(v) Oxytocin formulations manufactured by the public sector companies or undertakings licensed under the Drugs and Cosmetics Rules, 1945 for domestic use shall supply the formulations meant for human and veterinary use only,-*
> *(a) to the registered hospitals and clinics in public and private sector directly; or*
> *(b) to the Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP) and Affordable Medicines and Reliable Implants for Treatment (AMRIT) outlets or any other Government entity which may be specified by the Central Government for this purpose in the*

*country which shall further supply the drug to the registered hospitals and clinics in the public and private sector*
*(vi) The Oxytocin in any form or name shall not be allowed to be sold through retail Chemist.*
*2. This notification shall come into force on the first day of July 20 2018."*

72. By a notification dated 29th June, 2018, the date of coming into effect of the above notification was amended to 1st September, 2018.

*Point No.1: Do the impugned notification fall within the scope of Article 19 (6) (i) of the Constitution of India.*

73. The expression "reasonable restrictions" was amplified and the test appropriate to adjudge whether a regulation or law unduly abridges fundamental right so as to amount to unreasonable restriction, was first indicated in the *State of Madras v. V.G. Row* AIR (1952) SC 196**.** The state of law and the interpretation of the Constitution, led to the insertion of amendment to Article 19(6), through Constitution (1st Amendment) Act, 1951. The new Article 19 (6), which enables the state to impose, reasonable restrictions on the exercise of the right to trade etc., also enables it through a law either these or through a corporation owned or controlled by it to carry on trade business etc *"whether to the exclusion, complete or partial of citizens or otherwise"*. The relevant portions of Article 19(1)(g), the first amendment and the corresponding restrictions read as follows:

"*19. (1) All citizens shall have the right –*
*(g) to practice any profession, or to carry on any occupation, trade or business.*
*XXXXX*
*(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 sub-*

*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."*

74. The Supreme Court had interpreted the amended Article 19(6) in a second manner for the first time in *Saghir Ahmed v. State of U.P.*, AIR 1954 SC 728. The Court explained the effect of the amendment as follows:

*"23. The new clause in article 19 (6) has no doubt been introduced with a view to provide that a State can create a monopoly in its own favour in respect of any trade or business; but the amendment does not make the establishment of such monopoly a reasonable restriction within the meaning of the first clause of article 19 (6). The result of the amendment is that the State would not have to justify such action as reasonable at all in a Court of law and no objection could be taken to it on the ground that it is an infringement of the right guaranteed under Article 19 (1) (g)of the Constitution."*

75. Further, the Supreme Court in interpreting the amended article 19(6) in a case of *Akadasi Pradhan*(supra) held that the amendment of article 19(6) (ii) must be viewed from the broader standpoint social philosophy underlying the Constitution. The relevant paras are extracted hereunder for ready reference:

*"15. The amendment made in Art. 19(6) shows that it is open to the State to make laws for creating State monopolies, either partial or complete, in respect of any trade, business, industry or service. The State may enter trade as a monopolist either for administrative reasons, or with the object of mitigating the evils flowing from competition, or with a view to regulate prices, or improve the quality of goods, or even for the purpose of making profits in order to enrich the State exchequer. The Constitution-makers had apparently assumed that the State monopolies or schemes of nationalisation would fall under, and be protected by Art. 19(6) as it originally*

*stood; but when judicial decisions rendered the said assumption invalid, it was thought necessary to clarify the intention of the Constitution by making the amendment. It is because the amendment was thus made for purposes of clarification that it begins with the words "in particular". These words indicate that restrictions imposed on the fundamental rights guaranteed by Art. 19(1)(g) which are reasonable and which are in the interest of the general public, are saved by Art. 19(6) as it originally stood; the subject-matter covered by the said provision being justiciable, and the amendment adds that the State monopolies or nationalisation Schemes which may be introduced by legislation, are an illustration or reasonable restrictions imposed in the interests of the general public and must be treated as such. That is why the question about the validity of the laws covered by the amendment is no longer left to be tried in Courts. This brings out the doctrinaire approach adopted by the amendment in respect of a State monopoly as such.*

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*17. In dealing with the question about the precise denotation of the clause- a law relating to, it is necessary to bear in mind that this clause occurs in Article 19(6) which is, in a sense, an exception to the main provision of Article 19(1)(g). Laws protected by Article 19(6) are regarded as valid even though they impinge upon the fundamental right guaranteed under Article 19(1)(g). That is the effect of the scheme contained in Article 19(1) read with Clauses (2) to (6) of the said Article. That being so, it would be unreasonable to place upon the relevant clause an unduly wide and liberal construction. A law relating to a State monopoly cannot, in the context, include all the provisions contained in the said law whether they have direct relation with the creation of the monopoly or not. In our opinion, the said expression should be construed to mean the law relating to the monopoly in its absolutely essential features. If a law is passed creating a State monopoly, the Court should enquire what are the provisions of the said law which are basically and essentially necessary for creating the State monopoly. It is only those essential and basic provisions which are protected by the latter part of Article 19(6). If there are other provisions made by the Act which are subsidiary, incidental or helpful to the operation of the monopoly, they do not fall under the said part and their validity must be judged under the first part of Article 19(6). In other words, the effect of the amendment made in Article 19(6) is to protect the law*

*relating to the creation of monopoly and that means that it is only the provisions of the law which are integrally and essentially connected with the creation of the monopoly that are protected. The rest of the provisions which may be incidental do not fall under the latter part of Article 19(6) and would inevitably have to satisfy the test of the first part of Article 19(6).”*

76. On behalf of the Union certain judgments [*Glass Chatons Importers & Users v. Union Of India* AIR 1961 SC 1514; *Davason of Bhimji Gohil vs Joint Chief Controller Of Imports* (1962) SC 1796 and *M/s. Daruka & Co. v. UOI and Ors.* (1973AIR SC 2711)] were cited to argue that creation of regulation of export or import trade so as to canalize it also falls within Article 19(6)(ii). This Court notices that the justification given by the Union in each of those cases did not rest upon the power under Article 19(6)(2) (hereafter referred to as “monopoly clause”) but rather on the general reasonable restrictions in public interest i.e. the main body of Article 19(6). This is evident from the following submission of the prevision decisions and findings of the Court with respect to merits in all the cases before it in *Daruka* (supra):

*“16. Policies of imports or exports are fashioned not only with reference to internal or international trade but also on monetary policy, the development of agriculture and industries and even on the political policies of the country but rival theories and views may be held on such policies. If the Government decides an economic policy that import or export should be by a selected channel or through selected agencies the 'court would Proceed on the assumption that the decision is in the interest of the general public unless the contrary is shown.*

*17. This Court in glass Chatons case (supra) said that the scheme of canalisation is not acquisition of right to carry on trade. The canalisation scheme means that only the recognised agency can carry on trade. The effect of refusal of hence to other traders is that they cannot carry on trade in those goods. The Corporation carries on trade itself but not because of any acquisition by the Corporation of the right to carry on trade of the unsuccessful applicant for licence,. Therefore, there is no violation of Article 31 or Article*

*19(1)(f) of the Constitution by the canalisation of export through the State Trading Corporation.*

*18. In Devason of Bhimji Gohil case(1) (supra) it was said that the State Trading Corporation might be a special agency or channel for the purpose of enabling the country to maintain and develop the trade in the commodity both from the qualitative and quantitative points of view. The canalisation of export through the Corporation would ensure a uniform good quality of goods and also increase the volume of export.*

*19. Therefore the dominant purpose of the scheme is canalisation of export and not to acquire the business or goodwill of traders in favour of the Corporation. The restriction on traders is reasonable. There is no acquisition of property of traders. The Corporation is an agency through which export is canalised to the total exclusion of citizens."*

77. The Union had cited *Md. Serajuddin v. State of Orissa* (1975) 2 SCC 47. This Court notices that the case related to interpretation of provisions of the Central Sales Tax Act, 1956 in the context of four contracts for sale of chrome concentrates. Two of them were directly with foreign buyers and the other two were with the State Trading Corporation (STC) ever since export of ores were canalized through it. The issue was whether the sales through STC were exempt from sales tax as they were in the course of exports. There is no observation with respect to the creation of monopoly; secondly the Court did not notice or discuss or even deal with any argument with respect to creation of State monopoly or canalization or the use of the reasonable restriction clause.

78. The Union cited *L. Abu Kavur Bai* (supra). Interestingly, that was a case concerning the direct challenge to the Tamil Nadu State Carriages and Contract Carriages (Acquisition Act), 1973. By that enactment the State of Tamil Nadu nationalize the entire transport service as well as the part of the entire assets of units which provided this service. The Court relied upon *Akadasi Padhan* (supra) and further observed that a policy of nationalization is deemed to be in public interest and for public good and that some losses, damages and prejudices and

even harsh consequences are bound to follow. Nevertheless, the considerations of public good are bound to outweigh this private prejudices and consequences. The Court, therefore, rejected the stage carriage owners' argument that the compensation provided was inadequate or that their right to carry on transport business was extinguished. This Court notices, furthermore that the Supreme Court also uphold the Union's argument invoking Article 31-C of the Constitution which provides immunity to legislation giving effect to the policy of State towards securing the principles Article 39(b) and (c) of the Constitution. It was held that the enactment in pith and circumstances served and secured the objects contained in Article 39(b) and (c) and was therefore, immunized from the challenge on the ground of violation of Article 14 and 19 of the Constitution.

79. This brings the discussion to the question as to whether Section 26A of the Drugs Act is a law relating to creation of monopolies. A plain reading of the provision indicates that the Central Government undoubtedly is vested with the power to take appropriate measures, wherever the situation so warrants, upon satisfaction of the two essential pre-requisites (risk to human beings or animals or if a drug or cosmetic does not have a therapeutic value claimed), it can *"regulate restriction or prohibit"* the manufacture, sale, distribution etc. of such product. The provision is part of the Drugs and Cosmetics Act. The principal object of this enactment is to regulate the import, manufacture, distribution and sale of drugs and cosmetics. There is no provision which enables or authorizes *"take over"* of an existing drug business or even the licenses given upon satisfaction of the statutory conditions to private manufacturers. Undoubtedly, under the power to regulate, the authorities under the Drugs Act can suspend or cancel the licenses after following the prescribed procedure. Nevertheless, the fact remains that no provision in the enactment *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.

80. Furthermore, the Court notices that though the power to regulate is wide, it does not encompass the power to take over existing businesses or altogether exclude an existing line of business while creating a State monopoly. In this context, the decision of the Supreme Court which has categorically ruled that the power to *"regulate"* does not encompass the power to prohibit an activity, absent a statutory authorization (refer *K. Ramanathan v. State Of Tamil Nadu & Anr* AIR (1985)SCC 660and *State Of Mysore v. H. Sanjeeviah* AIR 67 SCC 1189). Thus in view of this position apparently the Drugs Act was amended to expressly enable the prohibition of certain activities i.e. manufacture, sale and distribution of certain drugs, which poses a risk to human or animal life altogether.

