2019 INSC 947

REPORTABLE

IN THE SUPREME COURT OF INDIA

CIVIL APPELLATE JURISDICTION

Civil Appeal Nos.6588-6591 of 2019

(Arising out of SLPs (Civil) Nos. 3296-3299 Of 2019)

UNION OF INDIA & ANR. ETC **APPELLANTS**

Versus

BGP PRODUCTS OPERATIONS GMBH
AND HAGENE IMMERMATT WEG. & ANR. ETC. **RESPONDENTS**

J U D G M E N T

INDU MALHOTRA, J.

Leave granted.

1. The issue which arises for consideration in the present appeals is the validity of the Notification dated 27.04.2018 issued under Section 26A of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the "**Act**") by the Ministry of Health and Family Welfare.

The impugned notification restricts the manufacture of Oxytocin formulations for domestic use, only by public sector

undertakings or companies, to the complete exclusion of the private sector companies. However, the manufacture of the drug for export purposes is open to both public and private sector companies.

It was notified that the notification would come into force on 01.07.18.

By a subsequent notification dated 29.06.2018, the date was extended to 01.09.18.

2. Till the issuance of the impugned notification, Oxytocin was being manufactured by private sector companies to meet the entire need in the country.

After the issuance of the impugned notification, Karnataka Antibiotics & Pharmaceuticals Ltd. ("KAPL"), a public sector company has commenced the manufacture of Oxytocin in May 2018.

3. The Active Pharmaceutical Ingredient ("API") or the bulk drug is manufactured in India only by one private sector company in India, *viz.* Hemmo Pharmaceuticals Pvt Ltd. ("Hemmo Pharma").

4. The impugned Notification dated 27.04.2018 was challenged in a group of Writ Petitions by various private sector companies who are *inter alia* manufacturing the drug Oxytocin in W.P.(C) No. 6084/2018, W.P.(C) No. 8555/2018, W.P.(C) No. 8666/2018 and W.P.(C) No. 9601/2018 before the Delhi High Court on various grounds. The Delhi High Court granted stay of the operation of the impugned notification *vide* Interim Order dated 31.08.2018. The order of stay was extended by subsequent

Orders, which remained in force till 15.12.2018. The Delhi High Court *vide* a detailed Judgment and Order dated 14.12.2018 has quashed the impugned notification. As a consequence, the impugned notification did not come into force at all.

5. The Appellant-Union of India has filed the present Special Leave Petitions before this Court, to challenge the judgment passed by the Delhi High Court.

6. The subject matter of the present appeals is the drug Oxytocin, which is notified as an essential drug by the World Health Organization (WHO) Model List of Essential Medicines since 2002. The concept of "Essential Medicines" was first introduced by the WHO in 1977, and has now been adopted by many countries, NGOs and international non-profit supply agencies. Oxytocin continues to be notified in the 21st edition of the WHO Model List of Essential Medicines published in 2019. It is listed under the head "Medicines For Reproductive Health And Perinatal Care" and the recommended form of dosage is "Injection: 10 IU in 1- mL".

6.1. Oxytocin is an essential life-saving drug, which is included in the National List of Essential Medicines, 2011 ("**NLEM**"). It continues to be listed at S.No. 26.1.5 in the latest notification published in 2015. The NLEM is published under the 1st Schedule to the Drugs (Prices) Control Order, 2013 ("**DPCO**") under Section 3 of the Essential Commodities Act, 1955 ("**EC Act**").

The NLEM specifies the recommended dosage and strength of Oxytocin injection as 5IU per 1 ml and 10IU per

1 ml. Oxytocin injection in the form of "5 IU per ml in 1ml ampoule pack" is included in the "Essential Drug List for the year 2016-2018" at Serial No. 228 published by the National Health Mission, Department of Health and Family Welfare, Government of Himachal Pradesh.

6.2. The objective of the National List of Essential Medicines (NLEM) is that the drugs included in it are adequate to meet the contemporary health needs of the general population of the country.[1] It is one of the key instruments in balanced healthcare delivery system of a country. The first NLEM was prepared and released in 1996. This list was subsequently revised in 2003, 2011 and 2015.

NLEM contains those essential medicines "*that satisfy the primary health needs of the country's population.*" NLEM medicines are required to be made available at all times in adequate quantities in the appropriate dosage forms to serve the larger public interest. The primary purpose of the NLEM is to promote rational use of medicines considering three important aspects i.e cost, safety and efficacy. The list is considered to include the most cost-effective medicines for a particular indication.

The criteria for the inclusion of a medicine in the NLEM *inter alia* includes that the medicine should be approved/licensed in India; the medicine should have

1 Press Release on "Essential Drugs" dated 15.03.2013 by the Press Information Bureau, Government of India, Ministry of Health and Family Welfare.

proven efficacy and safety profile based on valid scientific evidence; the medicine should be cost effective etc.[2]

The NLEM is prepared by an Expert Core Committee constituted by the Director General of Health Services (DGHS) out of the World Health Organization (WHO) Model List of Essential Medicines, Essential Drugs Lists of various States, and medicines used in various National Health Programmes and Emergency Care Drugs.[3]

6.3. Oxytocin is recommended as the first line drug for prevention and treatment of post-partum haemorrhage (excess bleeding immediately after child-birth).[4] Oxytocin is the drug of choice used for pregnant women to induce or augment labour at the time of delivery, to control post-partum bleeding and uterine hypo-tonicity and is placed under Schedule H1 of the said Act.[5] Oxytocin is also included in the Indian Pharmacopoeia published in 2010, 2014, and 2018.

6.4. The misuse of Oxytocin has been the subject matter of discussion because of rampant misuse of the drug on milch animals. The issue was under deliberation by the Drugs Technical Advisory Board ("**DTAB**") and the Drugs Consultative Committee ("**DCC**"), which are statutory bodies constituted under the said Act.

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2 Executive Summary, Report of the Core Committee for Revision of the National List of Essential Medicines published in 2015.

