IN THE HIGH COURT OF DELHI AT NEW DELHI

% Judgment delivered on: 18.02.2019

+ **W.P.(C) 10220/2018 & CM Appln. No.39861/2018**

HETERO HEALTHCARE LTD. ..... Petitioner

Versus

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

WITH

+ **W.P.(C) 12107/2018 & CM Appln. Nos.46974/2018**

BIOSTRASS THERAPEUTICS INC. ..... Petitioner

Versus

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

Advocates who appeared in this case:

For the Petitioners: Mr. Abhinav Vasisht, Sr. Adv. with Ms. Bina Gupta, Ms. Priya Singh, Mr. Kshitij Vaibhav, Mr. Avinash Tripathi and Binay Kumar.

For the Respondents: Ms Maninder Acharya, ASG Mr Anurag Ahluwalia, CGSC with Mr Abhimanyu Singh, Mr Abhigyan Sidhant and Mr Viplav Acharya.

CORAM
HON'BLE MR JUSTICE VIBHU BAKHRU

JUDGMENT

VIBHU BAKHRU, J

1. The petitioners have filed the present petitions impugning a notification (No. S.O. 4429(E)) issued by respondent no. 1 dated 07.09.2018 (hereafter 'the impugned notification'), proscribing the

Combikit of (i) Azithromycin; (ii) Secnidazole; and (iii) Fluconazole (hereafter referred to as 'the Combikit'). The impugned notification has been issued in exercise of powers under Section 26A of the Drugs and Cosmetics Act, 1940 (hereafter 'the Act'). It is the petitioners' case that the Combikit is not a drug or a fixed drug combination (FDC), but comprises of three separate drugs, which are administered at separate times. It is further contended that the Combikit is only a convenient package of three separate drugs in question and, therefore, the same could not have been considered as FDC.

Factual Background

2. The petitioner in W.P.(C) 10220/2018 manufactures and markets the Combikit under the brand name of "FAS-3 KIT", whereas the petitioner in W.P.(C) 12107/2018 is, *inter alia*, engaged in the manufacturing and marketing of a Combikit of the aforesaid combination, which is being sold under the brand name "CANTRAS KIT".

3. The Combikit is recommended for syndromic management and treatment of STDs, as each individual formulation operates as an anti-bacterial, anti-fungal and anti-trichomonal treatment.

4. The Central Drugs Standard Control Organization (CDSCO) had constituted an Expert Committee comprising of ten experts for examining the efficacy of various FDCs which were manufactured and sold in the market by various pharmaceutical companies. The Expert Committee so constituted did not recommend the Combikit. A similar

view was expressed by another Expert Committee constituted by the Central Government and headed by Prof. C.K. Kokate, Vice-Chancellor of KLE University of Belgaum, Karnataka (hereafter 'the Kokate Committee').

5. In view of the recommendations of the Expert Committee, the Central Government while exercising its power under Section 26A of the Act, issued 344 notifications dated 10.03.2016, prohibiting the manufacture, sale and distribution of 344 FDCs. The said 344 notifications also included the impugned notification, whereby the Central Government prohibited the manufacture, sale and distribution of the Combikit.

6. The impugned notification was challenged by the petitioners before this Court on several grounds including that the same had been issued without consultation with the Drugs Technical Advisory Board (DTAB). According to the petitioners, such consultation was mandatory and the failure on the part of the Central Government to do so had rendered the said notifications invalid.

7. The said petitions were considered along with a batch of petitions, which were disposed of by a common judgment dated 01.12.2016, whereby the impugned notification, along with other notifications, was set aside. Aggrieved by the said decision, the respondents preferred appeals and transfer petitions before the Supreme Court. The said petitions were disposed of by the common judgment in ***Union of India v. Pfizer Limited and Ors.: 2018 (2) SCC 39***. The Supreme Court did not

accept the view expressed by this Court that consultation with the DTAB was mandatory for issuing notifications under Section 26A of the Act. However, in the peculiar facts of the cases and considering that the recommendations made by the Kokate Committee were not clear, the Supreme Court remanded the matter to the DTAB/Sub-Committee to deliberate the matter, keeping in view the parameters as set out under Section 26A of the Act.

8. Thereafter, the DTAB recommended the constitution of a Sub-Committee under the Chairmanship of Dr Nilima Kshirsagar to review the matter pertaining to 344 + 5 FDCs that were the subject matter of petitions before the Supreme Court. In view of the aforesaid recommendations, a Sub-Committee was constituted by an Office Memorandum dated 19.02.2018. Admittedly, notices were issued inviting drug manufacturers and other concerned agencies to furnish information in the prescribed form. Thereafter, the Sub-Committee also heard the concerned parties and, subsequently, made the recommendations. It recommended prohibition on the manufacture and sale of the Combikit.

9. The report made by the Sub-Committee in respect of the Combikit indicated the following observations in support of their recommendations:

> "1. The three diseases most frequently associated with vaginal discharge are Bacterial vaginosis, T. vaginalis infection and candidiasis, (CDC STD Treatment guidelines), There is no role of azithromycin in the treatment any of these infections.

2. For the syndromic management of vaginal discharge, the National Guidelines on Prevention, Management and Control of Reproductive Tract Infections and Sexually Transmitted infections (July 2014) recommend: Tab Secnidazole 2gm orally, single dose (OR Tab, Tinidazole 500 mg orally, twice daily for 5days OR Tab Metronidazole 400mg, twice daily for 7 days)

Plus Tab Fluconaizole 150 mg orally single dose OR local Clotrimazole 500 mg vaginal pessary once.

Azithfomycin is not mentioned here.