81. The judgment in *Utkal Contractors v. State of Orissa* AIR 1987 SCC 2310 is instructive. In that the petitioners were holding long term mining leases by the Orissa forest produce. The State enacted a law aimed at smuggling foreign produce and also to provide State monopoly in forest produce and issued a notification specifying the areas where it was to operate. Complaining that the other fundamental rights were abridged, the lease holders challenged the enactment. The Supreme Court accepted that contention and held that the forest produce grown in Government forest was the subject of the law and the contracts could not be entered into before the enactment as rescinded. The decision was sought to be overturned by an amendment followed up by a notification. The Supreme Court, thereafter, in *Utkal Contractors* (supra) held that the State could make laws stating monopoly either partially or complete in respect of any trade or business and also enter into business with the objective mitigating evils in the trade. The rendering ineffective judgments and orders of the Court was held to be a well-known pattern and after considering the judgment of the Court, the Government felt that the enactment needed clarity and strengthening which it did by altering the definition of forest produce to include those found in line.

Consequently, the law related to the creation of a monopoly and could not therefore, held to be invalid.

82. A close analysis of the above judgments and decisions leads the conclusion that the Court is not precluded from inquiring whether the provisions of the law in question are essentially needed and have been enacted for the purpose of creating State monopoly. The provisions in question- i.e Section 26Adoes not relate to or does not create state monopoly or encompassed by matters covered by Article 19(6)(ii). It is not immune from judicial scrutiny and inquiry; they may amount to *"reasonable restrictions"*: but that is an altogether different aspect. In other words, if there are provisions which directly create or are aimed at creating monopolies or enable the creation of State monopolies (such as the Banks nationalization laws, insurance business nationalization laws, petroleum and oil companies nationalization laws, textile undertaking nationalization laws etc.), they would fall within the threshold of immunity provided by Article 19(6) (ii) as they can legitimately be called laws "relating to creation of monopoly". 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(1)(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.

*Point Nos. 2 and 3: Whether the impugned notification is ultra vires provisions of the Drugs Act, or amount to reasonable restriction under Article 19 (6) or are arbitrary*

83. These questions are to be considered together. The petitioners had urged that on a plain reading, Section 26A does not permit the prohibition in the manufacture, sale and distribution of a drug, by a licensed entity, unless the drug

causes or is likely to cause risk or danger to human life or has no therapeutic value or property, as claimed. This court notices that the expression used that the Central Government is satisfied that a drug or cosmetic, poses risk to human health and is lacking therapeutic value claimed or therapeutic justification.

84. The court is of opinion that the use of the expressions "regulate" and "prohibit" are of the widest import. If the facts of a given case, point overwhelmingly to a state of affairs, which calls for a particular kind of response by the state, then, the question would be, short of complete nationalization or a total ban, the power of regulation can well aid the State to tide over the emergency or the existing state of affairs, or the ill effects of the prevailing circumstances. In several decisions, i.e. *K. Ramanathan v. State of T.N. and Anr.* (1985) 2 SCC 116 and *D.K. Trivedi and Sons v. State of Gujarat and Ors*. 1986 (Supp) SCC 20 the width of the expression "regulate" was emphasized (Also see *Gujarat Urja Vikas Nigam Limited vs. Tarini Infrastructure Ltd. &Ors.*2016 (8) SCC 743). In *K. Ramanathan* it was held that:

> *"It has often been said that the power to regulate does not necessarily include the power to prohibit, and ordinarily the word "regulate" is not synonymous with the word "prohibit". This is true in a general sense and in the sense that mere Regulation is not the same as absolute prohibition. At the same time, the power to regulate carries with it full power over the thing subject to Regulation and in absence of restrictive words, the power must be regarded as plenary over the entire subject. It implies the power to rule, direct and control, and involves the adoption of a Rule or guiding principle to be followed, or the making of a Rule with respect to the subject to be regulated. The power to regulate implies the power to check and may imply the power to prohibit under certain circumstances, as where the best or only efficacious Regulation consists of suppression. It would therefore appear that the word "Regulation" cannot have any inflexible meaning as to exclude "prohibition". It has different shades of meaning and must take its colour from the context in which it is used having regard*

*to the purpose and object of the legislation, and the Court must necessarily keep in view the mischief which the legislature seeks to remedy."*

85. In *Indian Drugs & Pharmaceuticals Ltd. and Ors. v. Punjab Drugs Manufacturers Association and Ors.* (1999) 6 SCC 247 the validity of a policy of the State of Punjab was issuing directions to the purchasing authorities that certain medicines used in the government hospitals and dispensaries were to be purchased from public sector manufacturers only was challenged. The Supreme Court held that:

*"16. It is clear from the various judgments referred to above that a decision which would partially affect the sale prospects of a company, cannot be equated with creation of monopoly. In Ram Jawaya Kapur AIR 1955 SC 549 and Naraindas's [1974] 4 SCC 788 cases, the Constitution Bench also held that the policy restrictions, as discussed above, can be imposed by exercise of executive power of the State Under Article 162 of the Constitution. Therefore, the contention of the Appellants in regard to creation of monopoly and violation of the fundamental right Under Articles 19(1)(g) and 19(6) should fail. The judgment cited above also show that preference shown to cooperative institutions or public sector undertakings being in public interest, will not be construed as arbitrary so as to give rise to a contention of violation of Article 14 of the Constitution.*

*We have noted above that this Court in the cases of Oil & Natural Gas Commission v. Association of Natural Gas Consuming Industries of Gujarat (1990) Supp SCC 397; Krishna Kakkanth (1997) 9 SCC 495 and Hindustan Paper Corporation Ltd. v. Govt. of Kerala (1986) 3 SCC 398, has held that the preference shown to cooperative institutions or public sector undertakings being in public interest, will not be construed as arbitrary so as to give rise to a contention of violation of Article 14 of the Constitution.*

*XXX XXXXXX*

*19. For the above reasons, we are of the opinion that the High Court was right in coming to the conclusion that by the impugned*

*policy, there was no creation of any monopoly nor is there any violation Of Articles 14, 19(1)(g) or 19(6) of the Constitution."*

86. Likewise in *Minerva Talkies, Bangalore &Ors. v State of Karnataka &Ors.* 1988 Suppl. SCC 176 in which Rule 41-A of the Karnataka Cinemas (Regulation) Rules, 1971 came to be questioned as violative of Article 19(1)(g) of the Constitution of India, the argument made was that the income would be reduced as the Rule was prohibitive, not restrictive. This Court rejected the submission of violation of Article 19(1)(g) and observed thus:

*"12. The Appellants'/Petitioners' contention that restriction under Rule 41-A is unreasonable is founded on the premise that Rule 41-A is not regulatory in nature instead it totally prohibits exhibition of cinematograph films for one show and its impact is excessive as it reduces Appellants'/Petitioners' income to the extent of one-fifth. The Appellants/Petitioners have no unrestricted fundamental right to carry on business of exhibiting cinematograph films. Their right to carry on business is regulated by the provisions of the Act and the Rules framed thereunder. These provisions are necessary to ensure public safety, public health and other allied matters. As already discussed Rule 41-A has placed limit on the number of shows which a licensee can hold in a day. The Rule does not prohibit exhibition of cinematograph films instead it regulates it by providing that instead of five shows only four shows should be exhibited in a day. In Narender Kumar v. Union of India, (1960) 2 SCR 375, this Court held that a law made in the public interest prohibiting a business would be valid as the 'prohibition' is only a kind of 'restriction'. The expression "restriction" includes "prohibition" also. Rule 41-A, however, does not take away the licensees' right to carry on business of exhibiting cinematograph films. It merely regulates it. No Rule or law can be declared to be unreasonable merely because there is reduction in the income of a citizen on account of the Regulation of the business. In our opinion, Rule 41-A does not place any unreasonable restriction on the Appellants'/Petitioners' fundamental right guaranteed to them Under Article 19(1)(g) of the Constitution.*

87. In *T.V. Balakrishnan v. State of T.N. &Ors*. 1995 Suppl (4) SCC 236, where Rules 1-A (3)(b), 2, 3(ii) and 7(4) of Tamil Nadu Timber Transit Rules, 1968 was questioned on the ground of violation of Article 19 (1)(g). It was held that it was not restrictive but regulatory, hence was *intra vires*. This Court concluded that the High Court's ruling- upholding the regulation was correct as the rules regulated and prevented illicit felling of trees, which had to be prevented,on large extent of land with limited man power.

88. This court is of considered opinion that the nature of the regulatory power of the state is such that wide flexibility is afforded to the authorities, to consider prevailing and sometimes unforeseen situations. Though the power to regulate cannot ordinarily be expected to be used to prohibit, completely or partially any activity, yet, if there are certain situations which are to be handled, such extreme measures might be warranted. In this case, Section 26A does provide a statutory framework for such action. The wide nature of this power was underlined in *Pfizer* (supra) which ruled that it is not essential for the Union Government to seek prior approval of, or to consult the statutory advisory bodies (DTAB and DCC). The court held that:

> *"17. As has been stated hereinabove, Section 26A was brought in by an amendment in 1982. The amendment specifically made changes in Sections 33 and 33N in which it added the words "on the recommendation of the Board". From this, it is clear that Parliament in the very Amendment Act which introduced Section 26A made certain changes which involved the DTAB Under Section 5 of the said Act. It is clear that the additional power that is given to the Central Government Under Section 26A does not refer to and, therefore, mandate any previous consultation with the DTAB. On the contrary, the Central Government may be "satisfied" on any relevant material that a drug is likely to involve any risk to human beings etc. as a result of which it is necessary in public interest to regulate, restrict or prohibit manufacture, sale or distribution thereof. So long as the Central Government's satisfaction can be said to be based on relevant material, it is not possible to say that not having consulted the DTAB, the power*

*exercised under the said Section would be non est. Take the case of an FDC that is banned in 50 countries of the world owing to the fact that the said FDC involved significant risk to human beings. Assuming that the Central Government is satisfied based on this fact alone, which in turn is based on expert committee reports in various nations which pointed out the deleterious effects of the said drug, can it be said that without consulting the DTAB set up Under Section 5, the exercise of the power Under Section 26A to prohibit the manufacture or sale or distribution of a drug that is banned in 50 countries would be bad only because the DTAB has not been consulted? The obvious answer is no inasmuch as the Central Government's satisfaction is based upon relevant material, namely, the fact that 50 nations have banned the aforesaid drug, which in turn is based on expert committee reports taken in each of those nations. Take another example. Suppose the Central Government were to ban an FDC on the ground that, in the recent past, it has been apprised of the fact that the FDCs taken over a short period of time would lead to loss of life, which has come to the notice of the Central Government through reports from various district authorities, in let us say, a majority of districts in which the said FDC has been consumed. Could not the Central Government then base its ban order on material collected from district authorities which state that this particular drug leads to human mortality and ought, therefore, to be prohibited? The obvious answer again is yes for the reason that the Central Government has been satisfied on relevant material that it is necessary in public interest to ban such drug. Examples of this nature can be multiplied to show that the width of the power granted Under Section 26A cannot be cut down by artificially cutting down the language of Section 26A."*