3 Paragraph 3.1(ii) of the National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012) dated 07.12.12 published by the Ministry of Chemicals and Fertilizers, Government of India

4 World Health Organisation Recommendations For The Prevention And Treatment Of Postpartum Haemorrhage, 2012

5 Fifty-Ninth Report Of Parliamentary Standing Committee On Health And Family Welfare On The Functioning Of Central Drugs Standard Control Organization

The DTAB is a statutory body established under Section 5 of the said Act. The DTAB consists of technical experts to advise the Central Government and State Governments on technical issues arising under the said Act.

The DCC has been constituted under Section 7 of the said Act, which consists of representatives of the Central Government, and one representative of each of the State Governments to advise the Central and State Governments, and the DTAB, on any matter relating to secure uniformity in the administration of the Act.

6.5. The deliberations on the issue of rampant misuse of the drug commenced from 1997 onwards.

It is necessary to advert to the deliberations of the meetings of these statutory bodies to understand the background in which the impugned notification was passed.

6.6. The misuse of Oxytocin came up for discussion first in the 31st meeting of the DCC held on 21.08.1997 and 22.08.1997. The DCC noted that it had received several complaints on the misuse/abuse of Oxytocin in veterinary practice. Oxytocin injections were being misused to artificially extract milk from cows and buffaloes. The members of the Committee were requested to collect more information on the issue.

6.7. At the 48th meeting of the DTAB held on 08.07.1999, the DTAB discussed the misuse of Oxytocin in milch animals

and the deleterious effects due to consumption of such milk on consumers. The DTAB considered the suggestion of imposing a general ban on the manufacture of Oxytocin. However, 11 members opined that as the drug is "essential" in the medical field, and is included in the "Essential Drug list", the same could not be prohibited.

The Joint Secretary, Ministry of Food Processing, an invitee to the meeting mooted a suggestion that "*perhaps restricting the manufacture of Oxytocin to PSUs, and thereafter keeping a track on its distribution*" may be considered.

The representative of the Department of Consumer Affairs agreed that the whole issue of use and misuse of Oxytocin injection requires an in-depth examination and suggested that a detailed paper be prepared based on the outcome of such study.

6.8. At the 36st meeting of the DCC held on 23.07.05 and 24.07.05, the DCC advised not to ban Oxytocin injection since it formed a part of the NLEM. The DCC noted that the sale of Oxytocin had been regulated by amending the package size of Oxytocin to "single blister packs", as against the earlier prescribed larger packaging of 50-100 ampoules.

6.9. At the 40th Meeting of the DCC held on 29.06.2009, it was observed that the misuse of Oxytocin injection had been reported in many parts of the country, and a strong vigilance was required to stop the clandestine manufacture

of the drug. The DCC observed that the drug has a definite place in medical treatment, and is used by gynaecologists universally. The DCC urged the members/representatives of each State to ensure that the clandestine manufacture of the drug under their jurisdiction is curbed through extensive surveys and raids.

6.10. At the 43rd meeting of the DCC held on 14.11.2011, the DCC observed that there was an increasing misuse of the drug by dairy owners, because of the clandestine supply of the drug through illegal channels, and recommended that its misuse can only be curbed through increased surveillance.

6.11. At the 44th meeting held on 20.07.2012, the DCC noted the importance of continuous surveillance to stop the misuse of the Oxytocin. After deliberations, it was agreed that diversion of the bulk drug to illegal channels could be curtailed to a large extent, if it was ensured that the bulk drug is sold to licensed manufacturers only.

6.12. On 12.11.2013, the DCC convened its 46th meeting, wherein the misuse of oxytocin injections to milch animals came up for further discussion.

After deliberations, the DCC recommended that the manufacture and sale of Oxytocin injections should be banned for veterinary use under Section 26A of the Act coupled with the condition that the manufacturers of the bulk drug Oxytocin should supply the Active

Pharmaceutical Ingredient ("API") only to licensed manufacturers of Oxytocin formulations for human use.

6.13. At the 65th meeting of the DTAB held on 25.11.2013, the misuse of Oxytocin by dairy owners to extract milk from milch animals and its harmful effects on animals and human consumption was deliberated upon. While acknowledging that Oxytocin had proven medical use for inducing labour, and to control post-partum bleeding and uterine hypotonicity, the DTAB recognized the abundant availability and use of the drug in a clandestine manner, which was a matter of great concern for public health. In spite of the action taken by the authorities to place the drug under Schedule H of the Drugs & Cosmetics Rules, 1945, which requires the drug to be dispensed only on the prescription of a Registered Medical Practitioner, the manufacture and sale of the drug in a clandestine manner in large quantities, and its misuse by the farmers or dairy owners was rampant.

The opinion of the Department of Animal Husbandry, Dairying and Fisheries, Ministry of Agriculture, was sought with respect to the proposal for banning Oxytocin for Animal use. It was opined that ban on the production and use of Oxytocin for veterinary purposes, was not recommended, since the drug has therapeutic application in case of expulsion of foetus, and retention of placenta even in animals.

After deliberations, the DTAB noted that since the drug has a definite use for therapeutic purposes, it need not be prohibited. It was, however, opined that the manufacturer of the bulk drug should supply the API only to licensed manufacturers of the drug and veterinary hospitals. It was further recommended that the State Drugs Controllers 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 the drug, and take strict action against the offenders.

6.14. Pursuant to the recommendations made by the DTAB in the 65th meeting, the Ministry of Health and Family Welfare issued a Notification G.S.R 29(E) dated 17.01.2014 restricting the manufacture and sale of Oxytocin as under:

> *"Whereas the Central Government is satisfied that the drug Oxytocin has a definite therapeutic use in certain medical conditions;*
>
> *And whereas the Central Government is satisfied that it is necessary and expedient to regulate and restrict the manufacture, sale and distribution of the said drug in the country to prevent its misuse in public interest.*
>
> *Now, therefore, in exercise of the powers conferred by Section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby directs that the drug oxytocin shall be manufactured for sale or for distribution or sold in the manner specified below, in addition to the provisions contained in the said Act and Rules made thereunder, namely: -*
>
> *1. The 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.*
> *2. The formulations meant for veterinary use shall be sold to the veterinary hospitals only."*
>
> *(emphasis supplied)*

6.15. The validity of the aforesaid Notification dated 17.01.2014 was challenged before the Punjab & Haryana High Court in *Narang Medical Store v. Union of India* [W.P.(C) No.

