Intas Pharmaceuticals Limited vs.drugs Controller General of India & Anr

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Court : Delhi

Decided On : Feb-13-2019

Appellant : Intas Pharmaceuticals Limited

Respondent : Drugs Controller General of India & Anr

Judgement :

IN THE HIGH COURT OF DELHI AT NEW DELHI % + W.P.(C) 38874/2018 9978/2018 Judgment delivered on:

13. 02.2019 and CM APPL. 38873/2018 & M/S MICRO LABS LIMITED versus .....

... Petitioner
DRUGS CONTROLLER GENERAL OF INDIA AND ANR. .....

... RESPONDENTS
WITH + W.P.(C) 10757/2018 and CM APPL. 41978/2018 & 41979/2018 INTAS PHARMACEUTICALS LIMITED .....

... Petitioner
versus DRUGS CONTROLLER GENERAL OF INDIA & ANR .....

... RESPONDENTS
WITH + W.P.(C) 10936/2018 and CM APPL. 42605/2018 & 44745/2018 LUPIN LIMITED & ANR .....

... Petitioner

s versus UNION OF INDIA & ANR .....

... RESPONDENTS
AND W.P.(C) 9978/2018 & other connected matters Page 1 of 24 + W.P.(C) 11278/2018 and CM APPL. 43787/2018 & 43788/2018 ERIS LIFESCIENCES LIMITED .....

... Petitioner
versus UNION OF INDIA AND ANR. .....

... RESPONDENTS
Sahadeva Advocates who appeared in this case: For the

... Petitioner
s: Ms Archana 9978/2018. Ms Bitika Sharma, Ms Namrita Kochhar and Ms Vrinda Pathak in W.P.(C) 10757/2018. Mr Gopal Jain, Senior Advocate with Mr Ajay Bhargava, Mr Aseem Chaturvedi and Mr Karan Gupta in W.P.(C) 10936/2018. Mr R. Jawahar Lal, Mr Siddharth Bawa and Mr Shyamal Anand in W.P.(C) 11278/2018. in W.P.(C) For the

... RESPONDENTS
: Ms Maninder Acharya, ASG with Mr Kirtiman Singh, CGSC and Mr Ripu Daman Bhardwaj, CGSC with Mr Waize Ali Noor, GP, Mr Rishikant Singh, Mr Prateek Dhanda, Mr Parth Semwal, Ms Shruti Dutt, Mr Viplav Acharya, Mr Harshul Chowdhary and Mr Sahil Sood, Advocates in W.P.(C) 9978/2018. Mrs Suparna Srivastava and Ms Sanjna Dua, Advocates (C) 10757/2018. Mr Ripu Daman Bhardwaj, CGSC with Mr T.P. Singh, Advocate for UOI. Ms Tanya Agarwal, Advocate for Impleader in W.P. (C) 10936/2018. None in W.P. (C)11278/2018. for R-1 & 2 in W.P. W.P.(C) 9978/2018 & other connected matters Page 2 of 24 CORAM HONBLE MR JUSTICE VIBHU BAKHRU JUDGMENT VIBHU BAKHRU, J1 The petitioners have filed the present petitions impugning the notifications nos. S.O.4471(E) and S.O.4472(E) issued by respondent no.2 (the Central Government) under Section 26A of the Drugs and Cosmetics Act, 1940 (hereafter the Act). the impugn The petitioners in W.P.(C) Nos. 9978/2018; 10757/2018; and 2. dated no.S.O.4471(E) notification 10936/2018 07.09.2018, whereby the

manufacture and sale Fixed Drug Combinations (FDCs) of the formulations Glimepiride 1mg/ 2mg/ 3mg + Pioglitazone 15mg/ 15mg/ 15mg+ Metformin 1000 mg/ 1000 mg/ 1000 mg has been proscribed.