89. At the same time, what the court did emphasize upon was that the decision of the Central Government should be based on relevant materials and not irrelevant materials:

*"If the power Under Section 26A is exercised on the basis of irrelevant material or on the basis of no material, the satisfaction itself that is contemplated by Section 26A would not be there and the exercise of the power would be struck down on this ground. Further, it is argued that the provision may be read down to make*

*it constitutionally valid, but in so doing, words cannot be added as a matter of constitutional doctrine."*

90. Therefore, this court holds 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.

*Are the notifications indefeasible for the reason that they are legislative in character*

91. The Union had contended, with some emphasis, that a notification under Section 26A is pursuant to exercise of legislative power and the courts should therefore, exercise restraint while interfering with it. 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. In *Shri Sitaram Sugar Mills Company v Union of India* (1990) 3 SCC 223 (which concerned the zoning regulations for the purpose of levy sugar under the relevant statutory order, in terms of the Essential Commodities Act) the Supreme Court held as follows:

*"Power delegated by statute is limited by its terms and subordinate to its objects. The delegate must act in good faith, reasonably, intra vires the power granted, and on relevant consideration of material facts. All his decisions, whether characterised as legislative or administrative or quasi-judicial, must be in harmony with the Constitution and other laws of the land. They must be "reasonably related to the purposes of the enabling legislation". If they are*

*manifestly unjust or oppressive or outrageous or directed to an unauthorised end or do not tend in some degree to the accomplishment of the objects of delegation, court might well say, "Parliament never intended to give authority to make such rules; they are unreasonable and ultra vires.*
*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."*

92. Again, it was held in in *Khoday Distilleries v State of Karnataka* 1996 (10) SCC 304, that:

*"The tests of arbitrary action which apply to executive actions do not necessarily apply to delegated legislation. In order that delegated legislation can be struck down, such legislation must be manifestly arbitrary; a law which could not be reasonably expected to emanate from an authority delegated with the law-making power. In Indian Express Newspapers (Bombay) (P) Ltd. v. Union of India, this Court said that a piece of subordinate legislation does not carry the same degree of immunity which is enjoyed by a statute passed by a competent legislature. A subordinate legislation may be questioned under Article 14 on the ground that it is unreasonable; 'unreasonable not in the sense of not being reasonable, but in the sense that it is manifestly arbitrary'. Drawing a comparison between the law in England and in India, the Court further observed that in England the Judges would say, 'Parliament never intended the authority to make such Rules; they are unreasonable and ultra vires'. In India, arbitrariness is not a separate ground since it will come within the embargo of Article 14 of the Constitution. But subordinate legislation must be so arbitrary that it could not be said to be in conformity with the statute or that it offends Article 14 of the Constitution."*

93. In *Cellular Operators Association v Telecom Regulatory Authority of India* (2016) 7 SCC 703 the Supreme court held that subordinate regulatory legislation, can be set aside in judicial review, if they show no *rationale* or are arbitrary:

*"62. In view of the aforesaid, it is clear that the Quality of Service Regulations and the Consumer Regulations must be read together as part of a single scheme in order to test the reasonableness thereof. The countervailing advantage to service providers by way of the allowance of 2% average call drops per month, which has been granted under the 2009 Quality of Service Regulations, could not have been ignored by the impugned Regulation so as to affect the fundamental rights of the appellants, and having been so ignored, would render the impugned Regulation manifestly arbitrary and unreasonable.*

*63. Secondly, no facts have been shown to us which would indicate that a particular area would be filled with call drops thanks to the fault on the part of the service providers in which consumers would be severely inconvenienced. The mere ipse dixit of the learned Attorney General, without any facts being pleaded to this effect, cannot possibly make an unconstitutional regulation constitutional. We, therefore, hold that a strict penal liability laid down on the erroneous basis that the fault is entirely with the service provider is manifestly arbitrary and unreasonable. Also, the payment of such penalty to a consumer who may himself be at fault, and which gives an unjustifiable windfall to such consumer, is also manifestly arbitrary and unreasonable. In the circumstances, it is not necessary to go into the appellants' submissions that call drops take place because of four reasons, three of which are not attributable to the fault of the service provider, which includes sealing and shutting down towers by municipal authorities over which they have no control, or whether they are attributable to only two causes, as suggested by the Attorney General, being network-related causes or user-related causes. Equally, it is not necessary to determine finally as to whether the reason for a call drop can technologically be found out and whether it is a network-related reason or a user-related reason.*

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*66. The reason given in the Explanatory Memorandum for compensating the consumer is that the compensation given is only notional. The very notion that only notional compensation is awarded, is also entirely without basis. A consumer may well suffer a call drop after 3 or 4 seconds in a voice call. Whereas the consumer is charged only 4 or 5 paise for such dropped call, the service provider has to pay a sum of rupee one to the said consumer.*

*This cannot be called notional at all. It is also not clear as to why the Authority decided to limit compensation to three call drops per day or how it arrived at the figure of Re 1 to compensate inconvenience caused to the consumer. It is equally unclear as to why the calling party alone is provided compensation because, according to the Explanatory Memorandum, inconvenience is suffered due to the interruption of a call, and such inconvenience is suffered both by the calling party and the person who receives the call. The receiving party can legitimately claim that his inconvenience when a call drops, is as great as that of the calling party. And the receiving party may need to make the second call, in which case he receives nothing, and the calling party receives Re 1 for the additional expense made by the receiving party. All this betrays a complete lack of intelligent care and deliberation in framing such a regulation by the Authority, rendering the impugned Regulation manifestly arbitrary and unreasonable.*

*69. We have already seen that the impugned Regulation is dated 16-10-2015, which was to come into force only on 1-1-2016. We have been shown a technical paper issued by the same Authority on 13-11-2015 i.e a few days after the impugned Regulation, in which the Authority has itself recognised that 36.9% of call drops take place because of the fault at the consumer's end. Instead of having a relook at the problem in the light of the said technical paper, the Authority has gone ahead with the impugned Regulation, which states that the said Regulation has been brought into force because of deficiency of service by service providers leading to call drops. The very basis of this statement contained in the Explanatory Memorandum to the impugned Regulation is found by the self same Authority to be incorrect only a few days after publishing the impugned Regulation. This itself shows the manifest arbitrariness on the part of TRAI, which has not bothered to have a relook into the said problem. For all the aforesaid reasons, we find that the impugned Regulation is manifestly arbitrary and therefore violative of Article 14, and is an unreasonable restriction on the right of the appellants' fundamental right under Article 19(1)(g) to carry on business, and is therefore struck down as such."*

94. In view of the above discussion and given the nature of the authorities, it is held that the Union's argument that the impugned notification, as it is the product

of subordinate legislative exercise, carries a greater immunity than executive policy is without merit. The threshold of immunity in the case of both: executive policy or norms and statutory regulations is the same. The submission is therefore, rejected.

95. The Union had urged that inherent in the nature of the subject matter, i.e drug production regulation is the result of consideration of complex factors for which expert advice and executive policy judgment is necessary. The courts' approach should, it was argued, be not one involving a merits review, but examination of the process to see whether it conforms to law, or is procedurally regular. It was urged that on both counts, the impugned notification satisfied the tests, because the power to issue the notification exists and secondly, there was objective material to justify the measures contained in it. It is not for the courts to examine and probe whether the sufficiency of material and determine whether it fits the conclusion arrived at.

96. It is axiomatic that the courts, in judicial review, do not and cannot enter into a "merits review" of an executive decision (be it statutory or non-statutory decision making). In *Shimnit Utsch India (P) Ltd v West Bengal Transport Infrastructure Development Corporation Ltd &Ors*2010 (6) SCC 303 the Supreme Court held as follows:

> *"52…The courts have repeatedly held that government policy can be changed with changing circumstances and only on the ground of change, such policy will not be vitiated. The government has discretion to adopt a different policy or alter or change its policy calculated to serve public interest and make it more effective. Choice in the balancing of the pros and cons relevant to the change in policy lies with the authority. But like any discretion exercisable by the government or public authority, change in policy must be in conformity with Wednesbury reasonableness and free from arbitrariness, irrationality, bias and malice."*

97. Also, in *Essel Steel Ltd v Union of India* 2016 (11) SCC 1, the court echoed a similar reasoning. In *Gaurav Ashwin Jain,* (supra) the Supreme Court succinctly summarized the scope of judicial review:

> *"14. The scope of judicial review of governmental policy is now well defined. Courts do not and cannot act as Appellate Authorities examining the correctness, suitability and appropriateness of a policy. Nor are courts Advisors to the executive on matters of policy which the executive is entitled to formulate. The scope of judicial review when examining a policy of the government is to check whether it violates the fundamental rights of the citizens or is opposed to the provisions of the Constitution, or opposed to any statutory provision or manifestly arbitrary. Courts cannot interfere with policy either on the ground that it is erroneous or on the ground that a better, fairer or wiser alternative is available. Legality of the policy, and not the wisdom or soundness of the policy, is the subject of judicial review [vide : Asif Hameed v. State of J&K - 1989 Supp (2) SCC 364; Shri Sitaram Sugar Co. Ltd v Union of India 1990 (3) SCC 223;Khoday Distilleries v State of Karnataka 1996 (10) SCC 304, Balco Employees Union v Union of India 2002 (2) SCC 333), State of Orissa v Gopinath Dash 2005 (13) SCC 495 and Akhil Bharat Goseva Sangh v State of Andhra Pradesh 2006 (4) SCC 162]."*

98. In view of the previous discussion as regards the scope of judicial review, in determining the validity of the impugned notification, which is narrow and confined to examining whether the measure is *manifestly arbitrary* or vitiated because it did not take into account relevant considerations, this court proposes to examine whether the complete ban on manufacture for domestic sales, of Oxytocin, prohibiting existing licenses to engage in the production of that drug is justified, legal and a *reasonable restriction.*

99. Is Oxytocin a "risky" or "dangerous" drug or formulation? This court finds it hard to accept that Oxytocin is risky to human or even animal life. The drug is strongly recommended by the WHO as the choice pharmaceutical, injected at the time of human childbirth. The WHO states, in its report "*Recommendations for the*

*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 accessed at 13:55 PM, 28 November, 2018) that:

> *"1. The use of uterotonics for the prevention of PPH during the third stage of labour is recommended for all births. (Strong recommendation, moderate-quality evidence)*
> *2. Oxytocin (10 IU, IV/IM) is the recommended uterotonic drug for the prevention of PPH. (Strong recommendation, moderate-quality evidence)*
> *3. In settings where oxytocin is unavailable, the use of other injectable uterotonics (if appropriate ergometrine/methylergometrine or the fixed drug combination of oxytocin and ergo- metrine) or oral misoprostol (600 µg) is recommended. (Strong recommendation, moderate- quality evidence)*
> *4. In settings where skilled birth attendants are not present and oxytocin is unavailable, the administration of misoprostol (600 µg PO) by community health care workers and lay health workers is recommended for the prevention of PPH. (Strong recommendation, moderate- quality evidence)"*