7135/2014], *inter alia* on the ground that it was not in consonance with the provisions of Section 26A of the Act. The High Court *vide* judgment and order dated 28.01.2016, upheld the validity of the Notification, to avoid the misuse of the bulk drug or Active Pharmaceutical Ingredient used in Oxytocin injections.

6.16. At the 67th meeting of the DTAB held on 01.04.14, the DTAB once again recognized that the drug Oxytocin has a definite role in the medical field for both humans and animals, and as such the legitimate manufacture and sale of the drugs cannot be stopped by banning the drug. Even if the domestic manufacturers are prohibited from manufacturing the drug, 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.

After deliberations, the DTAB recommended that at the time of sale of oxytocin by retail chemists, the name and address of the purchaser, the name of the patient, and the quantity supplied shall be recorded. Such records shall be maintained for three years, and shall be kept 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.

6.17. The recommendations of DTAB came to be given statutory effect by an amendment to Rule 65 of the Drugs and

Cosmetics Rules,1945 *vide* Notification dated 30th August 2013 published by the Ministry of Health and Family Welfare.

6.18. On 05.11.2014, a meeting was convened by the Minister for Women and Child Development Ministry (MWCD), which was attended by Secretaries from various other Ministries. In this meeting, a suggestion was mooted that on account of the rampant misuse of Oxytocin, which led to cows and animals contracting diseases, and the illegal use for increasing milk production, could be effectively controlled if a "*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.*"

6.19. At the 69th DTAB meeting held on 22.04.15, the DTAB reiterated its earlier recommendation that Oxytocin "*need not be prohibited as it has definite use for therapeutic purposes. Shri A. K. Tiwari of IVRI stated that the drug oxytocin is an essential drug in the veterinary practice. He added that the Department of animal husbandry had also earlier given his opinion that the ban on production and use of oxytocin for veterinary used is not recommended.*" The DTAB observed that the misuse of the drug can be controlled by stricter control over the manufacture and sale of the drug, especially through clandestine channels. The DTAB noted that "*Constant surveillance by the State Drug Regulatory Authorities and other regulatory authorities can only curb the misuse of the drug.*"

6.20. In its 70th meeting dated 18.08.15, the DTAB was informed that dairy owners were getting the drug manufactured at dubious premises from unscrupulous suppliers. The DTAB noted that the raw material or the bulk drug was being clandestinely smuggled into the country from the border States, which was then being crudely manufactured clandestinely and sold to dairy owners at a very cheap rate. The DTAB reiterated its recommendation that "*the drug legitimately manufactured 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.*"

6.21. On 16.10.2015, the DCC in its 49th Meeting discussed the rampant misuse of Oxytocin through clandestine channels. It was *inter alia* recommended that officials from the State Drug Regulatory Authority must conduct periodic raids with the assistance of the Police at suspected outlets; and that the manufacture and sale of oxytocin formulations by the licenced manufacturers in the State, should be monitored regularly.

6.22. On 12.02.2018, the DTAB in its 78th meeting considered the proposal to restrict the supply of Oxytocin formulations for human use only to registered hospitals and clinics in public and private sector to prevent misuse of the drug. The members deliberated upon 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."

The DTAB accepted in principle the proposal to amend Rule 96 of the Drugs and Cosmetics Rules, 1945 to ensure that bar-coding system is adopted for the manufacture and sale of Oxytocin formulations so as to ensure track and traceability of the product, to avoid its misuse.

The DTAB had further agreed to prohibit the import of Oxytocin formulations under Section 10A of the said Act for human as well as animal use.

6.23. On 09.04.2018, the DCC at the 53rd meeting was informed about the recommendations of the 78th DTAB meeting held on 12.02.2018 to address the misuse of Oxytocin. The DCC, in principle, agreed with the recommendations of the DTAB.

6.24. On 18.04.2018, The Ministry of Health and Family Welfare, issued a Notification, containing "Draft Rules" *viz.* the "Drugs and Cosmetics (Amendment) Rules, 2018, on which objections and suggestions were invited to within 45 days. The Draft Rules proposed to amend Rule 96 of the Drugs and Cosmetics Rules, 1945 to ensure that a 3-tier bar-coding system is adopted by licensed manufacturers of Oxytocin formulations to facilitate and trace their products.

The relevant extracts of Rule 1 and 2 are extracted hereinbelow for ready reference:

DRAFT RULES

"1. (1) These rules may be called the Drugs and Cosmetics (Amendment) Rules, 2018.

(2) These rules shall come into effect after one hundred eighty days of the publication of the final rules in the Gazette of India. 2. In the Drugs and Cosmetics Rules, 1945, in rule 96, in sub-rule (1), after clause (xii) the following clause shall be inserted, namely:-

"(xiii) (A) The manufacturers of drug formulations of oxytocin shall print the details specified below to facilitate tracking and tracing of their products, namely:-

a. at primary level packaging of two dimensional barcode encoding unique and universal global product identification code in the 14 digits Global Trade Item Number format along with batch number, expiry date and a unique serial number of the primary pack;

b. at secondary level packaging of one or two dimensional barcode encoding unique and universal global product identification code in the 14 digits Global Trade Item Number format along with batch number, expiry date and a unique serial number of the secondary pack;

c. at tertiary level packaging of one dimensional barcode encoding unique and universal global product identification code in the 14 digits Global Trade Item Number format along with batch number, expiry date and a unique serial number of the Tertiary pack.

