

(2016) 03 P&H CK 0158
In the Punjab And Haryana At Chandigarh
Case No : LPA No. 444 of 2016 (O&M).

M/s Narang Medical Store

APPELLANT

Vs

Union of India and Others

RESPONDENT

Date of Decision : 22-03-2016

Acts Referred:

Drugs and Cosmetics Act, 1940 — Section 26-A

Citation : (2016) 4 CriCC 703 : (2016) 3 RCRCivil 572 : (2016) 3 RCRCriminal 421

Hon'ble Judges : Mahesh Grover;Mrs. Justice Lisa Gill, JJ.

Bench : Division Bench

Advocate : Gaurav Chopra, Advocate, for the Appellant

Final Decision : Dismissed

Judgement

Mahesh Grover, J. - CM No. 966-LPA of 2016

1. For the reasons mentioned in the application, delay of 16 days in filing the present appeal is condoned.
2. Application stands allowed.

LPA No. 444 of 2016

1. The appellant is in appeal against the judgment of the learned Single Judge dated 28.1.2016.
2. While preferring a civil writ petition bearing No.7135 of 2014, out of which the impugned judgment has emerged, the appellant had challenged a notification issued by the Ministry of Health and Family Welfare, Government of India, seeking to restrict and regulate the sale of a drug by the name of Oxytocin while exercising its powers under Section 26-A of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as "the Act").
3. The portion of the notification offensive to the petitioner's cause may be

extracted here below :-

"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."

4. Before the writ court as also this Court in appeal the argument has been similar that power under Section 26A of the Act can be exercised in three eventualities envisaged in the statute itself where, upon the satisfaction to be recorded, Central Government prohibits, regulates or restricts the use of a drug or cosmetic which is (i) likely to involve any risk to human beings or animals; (ii) the drug does not have the therapeutic value claimed or purported to be claimed; and (iii) it contains ingredients in such quantity for which there is no therapeutic justification.

5. Apart from this, notification is pleaded to be discriminatory and in violation of Article 14 of the Constitution of India.

6. Learned counsel for the appellant contends that the report of the Committee which led to the eventual issuance of the notification does not reflect any conscious thought to conclude in the manner indicated in the statute i.e. Section 26-A. According to him, there should have been a specific finding based on requisite material that the drug or cosmetic which is the subject matter of the intended regulation restriction or prohibition is likely to involve any risk to human beings and it does not have the therapeutic value claimed or has ingredients in excess of the therapeutic justification.

7. We have perused the experts' report and their opinion arrived at in the 65th meeting of Drugs Technical Advisory Board and would like to quote the relevant portion therefrom :-

".....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 of public health."

.....

"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 practise 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."

8. The notification which succeeded this deliberation virtually pirates the language of the expert body.

9. We are not inclined to agree with the contention raised by the learned counsel for the appellant as we are of the opinion that even if the best case of the appellant regarding notification"s conflict with intent and content of Section 26-A is accepted, it does not give him an absolute right to insist that he be given the right to stock and sell this particular drug simply because he is a licensed dealer under the Act.

10. There is a conscious thought which has gone into the issuance of notification that drug Oxytocin is essential for medical use in certain conditions for expulsion of foetus, retention of placenta and other related use which can be determined only by a mind trained in medicine. The report further goes on to acknowledge the rampant abuse of the drug by people at large who have access to this drug across the counter. It is for a good reason that this drug has been placed in Schedule-H of the Drugs and Cosmetics Act to be sold on the strength of a prescription of the Medical Practitioner. The notification intends to largely ensure this very objective. We would thus find no reason to interfere in the judgment of the learned Single Judge particularly when we are further of the opinion that the conditions envisaged in Section 26-A to warrant its use cannot be construed to be restricted to these three eventualities and it is largely the public interest which would command and dictate the exercise of such powers to be sustained on the basis of deliberations which in our considered opinion have been done by a body of experts. Merely because it does not employ and incorporate a certain language of the statute to conclude that it is risky to human beings and animals would be of no consequence and would not enhance the case of the appellant in any way for the reason that we have observed that Section 26-A and the exigencies noticed therein are not restrictive and in fact exercise of such a power

has to be driven by the underlying principle of public interest which is evident from the report of the expert committee where all concerns of Section 26-A manifest themselves even though the purity of the language of the statute has not been adopted. The experts acknowledge that it is a useful drug but to be made available through a regulatory process.

11. The argument that the aforesaid notification is violative of Article 14 of the Constitution of India would ring hollow as we are of the opinion that the classification brought out by the notification to regulate use and sale of the drug in question is based on a reasonable classification dictated largely by public interest as encompassed in Section 26-A. It does not exclude or include any particular class to the prejudice of any and only prescribes a regulated procedure applicable to all.

12. No other point has been argued.

13. No ground to interfere.

14. Dismissed.