100. The Fifty-ninth report of Parliamentary Standing Committee on Health and Family Welfare on the functioning of Central Drugs Standard Control Organization noted that Oxytocin *"has medical use for induction and augmentation of labour, to control post-partum bleeding and uterine hypo tonicity and is included under Schedule H."* The record also discloses that the meetings of the statutory expert committees (DTAB and DCC) on various dates between 2012 and 2018 consistently noticed that the drug had a *"definite role in the medical field both for humans and animals and as such the legitimate manufacture and sale of the drugs cannot be stopped"* (Ref. 67th meeting, 1st April, 2014 as well as earlier and subsequent meetings of the DTAB). The 69th DTAB meeting stated that the drug *"need not be prohibited as it has definite use for therapeutic purposes";* 70th DTAB meeting of 18th August, 2015 noted that *"the drug legitimately manufactured in the country is required for medical purposes and as such cannot*

*be prohibited. The misuse of the drug in a crude form, can only be curbed through constant surveillance by the Regulatory authorities."* This meeting also noted (as did the 49th DCC meeting held on 16th October, 2015) that the oxytocin injection manufactured in accordance with the provisions of the Drugs and Cosmetics Rules, 1945 has high costs and can, therefore not be used for extracting milk from cows. The DCC felt that raw material or the bulk drug for such use might be clandestinely smuggled into the country and crudely manufactured for sale to dairy owners at cheap rates; it therefore, again reiterated the need for strong measures. The copies of minutes of the 44th, 45th 46th DCC meetings also echo the same view- that Oxytocin has a significant medical role in treatment of postpartum haemorrhage and should not therefore be prohibited.

101. The 78th meeting of the DTAB (held on 12.02.2018) approved, significantly, *"to prohibit the import of the Oxytocin and its formulations for human use as well as animal use under section 10A of the Drugs and Cosmetics Act, 1940."* It also agreed and resolved to the proposal to

> *"amend rule 96 of the Drugs and Cosmetics Rules, 1945 to ensure that barcoding system is adopted for manufacture of Oxytocin formulations so as to ensure track and traceability of the product to avoid its misuse. It may however be ensured that there is no shortage of the drug in the country."*

102. The record also does not therefore, disclose that the drug Oxytocin *can be said to pose a threat or risk to human life*. As far as its risk to animals- i.e. cattle is concerned, there is undoubtedly a welter of material in the form of the minutes of meetings of the DCC and DTAB, which kept reiterating that the members felt that misuse – notably through illegal manufacture, and not in the licensed manner, caused predominantly because of clandestine import and smuggling of the bulk drug (API) across the border, would cause harm or injury to cattle health. As far as empirical evidence based on expert and informed opinion is concerned, it is significant that the Union Cabinet Minister for Health, in reply to an un-starred

question by a member of Parliament, on 1st August, 2014 as to (a) whether the misuse of oxytocin injection being administered to cattle by dairy owners and to increase the size of vegetables and fruits by the farmers has increased during each of the last three years and the current year; (and details thereof) and further whether the Government had any ill effects of *"its use on animals as well as human beings, particularly teenage girls"* answered that *"There have been some reports in the Media regarding misuse of oxytocin injection. However, scientific data on the extent of such practices is not available".* It was also stated that the *"Indian Council of Agriculture Research (ICAR) has informed that no ill effects have been observed in the animals in experiments carried out on the use of oxytocin."* In reply to similar un-starred queries on 22nd December, 2015, the Union Health Minister stated, on the floor of the Lok Sabha, that

> *"(a) There have been complaints that milk dairies are reportedly using Oxytocin to increase milk production.*
> *(b) 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 a progressive addiction, and lack of response to normal let down of milk."*

103. From the above discussion, 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. It is not disputed that it continues to be on the National List of essential drugs (the latest edition of which was published in 2015). Oxytocin injection in *"5iu per ml 1 ml ampoule"* dosage is listed at Serial No. 228 of the prevailing list of essential medicines (Ref to website of the listing the National list

at http://www.nrhmhp.gov.in/sites/default/files/files/List%20of%20EDL(2).pdf accessed at 17:29 hrs, 28-11-2018).

104. As to the beneficial use – even necessity of Oxytocin, the figures, in a sense speak for themselves. On 6th June, 2018, the Central Government released the latest maternal mortality data (MMR) compiled by the Sample Registration Survey (SRS), the most regular source for demographic statistics in India (Refer to the website http://www.censusindia.gov.in/vital_statistics/SRS_Bulletins/MMR%20Bulletin-2014-16.pdf accessed at 17:44 hrs, 28.11.2018). The data showed that maternal mortality had declined 22% over three years, from 167 maternal deaths per 100,000 live births in 2011-13 to 130 deaths per 100,000 live births in 2012-16. The report states:

> *"Maternal Mortality Ratio of India has declined from 167 in 2011-2013 to 130 in 2014-2016. The decline has been most significant in EAG States & Assam from 246 to 188. Among the Southern States, the decline has been from 93 to 77 and in the Other States from 115 to 93.*
>
> *4. The key statistics presented in the Bulletin is the Maternal Mortality Ratio (MMR). This is derived as the proportion of maternal deaths per 1,00,000 live births reported under the SRS. Besides, the 95% Confidence Intervals (95% CI) of the estimates based on the calculated Standard Error (SE) have also been presented. In addition, estimates of Maternal Mortality Rate viz. maternal deaths to women in the ages 15-49 per lakh of women in that age group, and the life time risk have been presented. The life time risk is defined as the probability that at least one women of reproductive age(15-49) will die due to child birth or puerperium assuming that chance of death is uniformly distributed across the entire reproductive span and has been worked out using the following formula.."*

105. 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.

106. The next consideration, germane to the issue is- did in fact the ground realities warrant a conclusion by the Central Government that Oxytocin – either in its bulk drug (API) form or in its pharmaceutical end-use form (manufactured by the 100 odd licensed producers) was misused in such manner that necessitated a ban on domestic manufacture and sale by the private sector. The record (i.e,. the UOI's files indicate that various steps – leading up to the issuance of the notification of 17.01.2014) stepping up enforcement action for clandestine import of the API and its unlicensed manufacture, etc were mooted; the actual enforcement measures met with limited success. However, prohibiting or banning Oxytocin manufacture was first considered on the file, on 05.11.2014- it was suggested by the Hon'ble Minister of Women and Child Welfare- despite the expert group finding that there was no data to support such allegation of misuse. The expert committee had concluded in its report's summing up *inter alia*, that *"there is no data on the scale of the alleged misuse of oxytocin and it would be necessary to gather more information in this regard".* Furthermore, all the statutory expert bodies' minutes of meetings recommended consistently that the drug had definite therapeutic use and could not be banned; however, enforcement to curb clandestine import and misuse had to be stringent. The notings record the need to see feedback from State level enforcement authorities with respect to data etc.

107. The file shown to the court contains an undated, 12 page comprehensive note on the medical use of Oxytocin including that its use to induce labour and to control post-partum uterine haemorrhage. This note discusses the past measures taken including (a) the inter-ministerial committee recommendations as well as the Ministry view with respect to prohibiting manufacture by private entities (b) the 69$^{th}$ and 70$^{th}$ meeting of the DTAB which highlighted that constant surveillance by

State Drug Regulatory Authorities can curb misuse of the drug and that *"the drug need not be proscribed as it as definite use for therapeutic purposes."* This is at Pages 340-362 of the file given to the Court (discussed earlier). It is important to note that this note also appeared to have been placed before the High level group which considered the issue on 8th February, 2018.

108. DGCI, on 15.04.2015 wrote a letter to all state controllers of drugs; a press release was also issued by the Central Government with respect to the information dated 13.04.2015 that raids were conducted on 15.04.2015 at hideouts by five officers of the North Zone of the Drug Controlling Authority in the Government of NCT of Delhi concerning Oxytocin misuse by a dairy at Gazipur. The tabular statement of this indicated that 390 bottles of Oxytocin injections (100 ml) manufactured by M/s. Priya Pharmaceuticals and 160 bottles of milk suspected to contain Oxytocin allegedly manufactured by M/s. Durga Chemicals of Gaya were seized. That apart 58 bottles of Oxytocin injections were also seized. The record also contains the report of investigations dated 15.04.2015, with respect to raids and profits, the details of the team that posted the various place followed by a detailed tabular chart (undated) with respect to action taken across the country in the form of seizures. This detailed tabular chart spans the period 2012 to 03.07.2015 and describes 25 instances which accounted for seizure of various quantities of Oxytocin across the country. Out of the 25 inspections/action reports listed in the tabular chart, 10 did not relate to Oxytocin as no ampoule or material was found or seized. In respect of two cases of seizures (both dated 13.05.2015), small quantities *of suspected Oxytocin injections were seized in one case* (relating to Gaya, Bihar); the other seizure was in respect of sealing and filling machine-not Oxytocin. The three year period covered one action from Himachal (254 injections seized); one in Odisha (97 ampoules seized); Tamil Nadu (3 seizures, 53 x 100, 54 x 100 & 126 x 100 ml of unlabelled Oxytocin injections were seized); Jammu (1 ml Oxytocin BP was sized); Andhra Pradesh (6 seizures resulting in 4

samples and 1 prosecution filled); Jharkhand (12 samples and prosecutions); Madhya Pradesh (2,38,195 Ampoules); Karnataka (700 1 ml ampoules); Delhi (quantities mentioned previously); Chhattisgarh (seized quantity unknown); Jalandhar, Punjab (case of suspected Oxytocin injections 46x100 ml). With regard to the Jharkhand, an investigation report of 2922 ampoules Oxytocin, I.P. 2 ml for human use and 339 for ampoules of Oxytocin injections veterinary 2 ml were seized from different unlicensed premises and three persons were arrested.

109. The record has a letter with respect to the case pending in HP High Court and also the opinion of the *amicus curiae* that

> *"Oxytocin misuse can be effectively checked and controlled only in one situation i.e., if manufacture of this drug is undertaken only in Public Sector. It can be easily presumed that the unauthorized and illegal inflow of such huge quantity of drug oxytocin in the market proved that the steps, if any, so far taken by the Government, have remained totally in efficient".*

*In the opinion of the court, this note and the later judgment – of the HP High Court proved to be the tipping point, or the catalyst for the eventual decision to impose the prohibition which is under challenge in these cases*. The file deals in some details with respect to measures to be taken in respect of a drug manufactured by one M/s. Durga Chemicals, towards enforcement of the Drugs and Cosmetics Act.