(B) The manufacturer of drug formulation shall maintain the data in the parent — child relationship for all three level of packaging and their movement in its supply chain.

(C) The data referred to in sub-rule (2) shall be uploaded on the central portal of the Central Government by the manufacturer or its designated agency before release of the drugs for sale or distribution. (D) The responsibility of the correctness, completeness and ensuring timely upload of data on the Central portal shall be that of the manufacturer."

The Central Government did not proceed with these Draft Rules, since the Impugned Notification came to be passed on 27.04.2018. As a consequence, the Draft Rules lapsed.

6.25. On 24.04.18, the Ministry of Health and Family Welfare in exercise of its powers under Section 10A of the Act issued a Notification completely prohibiting the import of 'Oxytocin and its formulation in any name or manner' into India.

6.26. On 27.04.18, the Ministry of Health and Family Welfare in exercise of its powers under Section 26A of the Act issued the Impugned Notification, which superseded the Notification dated 17.01.2014, and directed that the drug Oxytocin shall be manufactured only by public sector undertakings or companies for domestic use. However, the manufacture of Oxytocin formulations for export purposes shall be open to both public and private sector companies.

The impugned Notification date 27.04.2018 is extracted herein below for ready reference:

"*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 2018 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, 1945 for 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."

(emphasis supplied)

6.27. On 25.07.18, the DTAB in its 80th meeting recommended the amendment of the Impugned Notification by deleting Clause (v) and Clauses (vi) of the impugned Notification dated 27.04.18, so as to ensure availability of the drug for human use.

6.28. The Impugned Notification was subsequently amended by Notification dated 21.08.18. The Notification dated 21.08.18 substituted clauses (v) and (vi), with the following amended clause (v),

"(v) The Oxytocin formulations manufactured by the public sector companies or undertakings licensed under the Drugs and Cosmetics Rules, 1945 shall be distributed or sold in accordance with such rules."

As a consequence of this amendment, the effect of the impugned notification was diluted, and Oxytocin formulations could be sold and distributed by the public sector companies or undertakings in accordance with the Drugs and Cosmetics Rules, 1945 as against the earlier restriction wherein Oxytocin formulations could only be supplied to the registered hospitals and clinics in public and private sector directly; or through the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and Affordable

Medicines and Reliable Implants for Treatment (AMRIT) outlets.

6.29. On 30.07.2018, the DCC convened the 54th meeting where the Chairman of the DCC apprised the Committee of the Notification dated 27.04.2018 ("Impugned Notification") to restrict the manufacture for sale, sale or distribution of Oxytocin to only to public sector undertakings or companies for domestic use.

The Secretary, Ministry of Health & Family Welfare requested the State Drug Controllers to ensure the availability of Oxytocin in their respective States by placing purchase orders in time with Karnataka Antibiotics & Pharmaceuticals Ltd. ("KAPL").

6.30. The Ministry of Health and Family Welfare issued another Notification on the same date i.e. 21.08.18, wherein Oxytocin, which was included under Entry No. 382 of Schedule 'H' of the Drugs and Cosmetics Rules,1945 was now shifted to Schedule 'H1' at Entry No. 47. Schedule H1 refers to Rules 65 and 97 of the Drugs and Cosmetics Rules,1945.

As per the said Rules, Schedule H1 prescription drugs provide for stricter control and additional precautions when compared with Schedule H drugs.

The relevant extracts of the Rules are set out herein below for ready reference:

> "***65. Conditions of licences***. - *Licences in Forms 20, 20-A, 20-B, 20-F, 20-G, 21 and 21-B shall be subject to the conditions stated therein and to the following general conditions-*

....

(3)(1) The supply of any drug [other than those specified in Schedule X] on a prescription of a registered medical practitioner shall be recorded at the time of supply in a prescription register specially maintained for the purpose and the serial number of entry in this regard shall be entered on the prescription. The following particulars shall be entered in the register:-
(a) serial number of the entry,
(b) the date of supply,
(c) the name and address of the prescriber,
[(d) the name and address of the patient, or the name and address of the owner of the animal if the drug supplied is for veterinary use,]
(e) the name of the drug or preparation and the quantity or in the case of a medicine made up by the licensee, the ingredients and quantities thereof,
(f) in the case of a drug specified in Schedule C or Schedule H and Schedule H1, the name of manufacturer of the drug, its batch number and the date of expiry of potency, if any,
(g) the signature of the [registered Pharmacist] by or under whose supervision the medicine was made up or supplied
.....
(h) ***the supply of a drug specified in Schedule H1 shall be recorded in a separate register at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied and such records shall be maintained for three years and be open for inspection.***

....

(6) The licensee shall produce for inspection by an Inspector appointed under the Act on demand all registers and records maintained under these Rules, and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed.

(7) Except where otherwise provided in these Rules, all registers and records maintained under these Rules shall be preserved for a period of not less than two years from the date of the last entry therein.

(8) Notwithstanding anything contained in this Rule it shall not be necessary to record particulars in a register specially maintained for the purpose if the particulars are recorded in any other register specially maintained under any other law for the time being in force.

9) (a) ***Substances specified in Schedule H and Schedule H1 or Schedule X shall not be sold by retail except on and in accordance with the prescription of a Registered Medical Practitioner*** *and in the case of substances specified in Schedule X, the prescriptions shall be in duplicate, one copy of which shall be retained by the licensee for a period of two years.*
(b) ***The supply of drugs specified in Schedule H and Schedule H1 or Schedule X to Registered Medical Practitioners, Hospitals, Dispensaries and Nursing Homes shall be made only against the signed order in writing which shall be preserved by the licensee for a period of two years****.*

....

(11) The person dispensing a prescription containing a drug specified in Schedule H and Schedule H1 and Schedule X shall comply with the following requirements in addition to other requirement of these rules.