3. The petitioners in W.P.(C) 11278/2018 impugn the notification No.S.O. 4472(E) dated 07.09.2018, whereby the FDC of the formulation Glimepiride 1 mg/ 2 mg + Pioglitazone 15 mg/ 15 mg + Metformin 850mg/ 850mg has been proscribed. The Central Government has proscribed the manufacture, sale 4. and distribution of the aforesaid FDCs on account of inclusion of the formulation Metformin in the said FDCs. The Sub-Committee constituted to examine the matter of proscribing/restricting the said FDCs had, inter alia, found that there are safety concerns, as there is W.P.(C) 9978/2018 & other connected matters Page 3 of 24 no safety data available pertaining to the said FDCs. Accordingly, the sub-committee had recommended the prohibition of the said FDCs. Since, the principal issue involved is common, the said petitions were heard together. The 5. notifications, essentially, on the following grounds: petitioners herein have challenged the aforesaid (i) That the Drug Technical Advisory Board (DTAB) was not in existence at the material time when sub-committee was constituted for examining the matter regarding the FDCs in question, and therefore, the constitution of the sub-committee was void. the that (ii) That the impugned notifications are based on the recommendations of the sub-committee of Drug Technical Advisory Board (DTAB), which has been made without application of mind. (iii) That the finding of the sub-committee, that concerns regarding Metformin, material on record. there are safety is incorrect and contrary to the (iv) that the said FDCs have a sound therapeutic justification and pose no risk to human beings. (v) That the impugned notification has been passed without following the directives issued by the Supreme Court in Union of India v. Pfizer Limited and Ors. :

2018.

(2) SCC39 W.P.(C) 9978/2018 & other connected matters Page 4 of 24 It The respondents countered the aforesaid grounds. is

6. contended on their behalf that the Sub-Committee has acted in conformity with the directions issued by the Supreme Court in Pfizer Limited (supra). It was contended that the recommendations by the Sub-Committee were made after due application of mind and for cogent reasons, thus, the impugned notifications, which are based on the recommendations of the Sub-Committee of the DTAB, cannot be faulted. It is also contended that the impugned notifications have been issued in exercise of legislative powers and the principles of natural justice are not required to be followed in such exercise. Factual Background

7. The petitioners state that the FDCs in question are used for the treatment of Type-2 Diabetes Mellitus when diet, exercise and the usage of dual therapy do not result in adequate glycemic control. In the year 2013, pursuant

8. to the directions of the Drug Controller General of India (DCGI), the manufacturers of various FDCs were called upon to prove the safety and efficacy of the FDCs which were issued prior to 01.10.2012, without the required approval of DCGI. Thereafter, an Expert Committee of ten experts was constituted

9. by the Central Drugs Standard Control Organisation (CDSCO) for examining the applications received from various manufacturers pursuant to the aforesaid directions of the DCGI. W.P.(C) 9978/2018 & other connected matters Page 5 of 24 the FDCs in question. The Central Drugs Standard Control Organization (CDSCO)

10. had constituted an Expert Committee of comprising of ten experts for examining the efficacy of The Expert Committee so constituted did not recommend the FDCs in question, as it was of the view that the studies provided were not sufficient to justify 15 mg dose of Pioglitazone in the FDCs. Thereafter, another committee was constituted under the Chairmanship of Professor C.K. Kokate, Vice-Chancellor of KLE University of Belgaum, Karnataka to examine the same (the Kokate Committee). The Kokate Committee recommended the prohibition of the FDCs in question, inter alia, observing that the Pioglitazone has safety concerns. The Kokate Committee also recommended banning several other FDC drugs. the Central Government In view of the recommendations of the Kokate Committee, on

11. 10.03.2016, issued notifications (three hundred and forty four in number) proscribing the manufacture, sale and distribution of 344 FDCs with immediate effect. Two of the said notifications being S.O. 806(E) and S.O. 807(E) prohibited the manufacture, sale and distribution of the FDCs of Glimepiride 1mg/2mg/3mg, Metformin 1000mg and Pioglitazone 15 mg, and Glimepiride of 1mg/2mg, Metformin 850 mg and Pioglitazone 15 mg, respectively (the FDCs in question, which are banned in terms of the impugned notifications).