110. The Central Government file contains the note of the DCC – approved by the Drug Controller General (DGCI) dated 01.09.2015 stating that there is only one drug bulk manufacturer. The note also states that according to the 40th DCC there is medical use of Oxytocin for induction and augmentation of labour, to control postpartum bleeding and Uterine hypo tonicity. This was repeated in the 65th meeting of the DTAB. The note further stated that the Department of Animal Husbandry, Dairy and Fisheries, Ministry of Agriculture whose opinion was sought, had stated *"in respect of production and use of oxytocin for veterinary use*

*is not recommended. The drug has therapeutic application in case of expulsion of fetus, retention of placenta".* The proposal – ultimately accepted was that the affidavit to be filed in the Court in the Himachal Pradesh High Court was only to provide information without indicating the intention to discontinue manufacture of Oxytocin or its manufacture only by Public Sector companies.

111. The Central Government file contains a detailed note running into 8 sub-paragraphs – largely describing the directions containing in the HP High Court judgment (i.e. note dated 19.04.2016). The note then suggests the setting up of a cell to monitor action and also to impart training to the concerned officials. Apparently, pursuant to the judgment of the Court discussions took place between the Ministry of Health and Family Welfare and Department to Industrial Policy and Planning (DIPP) - noting dated 21.07.2016 stated that according to the DIPP to reserve any item for exclusive manufacture in Public Sector Undertaking, amendment in the Notification of 25.07.1991 (issued by DIPP) was necessary and for which prior Cabinet approval was also sought to be required. It was also stated that the administrative Ministry needed to *"justify the same with detailed facts and figures and reasons for not bringing similar commodities under compulsory licensing along with Oxytocin". Therefore, DIPP suggest that this Ministry may consult Department of Pharmaceuticals, being the concerned administrative Ministry in the subject issue".*

112. The Joint Secretary in the Union Ministry (Health and Family Welfare) on 29.12.2016 quoted that the Department could not take any action to reserve exclusive manufacture of Oxytocin by the Public Sector as involvement of other Ministries and clearance by them was necessary. The file then talks about the KAPL and its future plan for it with respect to exclusive manufacture, volume-wise and whether it was producing it as of then or not. This note is dated 15.02.2017. A further note (dated 21.02.2017) proposed that according to the

Department of Pharmaceuticals – OM dated 02.02.2017, KAPL could be considered for exclusive manufacture for *veterinary use*.

113. The noting (BD/VET.CELL/13.2014(Pt.-1), of the Drug Regulation Section of the Department of Health and Family Welfare contains states(inpara 3(iv)) that the only PSU i.e. KAPL has competition and that "its viability is uncertain". The note also stated *inter alia* as follows:

> *"3(iv) Manufacturing facilities for Oxytocin in the company is non-existent today, and as per Department of Pharmaceuticals, this needs to be created.*
> *(v) As per the submission of KAPL, the earliest production of Oxytocin can be possible only after 3 years, that too for bulk (API) production and one more year for manufacturing of formulation of Oxytocin.*
> *(v) As per the submission of KAPL, the earliest production of Oxytocin can be possible only after 3 years, that too for bulk (API) production and one more year for manufacturing of formulation of Oxytocin.*
> *4. Department of Pharma has also stated that the real issue is not about controlled production, but of the controlled end use of the product. According to them the objective is to control the end use of Oxytocin, so that it is not diverted to non-authorized users by wholesalers and retailers. It is further explained that if this is the objective, the same can be achieved better by bringing an efficient drug regulatory system, scrupulously enforcing the same, monitoring the controlling the sale and use of the product and sensitizing the general public about the ill effects of misuse and abuse of Oxytocin."*

114. This noting, clearly shows that the decision to prohibit private sector manufacture of Oxytocin had all but been taken, as a consequence of the HP High Court's direction. It seems to have been *assumed* – even at this stage that the Central Government had a compulsion to take that measure to stop misuse of the drug in the diary sector. No attempt at seriously considering scientific or empirical data, revealing the *extent of misuse* and whether it was significant (not serious or widespread) *and weigh the competing public interests* was even made. The file

noting of 18.04.2017 expressed the lack of support by the Department of Pharmaceuticals. On 15.05.2017, sanction to place firm orders for exclusive manufacture (by KAPL) for ₹ 7.95 crores were sought. Thenceforth, the notings relate to the figures and manufacture of the private licence manufactures in the country.

115. An office memorandum of 21.09.2015 indicating that a meeting was to be held in the highest quarters in the UOI regarding harmful effects of Oxytocin that was accompanied by the detailed 12 page note (described previously). The minutes of that meeting recorded that importers, export, domestic supplies, raw material furnished by drugs etc had to be reviewed to ensure that drugs were not illegally available to clandestine manufacturers. The series of actions suggested were:

a) advisory to send to ports to examine of imports of oxytocin;

b) regulation of crude bulk material (pre-API) for non-medical purposes at all entry points;

c) detailed study by ICMR and ICR in consultation with the Department of Animal Husbandry, Dairy and Fisheries to consider the effect of Oxytocin on milch cattle and its impact on humans;

d) details of international regulatory practices eg in EU, USA to curb misuse of Oxytocin;

e) advisory to Department of Animal Husbandry, Dairy and Fisheries in States to educate farmers;

f) review of information collected from local manufacturers about quantity of bulk Oxytocin purchased, formulations manufactured and sold;

g) Inspection of chemists and retailers and issue instructions for strict observance;

h) harmonization of Indian Standards;

i) enhanced surveillance and follow up of clandestine manufacturing/import/sale of oxytocin/sale of oxytocin by unlicensed manufacturers.

116. A meeting of 29.09.2017 was held by the Joint Secretary to the PMO; its participants included Secretaries of Agriculture, Revenue, Animal Husbandry, Pharmaceuticals, Health and Family Welfare; Director General (Health Services and the DGCI. The note on the file (No #37) dated 20.09.2017 reads as follows:

> *"DoP vide OM dated 02.05.2017 has further informed that the production of Oxytocin in the public sector was discussed with Managing Director, Karnataka Antibiotics & Pharmaceuticals Limited (KAPL) on 25th April, 2017 in the chambers of Secretary (Pharmaceuticals). In response thereto, the company has furnished details of equipments/instructions requires along with the budgetary cost thereof amounting to Rs.7.95 crores. In this regard, DoP has requested this Ministry to indicate the quantity of Oxytocin required and placed firm orders for Oxytocin manufacture along with necessary sanction of Rs.7.95 crores at the earliest.*
>
> *9. In this regard, an OM dated 01.08.2017 was sent to DoP informing that this Department as of now does not have any budgetary provision/object/head/scheme from which the funds could be released to KAPL. As KAPL comes under the domain of Department of Pharmaceuticals, it would be appropriate, if Department of Pharmaceuticals provides requisite funds so that order of the Court could be implemented. However, in principle, there is no objection to provision of funds to KAPL by this Department and efforts would be made to locate an appropriate object head and obtain the approval of Competent authority for the purpose.*
>
> *10. D/o Pharmaceuticals was further informed that the details of production and sale of Oxytocin (both domestic and export) for the year 2015 to 2016 & 2016 to 2017 received from M/s Hemmo Pharmaceuticals Pvt. Ltd Mumbai has been sent to DoP. The Drugs Controller General (India) has informed that M/s Hemmo Pharmaceuticals is the only Bulk Drug (Active pharmaceuticals Ingredients) manufacturer of oxytocin in India. Till date, no importer has applied for grant of Import License to DCG(I). Therefore, it can be concluded that the domestic sale from M/s Hemmo Pharmaceuticals is the approximate total consumption*

*quantity in India, which is 959 Million International Units for year April 2015 – March 2016; and 1289 Million International Units for year 2016.*

*11. D/o Pharmaceuticals was also requested to ensure that the production of oxytocin by KAPL is initiated at the earliest. Only after the production is initiated, which can meet the legitimate demand will be question of restricting its manufacture to public sector arise, else it may create an unavoidable situation of shortage of oxytocin.*

*12. After not receiving any information from D/o Pharmaceuticals with reference to OM dated 01.08.2017, a reminder dated 04.09.207 has been sent requesting to provide information about updated status regarding initiation of production of oxytocin by KAPL.*

*13. D/o Pharmaceuticals vide OM dated 07.09.2017 has informed that KAPL has already initiated requisite actions for manufacture of Oxytocin. The company has obtained Test Licence from the Drugs Controller, Government of Karnataka for procurement of the raw material, manufactured the prototype batches of the product and is in process of manufacturing development and stability batches. DoP has further informed that it is expected that manufacturing of commercial batches of the drug can be started from May, 2018 onwards".*

117. The decisive minutes of the meeting held on 08.02.2018, reads as follows:

*"2. A presentation was made by Secretary, D/o Health and Family Welfare (DHoFW) on the subject. The following decisions were taken after detailed deliberations:*

*i) As all bonafide requirements of Oxytocin would be met by indigenous production, all the imports of Oxytocin/API in any name should be banned with immediate effect;*

*ii) DCGI and Department of Revenue (DoR) to step up vigilance mechanism to check smuggling of Oxytocin after the ban, in any form.*

*(iii) In view of the directives of the High Court of Himachal Pradesh, DoHFW and DoP to ensure that production of Oxytocin is started in public sector, as the earliest. Accordingly, the Karnataka Antibiotic & Pharmaceutical Ltd. (KAPL) should complete all the statutory requirements and start manufacturing Oxytocin from April, 2018. DCGI to facilitate the necessary permissions to KAPL in collaboration with Govt. of Karnataka.*

*(iv) Till the time KAPL is able to produce Oxytocin to meet the entire requirement in the country for humans and veterinary purpose, the existing licensed manufacturers of Oxytocin formulation may be allowed to continue with the production. The list of all such licensed manufacturers should be displayed on the website by DCGI.*
*However, all the existing licensed manufacturers of Oxytocin and the KAPL should ensure that the Oxytocin is supplied only to the registered hospitals and clinics in public & private sector and is not made available to any chemist, agency or any individual.*
*v) DCGI to give the data to Oxytocin formulations required for human and veterinary purpose to KAPL.*
*vi) The API for Oxytocin is being manufactured by one indigenous manufacturer. DoP to put up a vigilance mechanism to ensure that the API being manufactured is either sold to KAPL and licensed manufacturers of Oxytocin in the country or is exported. In any case, API should not be made available by the indigenous manufacturer to any other entity or individual in the country.*
*vii) HLL, a PSU under DoHFW to take up the task of working as the distributor of Oxytocin across the country. Further, oxytocin should also be made available through all the PMBJP and AMRIT outlets in the country, for usage by registered hospitals and clinics in public and private sector.*
*viii) DoHFW in collaboration with KAPL, HLL, DoP and DARE to design a comprehensive MIS to track production, distribution and end-use of Oxytocin produced by KAPL and other licensed manufacturers and collate the data with the bonafide requirements/usage for human and veterinary purposes so as to avoid any misuse of Oxytocin produced. JS, DoHFW to lead the process.*
*ix) DARE should immediately issue circular to all agricultural universities to regulate the misuse of Oxytocin.*
*x) DoHFW and DoP to ensure that bar coding practice is adopted in manufacturing of Oxytocin formulation, within three months.*
*x) An intensive education and awareness campaign be undertaken highlighting the adverse effects of misuse off Oxytocin and the punishments for illegal production, distribution or use.*
*xi) DCGI to give the data on Oxytocin formulations required for human and veterinary purpose to KAPL".*

118. It was after this decision, that the communication dated 16th February, 2018 and the public notice, dated 28th February, 2018 were issued, by the

Central Government inviting all stakeholders for their comments and suggestions to the proposal to prohibit the manufacture and distribution of Oxytocin injection for human use by private sector companies.