(a) the prescription must not be dispensed more than once unless the prescriber has stated thereon that it may be dispensed more than once;
(b) if the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals it must not be dispensed otherwise than in accordance with the directions;
(c) at the time of dispensing there must be noted on the prescription above the signature of the prescriber the name and address of the seller and the date on which the prescription is dispensed.

.....

(11-A) No person dispensing a prescription containing substances specified in Schedule H and Schedule H1 or X, may supply any other preparation, whether containing the same substance or not, in lieu thereof.

97. Labelling of medicines.— 1 [(1) The container of a medicine for internal use shall—

(b) if it contains a substance specified in Schedule H, be labelled with the symbol Rx and conspicuously displayed on the left top corner of the label and shall also be labelled with the following words in legible black coloured font size in completely red rectangular box:
'Schedule H Prescription Drug- Caution: Not to be sold by retail without the prescription of a Registered Medical Practitioner'

(e) ***if it contains a drug substance specified in Schedule H1, be labelled with the symbol Rx, which shall be in red and conspicuously displayed on the left top corner of the label, and shall also be labelled with the following words in legible black coloured font size in completely red rectangular box:***

*"**SCHEDULE H1 PRESCRIPTION DRUG – CAUTION. –***
*- **It is dangerous to take this preparation except in accordance with the medical advice.***
*- **Not to be sold by retail without the prescription of a Registered Medical Practitioner.***

(emphasis supplied)

7. The Impugned Notification dated 27.04.18 was challenged by the Respondents – BGP Products Operations GmBH, Mylan Pharmaceuticals Pvt. Ltd., All India Drug Action Network, Neon Laboratories Ltd. and Ciron Drugs And Pharmaceuticals Pvt. Ltd before the Delhi High Court in May 2018.

8. The Delhi High Court *vide* the Impugned Judgment dated 14.12.2018 quashed the impugned Notification as being arbitrary and unreasonable. It was held there was no scientific basis, and insufficient data to support the conclusion that the existing availability or manner of distribution of Oxytocin posed a risk to human life or animals, which is one of the pre-conditions for exercise of power under Section 26A of the Act. The High Court held that the trigger and catalyst to the passing of the impugned Notification was the decision of the High Court of Himachal Pradesh, Shimla dated 15.03.2016 in *Court On Its Own Motion vs State of Himachal Pradesh*[6], which did not consider that Oxytocin was an essential drug which was included in the NLEM. It was further held that the Central Government did not adequately weigh the danger to the lives of the users of Oxytocin i.e pregnant women and young mothers, nor did it consider the deleterious effect to the public generally and women particularly, of the possible restricted supply of a life-saving drug, if the manufacture is confined to one single public sector enterprise, namely Karnataka Antibiotic and Pharmaceuticals Ltd. ("KAPL"), which admittedly has no prior experience in manufacturing the drug. The High Court opined that the risk of such a consequence can be drastic since the scarcity of the drug, or even a restricted availability can lead to increased maternal fatalities during childbirth, impairing lives of thousands of innocent young mothers. It was held that there is no provision in the Act, including Section 26A, which authorized the Central Government to create a State monopoly in favour of

6 CWPIL No. 16 of 2014

one licensee, which did not fall within the protective ambit of Article 19(1)(6)(ii).

9. We have heard the learned Counsel for the parties, and perused the pleadings and written submissions filed by the parties.

10. Mr. Tushar Mehta, Learned Solicitor General and Mr. Vikramjeet Banerjee, Learned Additional Solicitor General of India appeared on behalf of the Appellant-Union of India.

The Senior Counsel for the Union of India assailed the impugned Judgment on the ground that the High Court had exceeded its jurisdiction by reviewing the sufficiency of the material relied upon by the Central Government in exercise of its legislative powers under Section 26A of the Act. The Counsel for the Union of India-Appellants submitted as follows:

> 10.1. The exercise of power under Section 26A being legislative in nature, the grounds for judicial review are limited. The Court should exercise judicial restraint in review of policy matters and cannot sit in appeal over a policy decision. Since the impugned notification creates a general restriction with respect to all licensed manufacturers, it would not amount to an executive action.
>
> 10.2. It was further submitted that there is a presumption in favour of constitutionality or validity of a subordinate legislation and the burden is upon the Respondents to show that it is invalid. Reliance was placed on *Akadasi Pradhan vs State of Orissa*[7], *State of*

7 1963 Supp (2) SCR 691 : AIR 1963 SC 1047

T.N. v. P. Krishnamurthy[8], *UOI v. Cynamide India Pvt. Ltd*[9]; *E Merck (India) Limited v. UOI*[10]; *Macleods Pharmaceuticals Limited v. UOI*[11], *Drug Controller General of India vs West Bengal Small Scale Manufacturers*[12], *Uni-San Pharmaceuticals Ltd.& Anr. v UOI*[13]

10.3. It was further argued that the Court cannot exercise judicial review over a legislative act on the basis of sufficiency or insufficiency of material. The Court cannot weigh and sift through evidence or material relied upon by the Central Government in exercise of its powers under Section 26A. The Court cannot substitute its wisdom in place of the wisdom of the Central Government, particularly, in matters of public health and public interest. Reliance was placed on *Union of India vs Pfizer Ltd.*[14], *Khoday Distilleries Ltd. v State of Karnataka*[15], *Shimnit Utsch India (P) Ltd. v West Bengal Transport Infrastructure Development Ltd. & Ors.*[16], *Directorate of Film Festivals v. Gaurav Ashwin Jain & Ors.*[17], *Academy of Nutrition Improvement v Union of India*[18], *Vincent Panikurlangara v Union of India*[19], *Systopic Laboratories v Dr. Prem Gupta*[20].

