Before Rakesh Kumar Jain, J.

M/S NARANG MEDICAL STORE—*Petitioner*

versus

UNION OF INDIA AND OTHERS—*Respondents*

CWP No.7135 of 2014

January 28, 2016

Drugs And Cosmetics Act, 1940—S.26A—Active Pharmaceutical Drug—Supply of—Petitioner, a wholesaler chemist and druggist, challenged validity of notification dated 17.01.2014, issued under Section 26A of the Drugs and Cosmetics Act, by which sale/supply of Active Pharmaceutical Drug/Ingredient regulated to the effect that the manufacturers of the bulk Oxytocin drug supply the API only to the manufacturers, licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug—Held, risk involved to the health of animals, much less the milch animals, discussed in detail—Use at alarming rate by dairy owners—For augmenting milk produce—Powers of Central Government to prohibit manufacture, of drug and cosmetic in public interest—Drug does not have therapeutic value claimed—Manufacture, sale or distribution of such drug or cosmetic can be restricted or prohibited by Central Government—There were reasons with Government to issue the impugned notification—No error of jurisdiction by respondents in issuing impugned notification—Petition dismissed.

Held that, the petitioner, a wholesaler chemist and druggist, has challenged the validity of the notification dated 17.01.2014, issued under Section 26-A of the Drugs and Cosmetics Act, 1940 (for short "the Act") by which sale/supply of the Active Pharmaceutical Drug/Ingredient (for short "API") has been regulated to the effect that the manufacturers of the bulk Oxytocin drug shall supply the API only to the manufacturers, licensed under the Drugs and Cosmetics Rules, 1945 (for short "the Rules") for manufacture of formulations of the said drug. The text of the notification, for the ready reference, is reproduced as under:-

> "G.S.R. 29 (E)- 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 the 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 26-A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby directs that 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.

The order shall come into force on the date of its publications in the Official Gazette."

(Para 1)

Further held that, oxytocin is a prescription drug mentioned at Sr. No.382 of Schedule-H in the Rules. It is provided in Section 65(2) of the Rules that the supply, otherwise than by way of wholesale dealing of any drug, on the prescription of a Registered Medical Practitioner shall be effected only by or under the personal supervision of a registered pharmacist. It is further provided in Rule 97(1)(b) of the Rules that the container of a medicine specified in Schedule H be labelled with the symbol Rx, conspicuously displayed on the left top corner of the label and be also labelled with the following words:-

"Schedule H drug Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only"

(Para 2)

Further held that, it may be mentioned that the word used by the Legislature in Section 26A of the Act is "or" and not "and" wherein it is provided that if the Central Government is satisfied that the use of any drug or cosmetic likely to involve any risk to human beings or animals "or" that drug does not have the therapeutic value claimed or purported to be claimed, in that event, the manufacture, sale or distribution of such drug or cosmetic can be restricted or prohibited by the Central Government. (Para 17)

Further held that, the risk involved to the health of the animals much-less the milch animals has been discussed in detail because it is being used on the alarming rate by the dairy owners for the purpose of augmenting their milk produce, though it has also been found that it has medicinal value in certain conditions like induction and augmentation of labour, to control post partum bleeding and uterine hypo tonicity and to remove placenta etc. and it need not to be prohibited, but in order to avoid its misuse in between the process of manufacturing the bulk drug (API) to the final drug formulations/injections by the other manufacturer, the presence of the wholesaler of the API has been dispensed with in the public interest. Thus, it cannot be said that there was no reason with the Government to issue the impugned notification.

(Para 18)

Akshay Jain, Advocate,
for the petitioner.

Vivek Singla, Advocate
for the UOI.

RAKESH KUMAR JAIN, J.

(1) The petitioner, a wholesaler chemist and druggist, has challenged the validity of the notification dated 17.01.2014, issued under Section 26-A of the Drugs and Cosmetics Act, 1940 (for short "the Act") by which sale/supply of the Active Pharmaceutical Drug/Ingredient (for short "API") has been regulated to the effect that the manufacturers of the bulk Oxytocin drug shall supply the API only to the manufacturers, licensed under the Drugs and Cosmetics Rules, 1945 (for short "the Rules") for manufacture of formulations of the said drug. The text of the notification, for the ready reference, is reproduced as under:-

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2. The formulations meant for veterinary use shall be sold to the veterinary hospitals only.

The order shall come into force on the date of its publications in the Official Gazette."