*Analysis of data available with the respondents in support of Oxytocin misuse*

119. According to the counter affidavit of the Central Government in the AIDAN petition:

> *"From the data, it can be seen that there are approximately 17.31 lakh reported live births per month. Considering that two ampoules may be required per delivery, taking into account unreported births, breakage of ampoules, etc. approximately 50 lakh ampoules may be required everymonth."*

120. Though the UOI has relied on several charts and tables, to indicate that action was taken to curb Oxytocin misuse, it appears from those that 12 prosecutions were lodged in the period 2015-17 nationwide in that regard. These were predominantly respect of unlicensed establishments barring examples where the license of the establishments had expired. The examples for Andhra Pradesh show that for the period 2015-18 only 6 seizures were conducted and no information is given regarding the result of the prosecutions. For Bihar the data given specifically stated to be *"not for the misuse of Oxytocin injection in dairy and vegetable industry but for the violation of the provisions of the Drugs and Cosmetics Act & Rules"*. The data for Telangana after *"surprised raids were conducted throughout the state on cattle feed shops and dairy farms"* indicates that all the cases relate to unlicensed establishments. In any case, the results of the prosecutions are not known. In Karnataka one case is detected. This also appears to be an unlicensed establishment. In respect of Andhra Pradesh it is the data states that there appeared to be no case and it is also mentioned that 3 court cases had been lodged. For Rajasthan it is stated *"not reported any misuse"*. Thereafter it is

mentioned that 9 cases were reported. Similarly in Tamil Nadu it is mentioned that 4 cases have been initiated against animal feed traders. Regarding Uttar Pradesh it is mentioned that 11 FIRs were lodged during the period 2015-18 for illegal possession of Oxytocin injections. This also does not appear to be in respect of licensed establishments. It is further stated for UP that *"during 2018-19no case has been reported till date".* For Delhi it is stated that *"no such case of misuse in dairy and vegetable industry has been reported during the last 3 years and in the current year".* For Jharkhand it is stated that 9FIRs were lodged in the last 3 years. Details are given in respect of Bihar where all the establishments concerned appear to be unlicensed. Similarly, the data for Ghaziabad shows that the establishments were unlicensed.

121. In the letters annexed with the counter affidavit, the letter of the Drug Control Administration, Government of Telangana dated 17.7.2018 (at page 27) showed that the establishments mentioned were unlicensed. Similarly, the chart (at page 33) relates to the illegal import of Oxytocin. The chart at page 35 onwards relates to illegal manufacture.

122. Far back, in the decision of *Cynamide India Limited (supra),* the court emphasized that in an order under the Drugs Act, or for that matter, the Essential Commodities Act, being a subordinate legislative activity,

> *"may be questioned on the ground that the conditions stipulated by the order as relevant have not been taken into account. It may also be questioned on any ground on which a subordinate legislation may be questioned, such as being contrary to constitutional or other statutory provisions. It may be questioned on the ground of denial of the right guaranteed by Article 14, if it is arbitrary, that is if either the guidelines prescribed for determination are arbitrary or if even though the guidelines are not arbitrary, the guidelines are worked in an arbitrary fashion."*

123. In the present case, the point is whether in concluding that Oxytocin formulations cannot be sold by licensed manufacturers in the domestic market, did

the respondents satisfy themselves that the statutory conditions with respect to the level of risk to human or animal life was such as to eliminate all other possibilities but to issue the impugned measures. The previous narration of facts and the discussions of the materials on record are recapitulated in the following matter:

(i) The issue with respect to Oxytocin misuse in the dairy sector was brought up for a long time in the statutory committees' (DTAB and DCC) minutes of meetings. This is evident from the several minutes of meetings, for the last 7 years, between the period 01.04.2011 to 2018;

(ii) The question of tightening controls with respect to marketing of Oxytocin formulations by the licensed manufactures or its distribution was receiving considerable attention in all the minutes of meetings, placed on the record, of such statutory bodies/committees. These minutes of meetings undoubtedly are recommendatory.

(iii) The measures brought into force, notably the 17.01.2014 notification restricted the sale of Oxytocin formulations and provided that only bulk drug manufacturers "shall supply the Active Pharmaceutical Drug only to manufacturers licensed under the Drugs and Cosmetics Rules, 1945, to manufacture formulations" and further that "the formulations meant for veterinary use be sold to veterinary hospitals only." This was the direct result of the 65th meeting (dated 25.11.2013) of the DTAB.

(iv) All the statutory body meetings recommended against the ban of sale of Oxytocin having regard to its beneficial medical effects, i.e. the critical life-saving nature of the formulation, to control post-partum haemorrhage at the time of child birth.

(v) The 67$^{th}$ meeting of the DTAB; the 49$^{th}$ meeting of the DCC; the 69$^{th}$ meeting of the DCC and the 70$^{th}$ meeting of the DTAB, all consistently and clearly stated that Oxytocin could not be banned or prohibited as it has a defined use for therapeutic purposes. These and other statutory

Board/Committee recommendations were that misuse was related to stricter control and sale of the drug, especially prevention through clandestine channels.

(vi) Several documents – including more than half a dozen minutes of meetings of the statutory bodies reflect that the acute cause of clandestine supply and use of Oxytocin is illegal import of the bulk drug from neighbouring countries and its preparation in crude manner for improper use.

(vii) The Union Government's stand in Parliament – evident from its Union Cabinet Minister's statement had been that scientific data on the extent of Oxytocin misuse was not available. In reply to the question with respect to the use on animals and human beings, particularly teenage girls, on 01.08.2014, on the floor of the Parliament it was stated that ICAR *"has informed that no ill effects have been observed in the animals in experiments carried out on the use of Oxytocin."*

(viii) In reply to queries on 22.12.2015, the Union Cabinet Minister, while mentioning that while there were complaints that milk dairies were reportedly misusing Oxytocin also stated 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."*

(ix) The note - a comprehensive note on the Central Government file – consisting of 12 pages and summarized the reports of the inter-ministerial committees, the multi-disciplinary committee set up by the Government in July 2014 had highlighted that *"there was no data to support the allegation of misuse of Oxytocin"*; it was highlighted that

the drug was used to induce labour and to control post-partum haemorrhage. The note also discussed the above measures, including the discussion on the inter-ministerial committees' recommendations and the intent within the government to pro-actively managing by providing insights of the drug and the meetings of the DTAB, especially the 69th and 70th meeting which stated that *"the drug need not be proscribed as it has defined use for therapeutic purpose."*

(x) One of the petitioners – All India Drug Association, [W.P.(C) 8555/2015] had placed on record the Indian Journal of Medical Research (IJMR) study in its June 2014 issue, entitled, "the effect of Oxytocin injection with milch buffaloes for its content and stipulated in milk. The study noted that *"in the current state Oxytocin content of milk samples remain similar regardless of the Oxytocin injections used. In conclusion, the results of the present State indicate that Oxytocin is a natural constituent of buffalo milk and injection exogenous Oxytocin for milk let down has no effect on its milk content. Further, despite its stipulated cause, the Oxytocin present in milk is rapidly integrated due to intestinal digestion thus ruling out intestinal absorption and speculated health consequences, if any."*

(xi) Similarly, the same petitioner has relied upon the NDRI report in the website which noted that Oxytocin recorded in milk after administration of high doses (25 & 50 IU) were very low and similar to plasma oxytocin "levels". Similar to plasma oxytocin concentrations observed in untreated cows during milk let don. [Page 478 of W.P.(C) 855/2018].

(xii) After the recommendations of the expert inter-disciplinary committee, steps to strengthen the regulatory and enforcement methods and ensure greater coordination between the state drug enforcement agencies was

highlighted and many measures were taken; they also form the part of the discussion in the minutes of the DCC and DTAB.

(xiii) A public interest litigation (PIL) was initiated and with respect to Oxytocin misuse and the during the hearing of those proceedings, the HP High Court wished to consider suggestions for placing stringent restrictions on the misuse of Oxytocin in the veterinary sector.

(xiv) In the official files shown to the Court reveal that during the pendency of proceedings, before the HP High Court, the Central Government's specific stand was cited. The view of the *amicus curiae* which was presented to the Central Government was that Oxytocin misuse could be effectively checked only if its manufacture was undertaken exclusively in the public sector.

(xv) The judgment of the High Court dated 15.03.2013 [CWP (PWL) – *Court on its own motion v. State of Himachal Pradesh*] is on the record. It reveals that the proceedings were taken *suo motu* after taking into account the report in the Hindi vernacular *Amar Ujala* by an order dated 24.11.2014 and that the Court had appointed an *amicus curiae*. The judgment proceeds to discuss the various statutory committee/board minutes of meetings leading up to the first notification dated 17.01.2014. The judgment noted that the minutes of the meetings acknowledged that Oxytocin misuse was prevalent; it also took note of the notification dated 22.10.2014. Based upon these, the High Court issued direction in para 21 of its judgment. Para 21(ix) directed the Central Government to propose considering *"feasibility of restricting manufacture of Oxytocin only in public sector companies and also restricting and limiting manufacture of Oxytocin by companies whose licenses have already been granted."*

(xvi) Very significantly, the judgment 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.

(xvii) The HP High Court judgment disclose that Oxytocin's use, *considered so significant and therapeutic for human use that its formulations are/were to continue to be included in the list of National Essential Medicines; they also are based upon the WHO List of Essential Medicines,* was not even brought to its notice; it was not gone into or considered in any manner whatsoever by the court.

(xviii) During pendency of the case before the HP High Court, a meeting was held on 21.09.2015 in the office of the Principal Secretary to the PMO, which was attended by all the concerned functionaries. This meeting focused on the need to greater co-operation and enforcement, surveillance, etc.