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8 (2006) 4 SCC 517
9 1987 (2) SCC 720
10 2001 (90) DLT 16
11 2012 SCC Online Mad 1735
12 AIR 2000 Cal 133
13 AIR 2002 Ker 72: (2001) 1 KLJ 822
14 (2018) 2 SCC 39
15 (1996) 10 SCC 304
16 (2010) 6 SCC 303.
17 (2007) 4 SCC 737
18 (2011) 8 SCC 274
19 (1987) 2 SCC 165
20 (1994) Suppl. 1 SCC 160

10.4. It was submitted that Section 26-A confers wide powers on the Central Government to either regulate, restrict or prohibit the manufacture, sale or distribution of a drug, if the Central Government is "satisfied" that the conditions mentioned in Section 26-A exist.

Section 26-A of the Act reads as under:

> *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."*

The Central Government was not bound by recommendations of the DTAB or the DCC. The Central Government could independently arrive at a satisfaction with regard to the factum of misuse of the drug.

10.5. The misuse of Oxytocin was consistently deliberated by the DCC and DTAB since the past 21 years from 1997 onwards, and formed the basis of the impugned Notification. The minutes of the meetings of the DTAB and DCC reveal the *factum of misuse* of Oxytocin and its harmful effects on milch animals and humans through consumption of such milk. The subjective "satisfaction" of the Central Government was arrived at after considering

the *factum of misuse* which was deliberated by the DTAB and DCC. Reliance was placed on a Chart on Oxytocin Data Compilation from April 2015 to August 2018, which showed that licensed manufacturers were manufacturing far more Oxytocin than the legitimate national requirement, and there was a considerable amount of "leakage" in the production. The licensed manufacturers were responsible for this leakage as they were supplying the bulk drug or API manufactured by Hemmo Pharma to small illegal local units for production of spurious Oxytocin. The Central Government in public interest decided to strike a balance between two competing interests i.e animal and human health, and issued the impugned notification.

10.6.The impugned Notification does not violate or extinguish the right to carry on any trade or business or occupation of the Respondent-Manufacturers under Article 19(1)(g). The Impugned Notification does not create a State Monopoly in favour of KAPL, since the Respondent-manufacturers still have a right to export Oxytocin and sell their products overseas. They are restricted only insofar as domestic manufacture and distribution of Oxytocin is concerned. The Impugned Notification merely regulates the manufacture of Oxytocin, and does not completely prohibit it.

Even otherwise, the High Court in the impugned judgment has held in favour of the Appellants to the extent that the power to restrict or prohibit under Section 26A can be used 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".

Such a measure cannot be said to be ultra vires the power under the statute.

10.7.The Impugned Notification is protected under Article 19(6) of the Constitution of India. It was contended that Article 19(6)(ii) of the Constitution empowers the State to enact laws with regard to any trade, business, industry or service, to the complete or partial exclusion of citizens and private entities.

In the alternative, even if the impugned notification does create a State monopoly, there is no requirement under Article 19(6) to enact legislation for the creation of the same. Restrictions on trade can be created by way of notification as well. Such a measure should be presumed to be reasonable and constitutional. Reliance was placed on *Akadasi Pradhan vs State of Orissa*[21], *Khoday Distilleries Ltd. v State of Karnataka*[22], *Daruka & Co v Union of India & Ors.*[23], *Indian Drugs & Pharmaceuticals Ltd. v. Punjab Drugs Manufacturers Assn.*[24], *Municipal Committee, Amritsar v State of Punjab*[25].

10.8. It was further submitted that the impugned notification was issued in furtherance of legitimate public interest towards protection of bovine heath,

21 1963 Supp (2) SCR 691 : AIR 1963 SC 1047
22 (1995) 1 SCC 574
23 (1973) 2 SCC 617
24 (1999) 6 SCC 247
25 (1966) 1 SCC 475

maintenance of animal husbandry standards and protection of the environment. The impugned notification is also aimed to prevent the ill effects of Oxytocin, which may affect human life due to prolonged consumption of milk from milch animals injected with the drug. The Appellants placed reliance on Articles 48, 48A and 51A(g) of the Constitution, which form part of the Directive Principles of State Policy.

11. Mr. Kapil Sibal, Mr. Colin Gonsalves and Mr. S. Ganesh, Senior Advocates appeared on behalf of the Respondents. Ms. Meenakshi Arora, Senior Advocate appeared for the Federation of Obstetric and Gynaecological Societies of India, and Mr. Jayant Mehta, Advocate appeared on behalf of the Indian Medical Association (Intervenors).

The Respondents submitted as follows:

11.1 The Respondents – BGP Products Operations GmBH, Mylan Pharmaceuticals Pvt. Ltd., and Ciron Drugs And Pharmaceuticals Pvt. Ltd have been manufacturing Oxytocin injections I.P. 5IU per 1 ml under a license issued under Part VII of the Drugs and Cosmetics Rules, 1945 for over three decades in India. They manufacture the drug only for domestic use. It was submitted that the Respondents have at least 50% of the market share in terms of manufacturing the drug. It was submitted that the Respondent-manufacturers do not sell the drug directly to the end consumer and only sell by way of wholesale dealing to licensed distributors and licensed retail chemists, and use the very same chain of distribution that KAPL uses.

The license issued to the manufacturers under Part VII of the Act also carries with it the license to sell by way of wholesale dealing within the territory of India.

As a consequence of the Impugned Notification, the license issued to these Respondents, for all practical purposes, stood cancelled and terminated.

The impugned Notification impinges and violates Article 19(1)(g) of the Constitution in as much as it has completely prohibited the Respondents from manufacturing Oxytocin as they do not have a license to export the drug.

11.2 It was submitted that the Act provides for a level playing field in relation to the manufacture, distribution and sale of drugs by any person. Reliance was placed on Section 16 read with Schedule II of the Act, to contend that the Act is concerned with "*what*" is manufactured, distributed or sold; and, not with "*who*" is the manufacturer or distributor or seller of the drug.

11.3 It was submitted that there was no relevant material or evidence placed before the Central Government for it to arrive at a "satisfaction" to completely prohibit the manufacture and sale of the drug by the Respondent-Manufacturers. It was submitted that neither the DCC nor DTAB had recommended or approved the complete prohibition of manufacture of Oxytocin by private licensees. It was further submitted that the statutory bodies had never recommended that the manufacture of

Oxytocin for domestic use be exclusively reserved for the public sector.

