(2019) 02 DEL CK 0239

In the Delhi High Court

Case No : Civil Writ Petition No. 10917, 10965, 11271 Of 2018, Civil Miscellaneous Application No. 42724, 42725, 43773, 43774, 45389, Of 2018

Lupin Limited And Anr — APPELLANT

Vs

Lupin Limited And Anr — RESPONDENT

Date of Decision : 22-02-2019

Acts Referred:
Drugs And Cosmetics Act, 1940 — Section 5, 26A

Citation : (2019) 3 AD(Delhi) 401 : (2019) 174 DRJ 218

Hon'ble Judges : Vibhu Bakhru, J

Bench : Single Bench

Advocate : Gopal Jain, Ajay Bhargava, Vanita Bhargava, Aseem Chaturvedi, Arvind Ray, Karan Gupta, Maninder Acharya, Kirtiman Singh, Ripu Daman Bhardwaj, Waize Ali Noor, Shruti Dutt, Parth Semwal

Judgement

Vibhu Bakhru, J

1. The petitioners have filed the present petitions impugning notification no. S.O.4479(E)(hereafter 'the impugned notification') issued by the Central Government under Section 26A of the Drugs and Cosmetics Act, 1940 (hereafter 'the Act'), whereby the manufacture, sale and distribution of the Fixed Dose Combination (FDC) of "Pioglitazone 30 mg + Metformin 500 mg" has been proscribed by the Central Government.

2. The Central Government has proscribed the manufacture, sale and distribution of the aforesaid FDC on account of inclusion of the formulation "Pioglitazone 30 mg" in the said FDC. The Sub-committee constituted to examine the matter of proscribing/restricting the said FDC observed that the increased dose of Pioglitazone involves risks to the patients, and further that there is no scientific justification for the said FDC. Accordingly, the Sub-committee had recommended prohibition of the said FDC. Since, the principal issue involved is common, the said petitions were heard together.

3. The impugned notification has been challenged by the petitioners, essentially, on the following grounds:

(i) that the Drug Technical Advisory Board (DTAB) was not in existence at the material time, when the Sub-committee was constituted for examining the matter regarding the FDC in question, and therefore, the constitution of the sub-committee was void.

(ii) that the impugned notifications are based on recommendations, which are unreasoned and made without application of mind.

(iii) That the finding of the Sub-committee, that there are safety concerns regarding Pioglitazone 30 mg, is incorrect and contrary to the material on record.

(iv) that the FDC in question has a sound therapeutic justification and poses no risk to human beings.

(v) that the recommendations made by the Sub-committee of DTAB is not in conformity with the direction issued by the Supreme Court in Union of India v. Pfizer Limited and Ors. : 2018 (2) SCC 39.

4. The respondents countered the aforesaid submissions. The respondents dispute that the directions issued by the Supreme Court in Pfizer Limited (supra) have not been followed. It is also contended that the impugned notification has been issued in exercise of legislative powers and the principles of natural justice are not required to be followed in such exercise.

Factual Background

5. The petitioner in W.P.(C) 10917/2018 manufactures and markets the FDC comprising of "Pioglitazone 30 mg + Metformin 500 mg" under the brand name of "Gluconorm P 30"; the petitioner in W.P.(C) 11271/2018 in engaged in the manufacturing and sale of the FDC comprising of "Pioglitazone Hcl 30 mg + Metformin Hcl 500 mg (Sustained Release - SR) under the brand name of "Glitaris M 30"; and the petitioner in W.P.(C) 10965/2018 manufactures and sells the FDC comprising of "Pioglitazone Hydrochloride IP Equivalent to Pioglitazone 30 mg +Metformin Hydrochloride IP 500 mg (in sustained release form)" under the brand name of "PIO-M 30".

6. The aforesaid FDC (Pioglitazone 30 mg + Metformin 500 mg) is hereafter referred as "the FDC in question".

7. The Central Drugs Standard Control Organization (CDSCO) had constituted an Expert Committee of comprising of ten experts for examining the efficacy of the FDCs which were manufactured and sold in the market by various manufacturers. The Expert Committee so constituted did not recommend the FDC in question. 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 (Kokate Committee).