(xix) The noting of 02.02.2017 stated that KAPL could be considered for exclusive manufacture for *veterinary use;*

(xx) An undated noting (BD/VET.CELL/13.2014(Pt.-1), of the Drug Regulation Section of the Department of Health and Family Welfare states (in para 3(iv)) that the only PSU i.e. KAPL has competition and that "its viability is uncertain". The note also states *inter alia* that:

> *"3(iv) Manufacturing facilities for Oxytocin in the company is non-existent today, and as per Department of Pharmaceuticals, this needs to be created.*
> *(v) As per the submission of KAPL, the earliest production of Oxytocin can be possible only after 3 years, that too for bulk (API) production and one more year for manufacturing of formulation of Oxytocin.*
> *(v) As per the submission of KAPL, the earliest production of Oxytocin can be possible only after 3 years, that too for bulk (API) production and one more year for manufacturing of formulation of Oxytocin.*

*4. Department of Pharma has also stated that the real issue is not about controlled production, but of the controlled end use of the product. According to them the objective is to control the end use of Oxytocin, so that it is not diverted to non-authorized users by wholesalers and retailers. It is further explained that if this is the objective, the same can be achieved better by bringing an efficient drug regulatory system, scrupulously enforcing the same, monitoring the controlling the sale and use of the product and sensitizing the general public about the ill effects of misuse and abuse of Oxytocin."*

(xxi) The minutes of meeting of 29.09.2017 held by the Joint Secretary in the PMO noted that according to the *"OM dated 01.08.2017 was sent to DoP informing that this Department as of now does not have any budgetary provision/object/head/scheme from which the funds could be released to KAPL."*

(xxii) The minutes of meeting also noted that

*"11. D/o Pharmaceuticals was also requested to ensure that the production of oxytocin by KAPL is initiated at the earliest. Only after the production is initiated, which can meet the legitimate demand will be question of restricting its manufacture to public sector arise, else it may create an unavoidable situation of shortage of oxytocin.*

*12. After not receiving any information from D/o Pharmaceuticals with reference to OM dated 01.08.2017, a reminder dated 04.09.207 has been sent requesting to provide information about updated status regarding initiation of production of oxytocin by KAPL.*

*13. D/o Pharmaceuticals vide OM dated 07.09.2017 has informed that KAPL has already initiated requisite actions for manufacture of Oxytocin. The company has obtained Test Licence from the Drugs Controller, Government of Karnataka for procurement of the raw material, manufactured the prototype batches of the product and is in process of manufacturing development and stability batches. DoP has further informed that it is expected that manufacturing of commercial batches of the drug can be started from May, 2018 onwards".*

(xxiii) The decision, taken pursuant to the meeting of 8th February, 2018, is minuted; the minutes record that

> *"i) As all bonafide requirements of Oxytocin would be met by indigenous production, all the imports of Oxytocin/API in any name should be banned with immediate effect;"ii) DCGI and Department of Revenue (DoR) to step up vigilance mechanism to check smuggling of Oxytocin after the ban, in any form. (iii) In view of the directives of the High Court of Himachal Pradesh, DoHFW and DoP to ensure that production of Oxytocin is started in public sector, as the earliest. Accordingly, the Karnataka Antibiotic & Pharmaceutical Ltd. (KAPL) should complete all the statutory requirements and start manufacturing Oxytocin from April, 2018. DCGI to facilitate the necessary permissions to KAPL in collaboration with Govt. of Karnataka.*
> *(iv) Till the time KAPL is able to produce Oxytocin to meet the entire requirement in the country for humans and veterinary purpose, the existing licensed manufacturers of Oxytocin formulation may be allowed to continue with the production. The list of all such licensed manufacturers should be displayed on the website by DCGI.*
> *However, all the existing licensed manufacturers of Oxytocin and the KAPL should ensure that the Oxytocin is supplied only to the registered hospitals and clinics in public & private sector and is not made available to any chemist, agency or any individual."*

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. The Union has not confirmed that show cause notices were issued to licensed manufacturers or that any action has been taken against them. What is shown, instead, by the charts and tables that form part of the official file: as well as the two counter affidavits placed on the record, is that during the period 2014-2018, as against the conceded use of 24 crore ampoules (or their equivalent) in the country, which corresponded to approximately 8 kgs of the bulk drug (API), of the 88 kg produced (a tenth set apart annually, i.e. 2 kgs for domestic producers, i.e the

100 odd licensed manufacturers) the seizures/enforcement actions could relate to a few cases only; the details of these – for the relatively recent period of 2015-2018 (such of the facts as were available with the Union at the time of filing the affidavits) have been discussed in paras 104-15 above. 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. To justify the impugned notification, the respondents had filed an affidavit containing certain charts. The first of these were statistical calculations as to inferences drawn from data collected about supplies of Oxytocin from 79 manufacturers. The attempt of the respondents was to show that as against the availability of a certain quantity of bulk drug (about 2 kg per annum) if 30% wastage were accounted for a certain figure of production would be expected, whereas in reality, the actual product cleared was more. Now, this is an inference based on a general assumption that there is a one on one production and sale of the final product, not considering stocks lying with manufacturers at any given point of time. 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. Lastly, if the UOI's argument is sound, there ought to have been overall excess production in the given year (i.e more than 6 crore ampoules).

126. The second chart which was sought to be pressed into service was an undated table, stating that 2.14 kg of raw material (API) was seized overall during the three and half year period 2015-16 to the current year. Of this, 1.5 kgs were seized during the first year. Now, the origin of this data is not explained; furthermore 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. These figures and data were not part of the record, or proffered as justification at any time preceding the issue of the impugned notification. They were also not part of the two counter affidavits; rather they are part of the last compilation filed along with an affidavit at the fag-end of the hearing.

128. In the present case, the court perceives that more than one public interest is involved: the first interest is that of the consumer public, particularly, the *human consumer public and the pregnant women who are likely to be affected by any deterioration in the nature and quality of Oxytocin supplies.* This interest cannot be overstated; the previous discussion would show that the Central Government has put out data, disclosing a steep fall in maternal mortality. One of the prime causes of maternal mortality is inability or failure to stanch post-partum haemorrhage. This critical aspect was not considered by the HP High Court, in its decision; the respondents' various notings do not place this at the top of the list of important concerns. Possibly, this was an inarticulate or underlying premise. However, that the drug is part of the National list of Essential Medicines in terms of the Central Government's policy and continues to be so; that it is the recommended choice of drug by medical experts and the WHO, has not been highlighted nor is apparent as a consideration.

129. The second public interest, which appears to have ultimately trumped with the respondents, in issuing the impugned notification, is that Oxytocin has been

misused and all attempts to check or control it failed. While in judicial review a court cannot usually be expected to carry out a merits review, it cannot at the same time, when people's right- and here, the right to life, underlined by the fact that an essential life-saving medicine is involved, its duty to scrutinize the record and ensure that all materials pointing to the inevitability or the compelling nature of the choice exercised by the executive, exist, cannot also be understated. The file notings focus entirely on the allegations of misuse and clandestine supply of the bulk drug Oxytocin to the dairy sector. It is acknowledged that a major contributor to this misuse is the smuggling of the bulk drug from across the border and its crude manufacture for the dairy sector. Yet, hard convincing data of significant proportions, to assume criticality and an imminent, urgent need to prohibit altogether domestic licensed manufacturers from producing the life- saving drug, is lacking. Furthermore, even according to the record, there is no scientific evidence about long term adverse impact because of Oxytocin use on milch cattle- i.e. cows and buffaloes.

130. The third public interest – perhaps the last in the scale of importance, is the interest in the licensed manufacturers' right to carry on the business in the product, for which they had been continuing to engage in commercial activity. Here, it is important to notice that the bulk drug manufacturer's right to produce the formulation and sell it, has not been disturbed. *Equally, the licensed manufacturers' – including domestic manufacturer's right to produce the formulation and export it, or enter into export arrangements, has not been prohibited.* If one considers this aspect in the context of the fact that the total bulk drug manufactured in the country annually is about 22 kilos – of which only 2 kilos are used for manufacture of 6 crore ampoules and the rest (20) kilos are used for export (potentially equivalent to 60 crore ampoules), the arbitrary nature of the impugned prohibition is starkly apparent.

131. In *Om Kumar v. Union of India* (2001) 2 SCC 386 the Supreme Court observed that

> *28. By "proportionality", we mean the question whether, while regulating exercise of fundamental rights, the appropriate or least-restrictive choice of measures has been made by the legislature or the administrator so as to achieve the object of the legislation or the purpose of the administrative order, as the case may be. Under the principle, the court will see that the legislature and the administrative authority "maintain a proper balance between the adverse effects which the legislation or the administrative order may have on the rights, liberties or interests of persons keeping in mind the purpose which they were intended to serve". The legislature and the administrative authority are, however, given an area of discretion or a range of choices but as to whether the choice made infringes the rights excessively or not is for the court. That is what is meant by proportionality."*

132. The court however, also stated that when a measure is attacked on the ground of arbitrariness, the judicial review standard is that of *"Wednesbury reasonableness"*:

> *"68. Thus, when administrative action is attacked as discriminatory Under Article 14, the principle of primary review is for the courts by applying proportionality. However, where administrative action is questioned as "arbitrary" Under Article 14, the principle of secondary review based on Wednesbury principles applies."*

133. A little later, in *Coimbatore District Central Coop. Bank v. Employees Association* (2007) 4 SCC 669, the Supreme Court stated the principle in the following manner:

> *"17. So far as the doctrine of proportionality is concerned, there is no gainsaying that the said doctrine has not only arrived in our legal system but has come to stay. With the rapid growth of administrative law and the need and necessity to control possible abuse of discretionary powers by various administrative authorities, certain principles have been evolved by courts. 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".*

*18. "Proportionality" is a principle where the court is concerned with the process, method or manner in which the decision-maker has ordered his priorities, reached a conclusion or arrived at a decision. The very essence of decision-making consists in the attribution of relative importance to the factors and considerations in the case. The doctrine of proportionality thus steps in focus true nature of exercise-the elaboration of a rule of permissible priorities.*

*19. de Smith states that "proportionality" involves "balancing test" and "necessity test". Whereas the former (balancing test) permits scrutiny of excessive onerous penalties or infringement of rights or interests and a manifest imbalance of relevant considerations, the latter (necessity test) requires infringement of human rights to the least restrictive alternative. [Judicial Review of Administrative Action (1995), pp. 601-05, para 13.085; see also Wade & Forsyth: Administrative Law (2005), p. 366.]*

*20. In Halsbury's Laws of England (4th Edn.), Reissue, Vol. 1(1), pp. 144-45, para 78, it is stated:*

*'The court will quash exercise of discretionary powers in which there is no reasonable relationship between the objective which is sought to be achieved and the means used to that end, or where punishments imposed by administrative bodies or inferior courts are wholly out of proportion to the relevant misconduct. The principle of proportionality is well established in European law, and will be applied by English courts where European law is enforceable in the domestic courts. The principle of proportionality is still at a stage of development in English law; lack of proportionality is not usually treated as a separate ground for review in English law, but is regarded as one indication of manifest unreasonableness.''*

134. *Teri Oat Estates (P) Ltd. v. U.T. Chandigarh* (2004) 2 SCC 130, spelt out the principle of proportionality as follows:

*"46. By proportionality, it is meant that the question whether while regulating exercise of fundamental rights, the appropriate or least restrictive choice of measures has been made by the legislature or the administrator so as to achieve the object of the legislation or the*