(2) Oxytocin is a prescription drug mentioned at Sr. No.382 of Schedule-H in the Rules. It is provided in Section 65(2) of the Rules that the supply, otherwise than by way of wholesale dealing of any drug, on the prescription of a Registered Medical Practitioner shall be effected only by or under the personal supervision of a registered pharmacist. It is further provided in Rule 97(1)(b) of the Rules that the container of a medicine specified in Schedule H be labelled with the symbol Rx, conspicuously displayed on the left top corner of the label and be also labelled with the following words:-

"Schedule H drug Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only"

(3) The petitioner's grievance against the notification is regarding its exclusion from the chain of supply of API (bulk drug) from its manufacturer to the manufacturer of the formulations/injections, by illegally invoking the provisions of Section 26-A of the Act.

(4) In order to understand and appreciate the issue raised by the petitioner, it would be relevant to refer to the definition of "active pharmaceutical ingredients or bulk drug" (API) and the "formulation". The "active pharmaceutical ingredients or bulk drug" is not defined in the Act or the Rules but it is defined in Section 2(b) of the Drug Price Control Order, 2013 (for short "Price Control Order"), which reads as under:-

"**active pharmaceutical ingredients or bulk drug"** means any pharmaceutical, chemical, biological or plant product

including its salts, esters, isomers, analogues and derivatives, conforming to standards specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and which is used as such or as an ingredient in any formulation;"

(5) Similarly, Section 2(i) of the Price Control Order defines "formulation", which reads as under:-

"**formulation"** means a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include-

(i) anymedicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines;

(ii) any medicine included in the Homeopathic system of medicine; and

(iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply;"

(6) Section 26-A of the Act, under which the notification has been issued, for the ready reference, is also reproduced here-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."

(7) The following features of Section 26A of the Act may be highlighted on its dissection:-

1. Satisfaction of the Central Government;
2. That satisfaction has to relate to:

a. likely to involve risk to humans or animals, or

b. it does not have any therapeutic value as claimed or purported to be claimed for it, or

c. it contains ingredients and in such quantity for which there is no therapeutic justification; and

3. It is necessary or expedient in pubic interest to do so.

(8) It is needless to mention that the vires of Section 26A of the Act has already been upheld by the Division Bench of the Delhi High Court in the case of ***M/s. E. Merck (India) Ltd. and another*** versus ***Union of India and another***[1], in which the following observations have been made:-

> "18. The intention of the legislature is that the drugs which are hazardous or without therapeutic value or without any therapeutic justification should not be allowed to be manufactured, sold or distributed. The provision made has laudable objective and it is clearly a reasonable restriction on the freedom of carrying business by any person. In fact in Cynamide India case (supra) challenge to vires of Section 26A of the Act was repelled by Supreme Court. Further, the ingredients mentioned above clearly spell out that the power given to the Central Government is neither uncontrolled nor unguided. A particular drug would be banned only if the Government is satisfied about the hazardous nature of the drug or its nil therapeutic value, or no therapeutic justification. Above all, the Government is also to be satisfied that public interest warrants such prohibition. All these factors constitute definite guide-lines to the Central Government before it acts to issue the Notification under Section 26A of the Act prohibiting manufacture, sale or distribution of a drug or cosmetic and therefore removes the element of arbitrariness.
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> 19. For such a provision to sustain it is not necessary that statutory appeal has to be provided. Even in the absence of statutory appeal the aggrieved person has the constitutional remedy of challenging the Notification by filing Writ Petition under Article 226 to the High Court or under Article 32 to the Supreme Court. The Scheme of the Act further

[1] 2001 AIR (Delhi) 326

> provides for constitution of Drugs Technical Advisory Board, Central Drugs Laboratory and Drugs Consultative Committee for the purpose of carrying out the functions assigned to it by the Act. Before the Government records its satisfaction to prohibit the manufacture, sale, distribution etc. of a particular drug, opinion of the DTAB and/or Drugs Consultative Committee is obtained. Whenever decision of the Central Government taken under Section 26A of the Act is challenged, while exercising the power of judicial review of such a decision the Court can go into the question as to whether the satisfaction was based on material, which was relevant and germane to the issue and that it was not an arbitrary exercise of power. Thus, we hold that provision of Section 26A are not ultra vires the Constitution of India."

(9) Counsel for the petitioner has argued that the first ingredient of Section 26A of the Act is the satisfaction of the Central Government, which has not been disclosed in the notification, therefore, the notification is bad in law. In this regard, he has relied upon a judgment of the Madras High Court in the case of ***CIPLA Ltd., Regional Office, 106/A, Allapakkam Main Road, Allapakkam, Chennai 600 116, rep. by Depot Manager*** versus **Union of India, through Secretary, Ministry of Health and *Family Welfare, FDA Bhavan, ITO Kotla Road, New Delhi-110 002 and another***[2].