11.4 It was submitted that the basis of the impugned Notification was the decision of the High Court of Himachal Pradesh, Shimla dated 15.03.2016 in *Court On Its Own Motion vs State of Himachal Pradesh*[26], which was completely irrelevant for forming a "satisfaction" while issuing the Impugned Notification.

11.5 The Respondent-Manufacturers had never been prosecuted or even issued a Show-Cause Notice under the Act for any misuse or abuse of the drug, or violation of any provisions of the Act. There was no material or evidence to show any illegal or clandestine manufacture of Oxytocin by the Respondent-manufacturers who are licensed in accordance with law. The Chart on Oxytocin Data Compilation from April 2015 to August 2018 relied on by the Central Government to show unutilised quantity of the bulk drug or the API is wholly irrelevant, and was only prepared in August 2018, much after the impugned Notification was passed.

11.6 It was submitted that at the 78th meeting of the DTAB dated 12.02.18, which forms the basis of the Impugned Notification, the DTAB did not recommend to restrict the manufacture of Oxytocin to public sector companies only, nor did it determine that Oxytocin is likely to pose a risk to animals or humans.

26 CWPIL No. 16 of 2014

Rather, the DTAB agreed on a draft notification for regulating and restricting the supply of Oxytocin formulations only through registered hospitals and clinics in the '*public and private sector*'.

11.7 It was submitted that the Draft Rules published by the Ministry of Health and Family Welfare on 18.04.2018 suggested and recommended a *3-tier system of barcoding* of all Oxytocin formulations manufactured by licensed manufacturers "*so as to ensure track and traceability of the product to avoid its misuse*". The Central Government after 10 days i.e., on 27.04.2018, took the drastic course of prohibiting the manufacture of the drug by all private sector licensees, and arbitrarily issued the impugned notification.

It was submitted that there is no material on record to show on what basis the Central Government suddenly changed its stand between 18.04.2018 and 27.04.2018 from a 3-tier system of barcoding to that of complete prohibition on the manufacture of the drug by licensed private sector manufacturers.

11.8 It was submitted that the impugned notification is arbitrary, unreasonable and issued with complete non-application of mind. The power under S. 26A cannot be used in respect of a licensed drug, or in respect of a spurious, misbranded, adulterated and illegally or clandestinely manufactured drug. The "*use of any drug*" as used in Section 26A means its use only for the intended,

declared and avowed purpose, and does not cover its misuse. Therefore, Section 26A could not have been invoked to prohibit/regulate/restrict the misuse of an essential and licensed drug.

11.9 Section 26A cannot be invoked where the manufacture, sale or distribution of a drug is already "*prohibited*" under Section 18 of the Act. The Act and the accompanying Rules provide for a robust mechanism for countering any contravention of the Act by licensed manufacturers. Therefore, there was no public necessity to completely prohibit all licensed manufacturers from manufacturing the drug.

11.10 The exercise of power under Section 26A cannot be said to be legislative in nature, since it is based on the "satisfaction" of the Central Government alone. The Central Government in exercise of its executive/administrative powers under Section 26A, cannot create a State monopoly in the manufacture for domestic sale of a drug, and claim the protection of Article 19(6) of the Constitution. Reliance was placed on *Rai Sahab Ram Jawaya Kapur & Ors. v State of Punjab*[27].

11.11 It was further submitted that Memorandum of Delegated Legislation accompanying the Bill No.65 of 1982 introducing insertion of Section 26A in the Act, makes no reference to the exercise of powers under Section 26A as a form of delegated legislation.

27 (1955) 2 SCR 225

11.12 It was submitted that the Impugned notification discriminates between private sector licensed manufacturers and public sector manufacturers as a State monopoly has been created in favour of one public sector company, *viz.* KAPL. It was submitted that the impugned notification is hit by Article 14 of the Constitution of India as being arbitrary, unreasonable, discriminatory and disproportionate.

11.13 By virtue of the Impugned Notification, only one public sector company *viz.* Karnataka Antibiotic and Pharmaceuticals Ltd. ("KAPL"), would be allowed to manufacture the drug for domestic purposes. This would create a monopoly in favour of a public sector corporation, which could have a disastrous effect on the supply and availability of the drug to hospitals and patients in the country. It was further submitted that KAPL is completely inexperienced, since it obtained a license to manufacture the drug as recently as in April 2018 i.e. a couple of weeks before the impugned notification was passed. It was submitted that the manufacturing activity commenced in May 2018, after the impugned notification was passed.

11.14 It was further submitted that the Drug Control Department, Drug Testing Laboratory Karnataka had found that several drugs manufactured by KAPL, as recently as in October 2018 were of Non-Standard Quality (NSQ).

11.15 It was further submitted that on 01.11.2017, the Cabinet Committee on Economic Affairs had given its in-principle approval for the strategic disinvestment of the Central Government's 100% equity stake in KAPL though an auction sale. Since the Central Government owns at least 51% equity stake in KAPL, this would mean that upon such disinvestment KAPL would no longer be a public sector company/undertaking.

11.16 It was contended that the Central Government could not have invoked Section 26A of the Act, since Oxytocin is an "essential drug" enlisted under the NLEM. The NLEM is listed in the 1st Schedule to the DPCO notified by the Central Government in exercise of its powers under Section 3 of the Essential Commodities Act, 1955. It was submitted that power under Section 26A cannot be exercised in respect of NLEM drugs. Section 6 of the EC Act gives the DPCO an overriding effect over other statutes. The impugned notification issued under Section 26A is ultra vires the said provision since it runs counter to the DPCO and the Section 6 of the Essential Commodities Act, 1955.