*purpose of the administrative order, as the case may be. Under the principle, the court will see that the legislature and the administrative authority maintain a proper balance between the adverse effects which the legislation or the administrative order may have on the rights, liberties or interests of persons keeping in mind the purpose which they were intended to serve."*

135. Thus, in dealing with diverse- even competing interests, the legislative or the executive, which has to make choices, should *"maintain a proper balance between the adverse effects which the legislation or the administrative order may have on the rights, liberties or interests of persons keeping in mind the purpose which they were intended to serve".*

136. This court is also cognizant of the fact that one of the tests for deciding the legality of a subordinate legislation is manifest arbitrariness. Thus, for instance, in *State of Tamil Nadu v. P. Krishnamoorthy* (2006) 4 SCC 517 as follows:

*"There is a presumption in favour of constitutionality or validity of a subordinate legislation and the burden is upon him who attacks it to show that it is invalid. It is also well recognised that a subordinate legislation can be challenged under any of the following grounds:*
***************  *******************

*(e) Repugnancy to the laws of the land, that is, any enactment.*

*(f) Manifest arbitrariness/unreasonableness (to an extent where the court might well say that the legislature never intended to give authority to make such rules)."*

137. In *Sharma Transport v. Government of Andhra Pradesh* (2002) 2 SCC 188, the Court held as follows:

*"... The tests of arbitrary action applicable to executive action do not necessarily apply to delegated legislation. In order to strike down a delegated legislation as arbitrary it has to be established that there is manifest arbitrariness. In order to be described as arbitrary, it must be shown that it was not reasonable and manifestly arbitrary. The expression "arbitrarily" means: in an unreasonable manner, as fixed or done capriciously or at pleasure, without adequate determining principle, not founded in the nature of things,*

*non-rational, not done or acting according to reason or judgment, depending on the will alone."*

138. In *Cellular Operators Association of India &Ors.* (supra) the Supreme Court had to consider the legality of a call drop billing restrictive measure directed by the Telecom Regulatory Authority (TRAI). The court held that:

> *"52. We have already seen that the Impugned Regulation is dated 16.10.2015, which was to come into force only on 1.1.2016. We have been shown a technical paper issued by the same Authority on 13.11.2015 i.e. a few days after the Impugned Regulation, in which the Authority has itself recognised that 36.9% of call drops take place because of the fault at the consumer's end. Instead of having a relook at the problem in the light of the said technical paper, the Authority has gone ahead with the Impugned Regulation, which states that the said Regulation has been brought into force because of deficiency of service in service providers leading to call drops. The very basis of this statement contained in the Explanatory Memorandum to the Impugned Regulation is found by the self-same Authority to be incorrect only a few days after publishing the Impugned Regulation. This itself shows the manifest arbitrariness on the part of the TRAI, which has not bothered to have a relook into the said problem. For all the aforesaid reasons, we find that the Impugned Regulation is manifestly arbitrary and therefore violative of Article 14, and is an unreasonable restriction on the right of the Appellants' fundamental right under Article 19(1)(g) to carry on business, and is therefore struck down as such."*

139. The UOI had argued that the review that the petitioners demand is one that this court is ill equipped to make, and should not, having regard to the authorities, undertake. What would then be the role of the court, if confronted with a policy measure that appears to be unreasonable and faulty because it does not weigh in the competing public interests as in this case? On the one hand, is the overwhelming interest of pregnant women and new mothers, in stemming postpartum bleeding, which can be most effectively achieved by availability of Oxytocin in a dependable manner. The record bears out that till mid 2017, KAPL had no manufacturing ability to produce the drug; even it had to be given ₹ 7.5

crores by the Union Government to start production. One of the notes also records that *"As per the submission of KAPL, the earliest production of Oxytocin can be possible only after 3 years, that too for bulk (API) production and one more year for manufacturing of formulation of Oxytocin."*

140. Also, the possibility or danger of concentrating production in one unit (KAPL) and the inherent vulnerability (i.e. shutdown of operations on account of unforeseen situations like fire, disasters, strike, etc) does not seem to have been weighed in at all. Nor does the risk in the scarcity of the drug on account of failures or gaps in availability of Oxytocin formulation for human medical use, pan India, have been taken into account. 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. The availability of the drug through established channels and licensees with long experience in its quality and the potentially unsettling effect of a canalized supply with attendant shortages (as KAPL had no previous experience in its manufacture) was an important and vital consideration as it impacted the right to life under Article 21 of the Constitution, of thousands of pregnant women.

141. This court notices that the decision of prohibiting a country wide existing manufacturing base for Oxytocin, a life-saving drug (through the over hundred private licensed units spread across the country), for over three decades or so, on the one hand and reserving it to the public sector through a single manufacturing entity, which has no previous record in its production, is thus fraught with potential adverse consequences. One of the important directive principles of State Policy (Article 47) is the that *"The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public*

*health as among its primary duties..".* Maternal welfare too is considered a directive principle (Article 42).Correspondingly, the right of women, generally and pregnant women and young mothers in particular, to have a safe post-partum recovery and avoid risk of haemorrhaging that can be potentially fatal, is an integral part of Article 21 of the Constitution of India. The potential impact may or may not be direct; even if it leads to a few incidents, that would be a grave consequence contrary to public interest.

142. The court is also of the opinion that the weighing in of options so crucially necessary to balance these interests (elaborated previously) was not resorted to. The 78th Meeting of the DTAB, in its meeting held on 12th February, 2018 (contemporaneously with the decision taken that ultimately led to the impugned notification) *recommended that Oxytocin should be sold only to hospitals and licensed clinics.* Similarly, other such restrictive conditions with respect to sale and, possibily movement of the bulk drug could have been considered. What appeared to have weighed most, with the Central Government, instead was the direction by the HP High Court, and the view that Oxytocin was harmful to milch cattle (as discussed earlier, the record shows that even till December, 2015 the Central Government's official position was that scientific experts had ruled out that possibility).

143. The question as to the court's role in field of executive decision making has often arisen. Bernard Schwartz in *Administrative Law*, 2nd Edn., p. 584 has this to say about such function:

> *"If the scope of review is too broad, agencies are turned into little more than media for the transmission of cases to the courts. That would destroy the values of agencies created to secure the benefit of special knowledge acquired through continuous administration in complicated fields. At the same time, the scope of judicial inquiry must not be so restricted that it prevents full inquiry into the question of legality. If that question cannot be properly explored by the judge, the right to review becomes meaningless. 'It makes*

*judicial review of administrative orders a hopeless formality for the litigant. ... It reduces the judicial process in such cases to a mere feint.'*

144. The Supreme Court had in *Shri Kihota Hollohon v. Mr. Zachilhu* AIR 1993 SC 412 considered the question of the role of the court and the lines it has to cross, sometimes, in the context of constitutional adjudication:

> *"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. In his work "Oliver Wendell Holmes - Free Speech and the Living Constitution" (1991 Edition: New York University Publication) Pohlman says:*
> *All distinctions of law, as Holmes never tired of saying, were therefore "matters of degree." Even in the case of constitutional adjudication, in which the issue was whether a particular exercise of power was within or without the legislature's authority, the judge's decision "will depend on a judgment or intuition more subtle than any articulate major premise." As the particular exertion of legislative power approached the hazy gray line separating individual rights from legislative powers, the judge's assessment of constitutionality became a subtle value judgment. The judge's decision was therefore not deductive, formal, or conceptual in any sense. [page 217] (emphasis supplied) "*

145. In somewhat more apt terms, the court had explored the issue and stated, in *Collector of Central Excise, New Delhi v. Ballarpur Industries Ltd.* 1989 (4) SCC 566 thus:

> *"Though in many cases it might be difficult to draw a line of demarcation, it is easy to discern on which side of the borderline a particular case falls….*
>
> *Sri Ganguly's insistence, however, serves to recall the pertinent observations of an eminent author on the point. It was said :*
>
> *'...A common form of argument used by counsel in legal cases is to suggest that if the Court decides in favour of the opposing counsel's arguments, it will become necessary to draw lines which may be very difficult or impossible to draw. "Where will you draw the line"? is, of course, a question which must be faced by a legislator who is actually proposing to lay down lines for all future cases, but it is not*

*a question which needs in general to be faced by common law courts who proceed in slow stages, moving from case to case....'*

*See: "Pragmatism and Theory in English Law: page 75 : Hamlin Lectures of 1987*

*The learned Author recalls Lord Lindley's "robust answer" to the question where will you draw the line?*

*Nothing is more common in life than to be unable to draw the line between two things. Who can draw the line between plants and animals? And yet who has any difficulty in saying that an oak-tree is a plant and not an animal.*
*(See: Att.-Gen. v. Brighton & Hove Cooperative Assoc. (1900) 1 Ch 276 )*

*Again, Lord Coleriage in Mayor of South-port v. Morris (1893) 1 QB 359 said:*

*The Attorney-General has asked where we are to draw the line. The answer is that it is not necessary' to draw it at any precise point. It is enough for us to say that the present case is on the right side of any line that could reasonably be drawn."*

147. In view of the preceding discussion, it is held that the impugned notification is both unreasonable and arbitrary; the UOI did not adequately weigh in the danger to the users of Oxytocin, nor consider the deleterious effect to the public generally and women particularly, of possible restricted supply if manufacture is confined to one unit, to the pregnant women and young mothers, of a potentially life-saving drug. The risk of such a consequence can be drastic: the scarcity of the drug, or even a restricted availability can cause increase in maternal fatalities, during childbirth, impairing lives of thousands of innocent young mothers. The impugned notification and preceding decision making process placed far greater importance on the need to prohibit availability of Oxytocin from what was perceived to be widespread veterinary misuse: clearly the trigger for the move was the HP High Court judgment, *which did not notice that Oxytocin was an essential drug.*

Correspondingly there was no scientific basis, and insufficient data to support the conclusion that the drugs existing availability or manner of distribution posed a risk to human life (a requirement of Section 26A). The weighing of options or balancing act, to bring in a suitable measure geared to achieve the same objective in a different, or drastic manner was not undertaken. It would not be out of context here to say that the welfare of the citizen and the interests of the public are paramount, in any decision that the State takes; in this case, the absence of such weighing or balancing process, and the choosing of the most drastic option renders the decision to issue the impugned notification both arbitrary and unreasonable. 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 are *"enough for us to say that the present case is on the right side of any line that could reasonably be drawn."*

147. During pendency of these proceedings, operation of the impugned notification was suspended by a reasoned interim order dated 31.08.2018 which was extended later till 15.12.2018. In view of the above conclusions, the writ petitions have to succeed; the impugned notification and all the consequential orders are hereby declared as arbitrary and unreasonable; it is, therefore, quashed and set aside. All writ petitions are accordingly allowed.

Order *dasti.*

**S. RAVINDRA BHAT**
**(JUDGE)**

**A.K. CHAWLA**
**(JUDGE)**

**DECEMBER 14, 2018**