12. Aggrieved, the petitioners herein preferred writ petitions before this Court challenging the aforesaid notifications [S.O. 806(E) and S.O. 807(E)]., inter alia, on the ground that the same had been issued W.P.(C) 9978/2018 & other connected matters Page 6 of 24 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.

13. The said petitions were considered alongwith a batch of petitions impugning the other notifications, which were disposed of by a common judgment dated 01.12.2016, whereby all the 344 impugned notifications therein, including S.O. 806(E), were set aside while holding that it was mandatory for the Central Government to seek consultation of DTAB.

14. 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 dated 15.12.2017 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 the recommendations made by the 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:-

"considering cases that facts of the and 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 W.P.(C) 9978/2018 & other connected matters Page 7 of 24 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 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 that W.P.(C) 9978/2018 & other connected matters Page 8 of 24 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 in question is likely to involve any one of the aforesaid three things: the Fixed Dose Combinations (FDC) (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: factors indicated above (1) as to why, according to it, any one of the is three 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 W.P.(C) 9978/2018 & other connected matters Page 9 of 24 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 relevant information, and ultimately apply its mind to the parameters contained in Section 26A of the Drugs Act the notifications already issued, or modify/substitute them or withdraw them. the DTAB and to any other either maintain and, accordingly, 15. In compliance with 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 the subject matter of the 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 requesting 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 the recommendations.

16. It is stated that the Sub-committee also provided an opportunity to All India Drug Action Network (AIDAN) to make its submissions.

17. Thereafter, the Sub-committee reviewed the FDCs in question and submitted its report. The sub-committee, in relation to the FDC W.P.(C) 9978/2018 & other

connected matters Page 10 of 24 Glimepiride 1mg/2mg/3mg, Metformin 1000mg and Pioglitazone 15mg, made the following observations: 1. As per gazette notification under No.520(E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension revoked with certain conditions.

2. As per the standard treatment guidelines for type2 diabetes followed. In India, patients not responding to diet, exercise, monotherapy (Metformin) or dual therapy (Sulfonylurea/Biguanide) are treated with tripledrug therapy. responding 3. There is sufficiently large population of patients along with not monotherapy triple drug combinationis appropriate for patient compliance in this chronic disease. exercise therapy, diet, dual to and 4. The DCGI has approved FDC of Glimepiride(1mg/ 2mg) + Pioglitazone (15mg) + Metformin (500 mg ER) uncoated tablet for indication: As 3rd line treatment of Type II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not resultin adequate glycemic control on 16.08.2005 with certain precautions to address Pioglitazones safety concerns. The FDC Glimepiride + Metformin 5. 1mg/2mg/3mg +Pioglitazone HCI IP eq. to Pioglitazone 15mg/15mg/ (Immediate 15mg Release/Sustained Release) 1000mg/ contains recommended and approved therapeutic dosage of each ingredient. Release/Extended 1000mg 1000mg/ tablets HCI IP6 The subcommittee concluded that the FDC has therapeutic value and has the potential to address the W.P.(C) 9978/2018 & other connected matters Page 11 of 24 need of patients with type II diabetes hot responding to diet, exercise,mono or dual therapy when the dose of individual drugs has been determined/stabilized with single ingredient tablets.

7. However, the FDC can lead to risk of hypoglycemia. There is no safety data pertaining to this FDC. In view of the aforesaid observations, 18. the Sub-Committee recommended a prohibition on the manufacture, sale and distribution of the FDC Glimepiride 1mg/2mg/3mg, Metformin 1000mg and Pioglitazone 15 mg. The recommendations made by the Sub- Committee are set out below:-

"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 the Drugs and Cosmetics Act, 1940. In view of the 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. 19. The Sub-committeealso recommended the prohibition of the FDC Glimepiride of 1mg/2mg, Metformin 850 mg and Pioglitazone 15 mg based on the following observations: 1. There are sufficient therapeutic options already available.