8. Thereafter, the Central Government issued 344 notifications prohibiting proscribing the manufacture, sale and distribution of 344 FDCs with immediate effect. One of the said notifications - being S.O. No.814(E) - prohibited the manufacture and sale of the FDC in question (Pioglitazone 30 mg and Metformin 500 mg).

9. Aggrieved by the said notification, the petitioners herein preferred writ petitions before this Court challenging the aforesaid notification [S.O. 814(E)], inter alia, on the ground that the same had been issued without consultation with 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.

10. The said petitions were considered alongwith a batch of petitions impugning notifications issued under Section 26A of the Act. These petitions were disposed of by a common judgment dated 01.12.2016. All the aforesaid notifications including S.O. 814(E), were set aside as the Court held holding that it was mandatory for the Central Government to seek consultation of DTAB before issuing the said notifications.

11. 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 Pfizer Ltd. (supra). The Supreme Court did not accept the view expressed by this Court that consultation with 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 Expert Committee (referred to as Kokate Committee) were not clear, the Supreme Court remanded the matter to DTAB/Sub-Committee to deliberate the matter keeping in view the parameters as set out in Section 26A of the Act. The relevant extract of the said decision is set out below:-

"31. On the facts of these cases, a suggested course of action was stated by the learned counsel appearing on behalf of the appellant-petitioners. This course is that instead of now remitting the matter back to the Delhi High Court for an adjudication on the other points raised in the writ petitions, the case of 344 FDCs that have been banned, plus another 5 FDCs that have been banned, which comes to 349 FDCs [barring 15 FDCs that are pre-1988 and 17 FDCs which have DCG(I) approval) pursuant to the Kokate Committee report, by notifications of the Central Government under Section 26-A of the Drugs Act, should be sent to the DTAB, constituted under Section 5 of the Drugs Act, so that it can examine each of these cases and ultimately send a report to the Central Government.We reiterate that only on the peculiar facts of these cases, we think that such a course commends itself to us, which would obviate further litigation and finally set at rest all other contentions raised by the petitioners. We say so because we find that the Kokate Committee did deliberate on the 344 FDCs plus 5 FDCs and did come to a conclusion that the aforesaid FDCs be banned, but we are not clear as to what exactly the reasons for such conclusions are, and whether it was

necessary in the public interest to take the extreme step of prohibiting such FDCs, instead of restricting or regulating their manufacture and supply. In order that an analysis be made in greater depth, we, therefore, feel that these cases should go to the DTAB and/or a sub-committee formed by the DTAB for the purpose of having a relook into these cases. It is important, however, that the DTAB/sub-committee appointed for this purpose will not only hear the petitioners-appellants before us, but that they also hear submissions from the All-India Drugs Action Network. The DTAB/sub-committee set up for this purpose will deliberate on the parameters set out in Section 26-A of the Drugs Act, as follows.

32. First and foremost in each case, the DTAB/Sub-Committee appointed by it must satisfy itself that the use of the Fixed Dose Combinations (FDC) in question is likely to involve any one of the aforesaid three things:

(a) that they are likely to involve any risk to human beings or animals; or

(b) that the said FDCs do not have the therapeutic value claimed or purported to be claimed for them; or

(c) that such FDCs contain ingredients and in such quantity for which there is no therapeutic justification.

33. The DTAB/Sub-Committee must also apply its mind as to whether it is then necessary or expedient, in the larger public interest, to regulate, restrict or prohibit the manufacture, sale or distribution of such FDCs. In short, the DTAB/ Sub-Committee must clearly indicate in its report:

(1) as to why, according to it, any one of the three factors indicated above is attracted;

(2) post such satisfaction, that in the larger public interest, it is necessary or expedient to (i) regulate, (ii) restrict, or (iii) prohibit the manufacture, sale or distribution of such FDCs.