12. After having heard the Senior Counsel appearing for parties on both sides, we are of the view that the present group of appeals raise serious issues having far reaching implications. The twin issues which arise for consideration are on the one hand, the unregulated and clandestine manufacture of the drug Oxytocin, which is reportedly misused in milch animals; and on the other hand, the continued supply of an essential life-saving drug, which is used as the first line drug for

prevention and treatment of post-partum haemorrhage at the time of childbirth.

The following substantial questions of law arise for consideration:

(i) Whether a drug included in the National List of Essential Medicines published under Schedule 1 of the Drugs (Prices Control) Order, 2013 notified under Section 3 of the Essential Commodities Act, 1955 would be subject to the provisions of Section 26A of the Drugs and Cosmetics Act, 1940?

(ii) Whether the impugned notification has resulted in creating a monopoly in favour of public sector companies, to the complete exclusion of private sector companies, and if so, whether it would be protected by Article 19(6)(ii) read with Article 14 of the Constitution?

(iii) Whether the classification made by the impugned notification between licensed public sector and private sector companies, in the manufacture of the drug Oxytocin for domestic use, would achieve the object and purpose of preventing the unregulated and illegal use of the drug?

(iv) Whether it would be in public interest to restrict the manufacture of a life-saving drug for domestic use, to a single public sector undertaking, to the complete exclusion of the private sector companies, particularly in view of the high maternal mortality rates in the country?

(v) Whether there was relevant and objective material before the Central Government to form the basis of satisfaction to exercise the power to prohibit the manufacture of the drug by the private sector companies for domestic use, under Section 26A of the Drugs and Cosmetics Act, 1940?

(vi) Whether the object of curbing the clandestine manufacture and unregulated use of the drug Oxytocin, which is covered by Section 18 of the Drugs and Cosmetics Act, 1940, can be achieved by taking recourse to Section 26A by imposing a ban on the manufacture of licensed drugs by private sector companies?

(vii) Whether the exercise of power by the Central Government under Section 26A of the Drugs and Cosmetics Act, 1940 is legislative or executive in nature?

13. We are of the considered view that this is a fit case to refer the matter to a larger Bench of three Judges to consider the aforesaid questions of law, and authoritatively pronounce upon the same. Accordingly, we direct the Registry to place the present group of appeals before the Hon'ble Chief Justice of India for necessary directions.

.....J.
(ABHAY MANOHAR SAPRE)

.....J.
(INDU MALHOTRA)

New Delhi;
August 22, 2019.

REPORTABLE

IN THE SUPREME COURT OF INDIA

CIVIL APPELLATE JURISDICTION

CIVIL APPEAL Nos.6588-6591 OF 2019
(Arising out of S.L.P.(C) Nos.3296-3299 of 2019)

Union of India & Anr. Etc.Etc. ....Appellant(s)

VERSUS

BGP Products Operations GMBH
& Hagene Immermatt Weg. & Anr.
Etc.Etc. ....Respondent(s)

J U D G M E N T

Abhay Manohar Sapre, J.

1. I have had the advantage of going through an elaborate drafted judgment proposed by my learned sister Justice Indu Malhotra. I entirely agree with the reasoning and the conclusion arrived at by her.

2. I need not set out the facts and submissions of learned counsel for the parties as the same have been succinctly set out by my learned sister in her draft judgment.

3. Indeed, having heard very learned and persuasive arguments of Mr. Tushar Mehta, learned Solicitor General for the appellants and Mr. Kapil Sibal, learned senior counsel for the respondents at length and on perusal of the record, I am also of the considered opinion that having regard to the nature of controversy and the myriad issues, which arise in the appeals, they have far reaching consequences on the rights of the citizens *qua* State and, in particular, the abstract legal issues such as what is the nature of powers exercised by the Central Government under Section 26-A of the Drugs and Cosmetics Act, whether it is legislative or executive, because we find that there is no decision of this Court so far on this issue. (see observations of this Court in **Union of India & Anr. vs. Pfizer Ltd. & Ors.,** 2018 (2) SCC 39)

4. Secondly, what are the essential ingredients for invoking the powers under Section 26-A of the Drugs and Cosmetics Act in relation to any Drug and

whether such power is in conflict with the exercise of powers conferred under the Essential Commodities Act.

5. Thirdly, whether issuance of impugned notification has resulted in creating monopoly (whether partial or full) in favour of the State and, if so, whether it has satisfied the rigor of Article 14 read with Article 19 (6)(ii) of the Constitution of India.

6. Lastly, depending upon the answer to the nature of exercise of powers under Section 26-A of the Drugs and Cosmetics Act, whether material relied on by the Central Government can be held as sufficient to sustain the impugned action.

7. In my opinion, if the exercise of power under Section 26-A of the Drugs and Cosmetics Act is held as being legislative in nature, the parameters to examine the legality of the impugned notification would be different whereas if it is held to be executive in nature, the parameters to examine the legality of

impugned notification would be somewhat different than the former one.

8. In my considered opinion, the decision either way on any of these questions will have its far reaching effect on the rights and health of public at large and especially on the rights and health of the teenage girls, pregnant females and milching animals. It will also decide the scope of the powers of the Central Government under Section 26-A of the Drugs and Cosmetics Act *qua* the rights of the persons, who are engaged in business of manufacture and sale of Drugs specified under the Drugs and Cosmetics Act read with Essential Commodities Act.

9. In effect, in my opinion, it will not be a judgment inter party but it will be in *rem* laying down the law on the questions.

10. It is for all these reasons, we have formulated the questions for being answered on their respective

merits in paragraph 12 of my sister's drafted judgment.

11. Let the matter, therefore, be placed before Hon'ble the Chief Justice of India under Rule VI (2) of the Supreme Court Rules for being dealt with by the larger bench for their authoritative pronouncement on the questions framed and for the disposal of the appeals accordingly.

12. Since I have also formed an opinion to refer the matter to be dealt with by the larger bench under VI (2) of the Supreme Court Rules, I also do not consider it necessary to give my opinion in detail on the questions formulated.

.....J
[ABHAY MANOHAR SAPRE]

New Delhi;
August 22, 2019