The National & International Standard Treatment guidelines for the management of PID, the anti-microbial combination recommended are Cefrazone + Doxycyclino + Metronidazole and for the vaginal discharge Tinidazole + Clindamycin + Fluconazole. Azithromycin is not mentioned as combination therapy in both of the above conditions. Azithromycin is mentioned for the use in Cervicitis/Urethritis/ Mucopurilent Gonococcal in combination with Ceftriaxone.

3. The combination of the three drugs in the treatment of indications mentioned by the company is not recommended by standard therapeutic guidelines.

The combikit of Fluconazole tablet, Azithiomycin tablet and Omidazole tablet was already considered as irrational by DTAB under the 294 FDCs category. –

The above combikit is similar in nature and hence should be considered is the same category as already considered as irrational by DTAB.

There is no convincing scientific/ clinical evidence/justification for the combikit."

10. In view of the aforesaid observations, the Sub-Committee recommended prohibiting the Combikit in question. The recommendations made by the Sub-Committee are set out below:-

> "There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.
>
> Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26A of Drugs and Cosmetics Act, 1940.
>
> In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended."

11. The said report was accepted and the Central Government issued the impugned notification, banning the Combikit. Aggrieved by the same, the petitioners have preferred the present petitions.

Reasons and Conclusion

12. At the outset, it will be relevant to refer to Section 26A of the Act, which 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, 124 [regulate, restrict or prohibit] the manufacture, sale or distribution of such drug or cosmetic.]"

13. A plain reading of Section 26A of the Act indicates that the Central Government is empowered to regulate, restrict or prohibit the manufacture, sale or distribution of any such drug or cosmetic, that is, (a) likely to involve any risk to human beings or animals, or (b) a drug which does not have the therapeutic value claimed or purported to be claimed for or contains ingredients, and in such quantity for which there is no therapeutic justification, and (c) where it is necessary to do so in public interest.

14. In the present case, there can be no dispute that the Combikit is not a drug. The Combikit comprises of three different types of tablets: (i) One Tablet of Fluconazole 150mg; (ii) one Tablet of Azithromycin 1gm; and (iii) two tablets of Secnidazole 1gm tablet. The four tablets are packaged in a single strip and sold as the Combikit. The petitioner is licensed to manufacture each of the said formulations.

15. It is also relevant to note that the batch number of each of the drugs is separate and is separately written on the strip as well as on the box in which the strip is packed. Similarly, the date of manufacture and expiry of each of these tablets has been separately printed. In view of the above, there can be little doubt that the Combikit cannot be classified as a drug. It is also not a FDC.

16. It is also relevant to note that the petitioner had applied to the Drug Comptroller General of India (DCGI) for an approval for manufacturing the Combikit as an FDC. The petitioner has produced a letter dated 07.06.1999 issued by the Drugs Comptroller General of India, rejecting the petitioner's application by stating that the Combikit is not a FDC and the petitioner was required to obtain a separate licence for manufacturing the drugs. The contents of the said letter are reproduced below :-

> "To,
>
> Dated, the 7 JUN 1999
>
> M/S. Lyka Labs Limited
>
> 77, Nehru Road,
>
> Vile Parle(B) Mumbal-400099.
>
> Sub:- Combination kit containing Azithromycin 250 Capsules + (4 capsules) + Fluconazole Tablets 150 mg(1 Tablets) + Secnidazole Tablets-lgm(2 Tablets).
>
> Ref:- Your letter dated 11.1.99.
>
> Dear Sirs,
>
> Combi-Kit containing Azithromycin 250 mg(Four Capsules) + Fluconazole 150 mg. (one tablet) + Secnidazole 1 mg(2tablet) for the syndromic management of vaginal discharge is not a fixed dose combination and each ingredient of the kit is not a new drug You are therefore requested to approach S.L.A. to obtain license to manufacture the said combipack.

Yours faithfully,

(A.B. RAMTEKE)

For Drugs Controller General (India)"

17. The photograph of the strip, indicating the manner in which the three drugs are packed, is reproduced below:

18. It is also relevant to note that each of the three drugs forming a part of the Combikit are to be administered at different times and are not to be taken together. This is also printed on the packing: Fluconazole is to be taken after breakfast; Azithromycin is to be taken one hour before lunch; and Secnidazole is to be taken after dinner. This also clearly establishes that the same cannot be treated as single drug or FDC. In view of the above, the provisions of Section 26A of the Act are wholly inapplicable to the Combikit.

19. The sub-committee had examined the Combikit and had recommended that the same be proscribed for the reasons stated therein

(and, as set out hereinbefore)

20. The learned counsel appearing for the respondents has submitted that in view of the observations made by the sub-committee, there could be no dispute that the therapy entailing the drugs comprised in the Combikit was irrational and could not be permitted.

21. This is countered by the petitioners.

22. It is apparent that there is a controversy as to whether there is any therapeutic justification for comprising the three drugs which are included in the Combikit. And, there may be good reasons not to prescribe such therapy. However, the provisions of Section 26A of the Act cannot be pressed into service for proscribing a therapy. As noticed above, the Combikit is not a drug and, therefore, a notification under Section 26A proscribing the same is unsustainable.

23. The Combikit cannot be sold except on a medical prescription prescribing all the three drugs, which are packed in a single strip. Plainly, if that therapy is irrational for the indication, the necessary action would have to be taken against the medical practitioner prescribing the said therapy, however recourse to Section 26A of the Act is unavailable to prohibit prescription of a therapy.

24. The issue relates to packaging of the three separate drugs in one single package. The said issue may also be addressed in the context of the regulations relating to packaging of drugs, if any. However, the powers under Section 26A of the Act cannot be exercised to proscribe

packaging of drugs in any particular manner.

25. The impugned notification is, accordingly, set aside. All pending applications are disposed of. The parties are left to bear their own costs.

VIBHU BAKHRU, J

FEBRUARY 18, 2019
pkv