2. The increments in dose of Metformin are made in steps of 500 mg as per treatment guidelines. W.P.(C) 9978/2018 & other connected matters Page 12 of 24 3. Availability of multiple strengths can lead to medication dispensing, administration) with risk of overdosing or under- dosing. (prescribing, error There is no convincing scientific/clinical evidence/ justification for the FDC. The recommendations to ban the said FDC based on the 20. aforesaid observations are set out below: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.

2. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26A of the Drugs and Cosmetics Act, 1940. In view of the 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.

21. The said report was accepted and the Central Government issued the impugned notifications banning the FDCs in question. Aggrieved by the same, the petitioners have preferred the present petition. Reasons and Conclusion

22. Ms Acharya, learned ASG contended that the present petition cannot be viewed with the prism of Article 19(1)(g) of the Constitution of India. She submitted that the petitioner had no fundamental right to carry on the manufacture of drugs, and it was W.P.(C) 9978/2018 & other connected matters Page 13 of 24 merely a statutory privilege granted to them. She referred to Article 47 of the Constitution of India and submitted that no person has a fundamental right to carry on trade in alcohol and drugs which are harmful. The aforesaid contention is plainly unsustainable. Undoubtedly,

23. no person has the fundamental right to carry on business in trade in alcohol and noxious substances, however, the principles of res extra commercium do not apply in case of life saving drugs and other medicinal products. The fact that certain drugs may have serious side effects would, of course, have to be considered while considering the reasonableness of the Constitution of India. restrictions in terms of Article 19(6) of

24. The aforesaid contention is not relevant to the controversy at hand as, concededly, the Central Government is empowered under Section 26A of the Act to proscribe any drug if the grounds, as stipulated therein, are established. In view of the above, this Court must confine its examination as to whether the impugned notifications can be sustained on the ground as stated in Section 26A of the Act, and whether the directions issued by the Supreme Court in Pfizer Limited and Ors (supra) have been duly complied with. It was contended on behalf of

25. 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 last time it was constituted on the petitioners that W.P.(C) 9978/2018 & other connected matters Page 14 of 24 29.12.2014, hence, its term expired on 28.12.2017. The petitioners submit that the DTAB was reconstituted on 15.05.2018 and, thus, there was not validly constituted body during the period of 28.12.2017 to 15.05.2018. It is stated that 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. The aforesaid issue has been examined by this Court in Unison

26. Pharmaceuticals Pvt. Ltd. and other connected matters v. Union of India &Anr.:

10403. 2018, decided on 08.01.2019, wherein the Court observed that the notification dated 29.12.2014, notifying the constitution of the DTAB, did not specify the term of the DTAB. This Court further observed that in terms of Section 5 of the Act, (i) the term of the elected and nominated members of the DTAB is for three years and after the expiry of their term, they would be eligible for nomination and re-election, the ex-officio members would continue to hold office as per their tenure, and (iii) the functions of the Board may be exercised notwithstanding any

vacancy therein. In this view, the Court held that notwithstanding the vacancy caused due to expiry of the term of some of the members, the DTAB would continue to function and there was no flaw in constitution of the Sub- Committee. (ii) 27. 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, the Sub- is contended that it W.P.(C) 9978/2018 & other connected matters Page 15 of 24 committee or the Central Government was not required necessarily to give any reason for banning the said FDC. It was further contended that the Sub-committee was constituted by experts in the given subject and the decision of the said committee is not amenable to judicial review. The said issue has been examined by this Court in Wockhardt 28. 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 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 XXXX94 In view of the above discussion and given the nature of the authorities, it is held that the Unions W.P.(C) 9978/2018 & other connected matters Page 16 of 24 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. Section 26A of the Act reads as under: to 26A. Power of Central Government 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 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.]. therapeutic value the It is clear from the above that 29. 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 to exercise the same in larger public interest. Plainly, the Central Governments satisfaction would be required to be based on W.P.(C) 9978/2018 & other connected matters Page 17 of 24 the relevant considerations; cogent material; and by excluding irrelevant considerations. Thus, the limited question that falls for consideration of this 30. Court is whether the Central Governments decision to ban the manufacture, sale and distribution of the FDCs in question is based on relevant material, and whether the impugned notification has been issued by due compliance of the directions of the Supreme Court in Pfizer (supra).