(10) In the cited judgment, the challenge was to the notification dated 10.02.2011 by which the drug Phenylpropanolamine (for short "PPA"), a synthetic sympathomimetic amine which is commonly used in cough and cold preparations and as a nasal decongestant and respirator, was banned by the Government by way of the impugned notification, claiming that the Government is satisfied that there are risks in the use of PPA and that safer alternatives are available. The Court had found that though the ban has been imposed in the pubic interest but it is without consultation of the Drugs Technical Advisory Board (for short "DTAB") and the Drugs Consultative Committee (for short "DCC"). The relevant discussion in this regard is reproduced as under:-

> "65. It is to be next decided regarding the Government's power to regulate, restrict or prohibit the manufacture, sale, distribution of drugs and cosmetics in public interest, and as

[2] 2012(7) R.C.R. (Civil) 471

to under what circumstances, how that power is to be exercised to prohibit a drug. Section 26-A of the Act deals with the power of Central Government to regulate or restrict, manufacture, etc., of drug in public interest and Section 26-A of the Act mandates that, "without prejudice to any other provision contained in this Chapter (i.e. Chapter-IV relating to manufacture, sale and distribution of drugs and cosmetics), 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."

66. In the absence of the consultative process and the advise of the DTAB, it is to be seen as to whether the Central Government has satisfaction to prohibit a drug, in this case, PPA. The Supreme Court, in the case of ***Systopic Laboratories (Pvt.) Ltd.*** versus ***Dr.Prem Gupta (1994 Supp (1) SCC 160)***, considered about the satisfaction of the Central Government. In paragraph 19 of the said case, the Supreme Court held as follows:

"19. Having considered the submissions made by the learned counsel for the petitioners and the learned Additional Solicitor General in this regard, we must express our inability to make an assessment about the relative merits of the various studies and reports which have been placed before us. Such an evaluation is required to be done by the Central Government while exercising its powers under Section 26-A of the Act on the basis of expert advice and the Act makes provision for obtaining such advice through the Board and the DCC."

67. Further, in a decision of the Delhi High Court reported in **AIR 2001 Delhi 326 = CDJ 2000 DHC 1111 (E.Merck India Limited** versus **Union of India)**, in paragraph 18, it was held as follows:

"18. Before imposition of such ban following ingredients as

contained in Section 26-A of the Act are to be fulfilled : (i)Satisfaction of the Central Government; (ii)Satisfaction has to relate to: (a) likely to involve risk to humans and animals or (b) it does not have a therapeutic value as claimed or purported to be claimed for it; or (c) it contains ingredients and in such quantity for which there is no therapeutic justification; (iii) it is necessary or expedient in public interest to do so."

68. The ratio laid down in the above decisions would manifestly makes it clear that it is mandatory that the Central Government, while exercising its power under Section 26-A of the Act, shall act on the basis of the expert advise through the DTAB and DCC and in examining this case, on a perusal of the entire records, it would reveal that it is admitted fact that the Government of India was not having the DTAB during the relevant period of time and only based on the Expert Committee's opinion, they have to come to such a conclusion without taking the necessary advise from the expert body as constituted under Section 5(2) and 5(5) of the Act. This Court has no other option except to hold that it is no doubt true that the Government is empowered to prohibit any drug which is likely to involve any risk to human-beings and that any drug does not have a therapeutic value claimed or purported to be claimed for it or contains the ingredients and in such quantity, as there is no therapeutic justification and that in public interest, it is necessary or expedient to do so, and it can be done only with the satisfaction and for that purpose it is mandatorily provided that the DTAB is an advisory body to take such a decision."

(11) It may be pertinent to mention that Section 5 of the Act provides for the DTAB and its duty is to advise the Central Government and the State Government on technical matters arising out of the administration of the Act and to carry out the other functions assigned to it by the Act. Section 7 of the Act provides for constitution of the DCC and its duty is to advise the Central Government, the State Governments and the DTAB on any matter tending to secure uniformity throughout India in the administration of the Act.

(12) In the present case, 46th meeting of the DCC was held on 12/13-11-2013 to consider the issue of misuse of Oxytocin injection by

the dairy owners to extract milk from milch animals and its harmful effects, under agenda no.1, the proceedings of the aforesaid meeting, under agenda item no.1 are as under:-

> "Smt. Maneka Gandhi, MP, Lok Sabha has written to the Secretary, Ministry of Health and Family Welfare regarding the 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 as well as on the consumers. Even though the drug is considered as an essential drug in medical practice for certain conditions in human as well as veterinary field, the alleged abundant availability and use of the drug, in a clandestine way is a matter of great concern for public health.
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> The drug oxytocin has medical use for induction and augmentation of labour, to control post partum bleeding and uterine hypo tonicity. The sale of the oxytocin injection is regulated under Schedule H of the Drugs and Cosmetics Rules, 1945 which require the drug to be dispensed on the prescription of a Registered Medical Practitioner only. Further, to avoid its bulk sale oxytocin injection is required to be packed in single unit blister pack only.
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> The use of oxytocin injection for extracting milk from milch animals is also prohibited under the Cruelty to Animals Act, 1960. It is provided under section 11(1)(c) that if any person willfully and unreasonably administers any injurious drug or injurious substance to any animal or willfully and unreasonably causes or attempts to cause any such drug or substance to be taken by any animal, he is punishable under the Act.
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> In spite of the above provisions 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. The office DCG(I) had earlier also 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 provisions 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 behandled 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 matter was earlier considered in the 44th DCC held on 20th July, 2012 and the following recommendations were made:-

"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."