34. The DTAB/Sub-Committee must also indicate in its report as to why, in case it prohibits a particular FDC, restriction or Regulation is not sufficient to control the manufacture and use of the FDC. We request the DTAB/Sub-Committee to be set up for this purpose to afford the necessary hearing to all concerned, and thereafter submit a consolidated report, insofar as these FDCs are concerned, to the Central Government within a period of six months from the date on which this judgment is received by the DTAB. We may also indicate that the Central Government, thereafter, must have due regard to the report of the DTAB and to any other relevant information, and ultimately apply its mind to the parameters contained in Section 26A of the Drugs Act and, accordingly, either maintain the notifications already issued, or modify/substitute them or withdraw them."

12. In compliance to the aforesaid directions, DTAB in its meeting dated 12.02.2018 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 subject matter of petitions before the Supreme Court. In view of the aforesaid recommendations, the Sub-committee was constituted by an Office Memorandum dated 19.02.2018. Thereafter, on 12.03.2018, notices were issued calling upon the drug manufacturers and other concerned agencies to submit information in the prescribed format by 07.04.2018 for further consideration. Thereafter, the Sub-committee also heard the concerned parties and, subsequently, made its recommendations.

13. The report made by the Sub-committee in respect of the FDC in question, comprising of Pioglitazone 30 mg and Metformin 500 mg, indicates the following reasons in support of its recommendations:

"1. The dose titration to increase the dose of Metformin will lead to inadvertent overdose of Pioglitazone with FDC of Pioglitazone 30mg+ Metformin 500mg. This involves risks to the patient population.

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

14. In view of the aforesaid observations, the Sub-committee recommended the prohibition on manufacture and sale of the FDC in question. The recommendations made by the Sub-committee are set out below:-

"Recommendation and grounds/reason for recommending prohibition/restriction/ regulation:

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."

15. The said report was accepted by the Central Government and it issued the impugned notification banning the FDC in question. Aggrieved by the same, the petitioners have preferred the present petition.

Reasons and Conclusion

16. It was contended on behalf of the petitioners that the constitution of the sub-committee is invalid, as it was constituted after the expiry of the term of DTAB. It is stated that the DTAB is reconstituted every three years and it was reconstituted on 29.12.2014, hence, its term expired on 28.12.2017. The petitioners submit that the DTAB was reconstituted on 15.05.2018 and, therefore, it was not a validly constituted body during the period 28.12.2017 to 15.05.2018. The Sub-committee of DTAB was constituted on 12.02.2018, which according to the petitioners, was invalid as it was constituted after the expiry of

the term of DTAB.

17. The aforesaid issue is covered by the decision of this Court in Unison Pharmaceuticals Pvt. Ltd. and other connected matters v. Union of India & Anr.: 10403/2018, decided on 08.01.2019, wherein the contention that there was any flaw in constitution of DTAB or the Sub-committee was rejected. This Court had held that notwithstanding the vacancy caused due to expiry of the term of some of the members, the DTAB would continue to function.

18. Next, it was contended by the respondents that the powers exercised by the Central Government under Section 26A of the Act are legislative powers and, therefore, the principles of natural justice are not applicable. Accordingly, it was contended that the Sub-committee or the Central Government was not required to give any reason for banning any drug. It was further contended that the Sub-committee was constituted by experts in the given subject and thus their recommendations are not amenable to judicial review.

19. The said issue has been examined by this Court in Wockhardt Limited and Anr. v. Union of India and Anr.: W.P.(C) 9739/2018 decided on 07.01.2019. Further, in BGP Products Operations GMBH & Anr. v. Union of India and Ors.: W.P. (C) 6084/2018 and other connected matters, decided on 14.12.2018, the Division Bench of this Court had also considered the scope of judicial review in the context of Section 26A of the Act and held as under:

"91. The Union had contended, with some emphasis, that a notification under Section 26A is pursuant to exercise of legislative power and the courts should therefore, exercise restraint while interfering with it. This court is of opinion that there is no per se bar to reviewing regulatory provisions, even if they are made in the exercise of subordinate legislative power. Such rules or regulations do not per se carry a threshold of immunity greater than what any other instrument, either statutory or non-statutory would. The relevant public law standards applicable would be no different, to adjudge their validity....."

XXXX XXXX XXXX

94. In view of the above discussion and given the nature of the authorities, it is held that the Union's argument that the impugned notification, as it is the product of subordinate legislative exercise, carries a greater immunity than executive policy is without merit. The threshold of immunity in the case of both: executive policy or norms and statutory regulations is the same. The submission is therefore, rejected."

20. At this stage it is relevant to refer to Section 26A of the Act, which reads as under:

"26A. Power 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, prohibit the manufacture, sale or distribution of such drug or cosmetic.]"

21. It is clear from the above that the notifications issued in exercise of powers under Section 26A of the Act are of general application and the power exercised by the Central Government under Section 26A of the Act is legislative in nature. However, such powers can be exercised only if the Central Government is satisfied that it is necessary in larger public interest and further the specified conditions for exercise of such power - the use is likely to involve risk to human beings or animals or the drugs do not have any therapeutic value - are established. Plainly, the Central Government's satisfaction would be required to be based on the relevant material.

22. Thus, the limited questions that fall for consideration of this Court are whether the Central Government's decision to ban the manufacture, sale and distribution of the FDC in question is based on relevant material and whether the directions of the Supreme Court in Pfizer (supra) have been duly complied with.

23. The combination of Pioglitazone 30 mg + Metformin 500 mg is used as a second line treatment for Type - II Diabetes. The DCGI has also approved the FDC comprising of Pioglitazone 15mg/30mg + Metformin ER 1000 mg. The assertion that Pioglitazone 30 mg and Metformin 500 mg could be prescribed in second line therapy for Type - II Diabetes is not disputed by the respondents. Mr Kirtiman Singh, learned counsel appearing for the respondents, submitted that since Pioglitazone 30 mg is a strong drug with significant risks, the Sub-committee had recommended prohibition of the FDC in question on the ground that titration of Metformin - that is, increasing the dose of Metformin - presents an inadvertent risk of Pioglitazone overdose. It is difficult to accept the aforesaid reason as a ground for proscribing the FDC in question, considering that the DCGI has approved FDCs of Pioglitazone 30mg/30mg + Glimepiride 1mg/2mg in uncoated tablet. It has also approved the FDC of Pioglitazone + 30mg + Metformin ER 1000mg. It is also not disputed that Metformin can be prescribed in the dose of upto 2500 mg per day.

24. Thus, the risk of overdose of one of the drugs constituting a FDC would always exist. If the matter is viewed in the context of titration of drugs constituting an FDC; any variation in the dosage of any drug included in an FDC would result in overdose of the other components. Titration of any component drug in an FDC is not feasible. FDCs by their very definition, include formulations in fixed doses.

25. Since, it is not disputed that Pioglitazone 30 mg and Metformin 500 mg can

be prescribed as a second line therapy in Type - II Diabetes, the observation that the FDC in question has no therapeutic justification, cannot be sustained.

26. If the Sub-committee was of the view that Pioglitazone in the strength of 30 mg would provide a significant risk of overdose in an FDC, it would have been apposite for all FDCs including Pioglitazone 30 mg as a component to be proscribed. However, since all FDCs, which include Pioglitazone 30 mg have not be proscribed, the reason as provided by Sub-Committee lacks clarity.

27. It is also relevant to note that the Supreme Court had given a specific direction that in cases where the DTAB/Sub-committee prohibits a particular FDC, it would also give its reasons as to why restricting or recalling the said FDC, would not be sufficient to control the manufacture and use of that FDC. In the present case, the Sub-committee had highlighted a risk of overdose, however, it did not indicate in its report as to why restricting or regulating its manufacture or use, would not suffice. Thus, the report submitted by Sub-committee also is not in conformity with the directions issued by the Supreme Court in Pfizer Limited (supra). Concededly, the Central Government has based its decision solely on the report of the Sub-committee. A decision founded on an unclear report without any deliberation is manifestly arbitrary.

28. In view of the above, this Court is of the view that the impugned notification cannot be sustained. The same is set aside. The matter is remanded to DTAB/ Subcommittee constituted by it to examine the issue regarding the FDC in question in accordance with the directions issued by the Supreme Court in Pfizer Ltd. (supra). The DTAB/Sub-committee shall submit a report to the Central Government. The Central Government may take an informed decision whether to proscribe, restrict, or approve the said FDC.

29. All pending applications are disposed of.