The matter has again been brought for the consideration of the DCC as to know what measures have since been taken by the concerned State Licensing Authorities and whether more stringent actions are called for ensuring that clandestine manufacture and unauthorized diversion of the oxytocin injections does not take place to the dairy owners."

(13) The recommendations of the DCC on the aforesaid agenda no.1 is also reproduced as under:-

"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."

(14) The DTAB also held its 65th meeting on 25.11.2013 in which again the same issue was discussed under agenda no.4 and for the ready reference, proceedings of agenda no.4 are also reproduced as under:-

"**CONSIDERATION OF THE ISSUE OF MISUSE OF OXYTOCIN INJECTION BY THE DAIRY OWNERS TO EXTRACT MILK FROM MILCH ANIMALS AND ITS HARMFUL EFFECTS**

The Members were briefed 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 as well as on the consumers was raised by Smt. Maneka Gandhi, Member of Parliament, Lok Sabha. The drug oxytocin has medical use for induction and augmentation of labour, to control post partum bleeding and uterine hypo tonicity. The alleged abundant availability and use of the drug in a clandestine way, however, is a matter of great concern for public health.

Under the Drugs & Cosmetics Rules, 1945, the sale of the oxytocin injection is regulated under Schedule H of the said Rules which require the drug to be dispensed on the prescription of a Registered Medical Practitioner only. Further, to avoid its bulk sale, oxytocin injection, a provision was made that the Oxytocin Injection shall be packed in single unit blister pack only.

In spite of the above provisions, the reports of

manufacture and sale of the drug in clandestine way in large quantities and its misuse by the farmers or dairy owners have been received from time to time and matter was raised on various forums. 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, 1940.

The matter was considered in the 46th meeting of the Drugs Consultative Committee held on 12th & 13th November, 2013 and the committee 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 manufactures of bulk drugs should supply the active pharmaceutical drug only to the manufacturers licensed for manufacture of formulations for human use.

The Department of Animal Husbandry, Dairying and Fisheries, Ministry of Agriculture, whose opinion was sought in respect of banning of Oxytocin for Animal use has opined that the ban on 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. However, that drug should be used strictly with the prescription of the veterinarian.

Dr. A.K.Tiwari, from IVRI also agreed that the drug has definite use in veterinary practice and as such should not be prohibited.

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."

(15) Thus, after taking into consideration the advice of the DCC

and the DTAB, the Central Government was satisfied and exercised its powers under Section 26A of the Act, therefore, it is not the case like ***CIPLA's*** case (supra) where there was no consultation or advice to the Central Government before the notification was issued to ban the PPA.

(16) Further submission made by counsel for the petitioner is that in order to apply Section 26A of the Act, all the ingredients have to be fulfilled and since it is mentioned in the notification that drug Oxytocin has a definite therapeutic use, therefore, the said provision could not have been invoked for the issuance of the notification regulating the sale/supply of API of Oxytocin by the manufacturer to the manufacturer of the formulations/injections.

(17) It may be mentioned that the word used by the Legislature in Section 26A of the Act is "or" and not "and" wherein it is provided that if the Central Government is satisfied that the use of any drug or cosmetic likely to involve any risk to human beings or animals "or" that drug does not have the therapeutic value claimed or purported to be claimed, in that event, the manufacture, sale or distribution of such drug or cosmetic can be restricted or prohibited by the Central Government.

(18) In the present case, the risk involved to the health of the animals much-less the milch animals has been discussed in detail because it is being used on the alarming rate by the dairy owners for the purpose of augmenting their milk produce, though it has also been found that it has medicinal value in certain conditions like induction and augmentation of labour, to control post partum bleeding and uterine hypo tonicity and to remove placenta etc. and it need not to be prohibited, but in order to avoid its misuse in between the process of manufacturing the bulk drug (API) to the final drug formulations/injections by the other manufacturer, the presence of the wholesaler of the API has been dispensed with in the public interest. Thus, it cannot be said that there was no reason with the Government to issue the impugned notification.

(19) In view thereof, looking from any angle, there is no error of jurisdiction on the part of the respondents in the issuance of the impugned notification and consequently, the present writ petition is hereby dismissed being denuded of any merit.

(20) No costs.

Shubreet Kaur