31. At the outset, it is relevant to note that the Sub Committee has approved an FDC comprising of Glimepiride 1/2mg + Pioglitazone 15 mg + Metformin 500 mg by a S.O. No.4711(E) dated 07.09.2018. It is, thus, apparent that the only objection in respect of the FDCs proscribed in terms of S.O. No.4471(E) and S.O. 4472(E) relate to the increased dosage of Metformin:

1000. g in FDCs proscribed by S.O. 4471(E)and 850 mg in FDCs proscribed by S.O. 4472(E). First six paragraph of the reasons indicated by the Sub- 32. Committee do not indicate any reason for proscribing the FDC. On the contrary, paragraph 3 of the said reasoning indicates that there is a sufficiently large population of patients that requires a triple drug combination for addressing the chronic disease. It is also noted in paragraph 4 of the said reasons that DCGI has approved the FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg) + Metformin

(500 mg ER) uncoated tablet for indication as the third line treatment of Type II diabetes mellitus in cases where diet, exercise and single agents and W.P.(C) 9978/2018 & other connected matters Page 18 of 24 second line therapy with two drugs, do not result in adequate glycemic control. It is important to note that in paragraph 5 of its report, the Sub 33. the FDCs in question contain Committee expressly noticed that therapeutic dosage of each recommended and approved ingredient. Thus, there is no dispute that the FDC in question have a therapeutic justification and are prescribed for certain patients. This is also the conclusion drawn by the Sub-Committee, as is apparent from paragraph 6 of their observations quoted above. It is expressly stated that the said FDC has therapeutic value and has the potential to address the need of patients with Type II Diabetes, who are not responding to mono or dual therapy.

34. The only reason provided by the Sub-Committee for proscribing the said FDC is that it can lead to risk of hypoglycemia and there is no safety data pertaining to this FDC. Once it the is accepted that formulations in the dosages, as included in the said FDC, is recommended and approved therapeutic dosages for treatment of Type II Diabetes in certain cases, it is difficult to understand the reason for proscribing the said FDCs on ground of lack of safety data. Insofar as the observation that the said FDC can lead to risk of 35. hypoglycemia is concerned, the petitioners have produced material on record, which indicates that the risk of hypoglycemia in Metformin is minimum. However, this is not an area of controversy which is required to be examined by this Court. The question whether a W.P.(C) 9978/2018 & other connected matters Page 19 of 24 particular drug has any adverse effects is required to be examined by the experts, and the observation that the FDC can lead to hypoglycemia, must be accepted. However, it is difficult to understand the rationale to proscribe the said FDC on this count, considering that it is accepted that the formulations in that dosage included in the FDC is said FDC hastherapeutic value in certain cases. approved. Admittedly, recommended and the The Supreme Court, in the case of Pfizer Limited (supra), had 36. remanded the matter to DTAB/Sub-Committee for the reason that the reasons given by the Kokate Committee were cryptic. Plainly, the decision of Central Government founded on such reasons could not be sustained. This malady continues to subsist with the observations made by the Sub-Committee, as

it provides little clarity for sustaining an action under Section 26A of the Act. It any is also conceded that other material the Central Government had not 37. examined observations/ recommendations of the Sub-Committee for issuing the impugned notification. In absence of clear and cogent reasons, such a decision would be manifestly arbitrary and not sustainable. other than the It is also relevant to note that in Pfizer Limited (supra), the 38. Supreme Court had expressly directed that in case where DTAB/Sub- Committee prohibits a particular FDC, it must also indicate in its report as to why restrictions or regulations are not sufficient to control the manufacture and use of the FDC. The recommendations of the W.P.(C) 9978/2018 & other connected matters Page 20 of 24 Sub-Committee, read in conjunction with the risks indicated,do not indicate why regulations or restrictions are insufficient in controlling the use of the FDC.

39. In view of the above, the notification S.O. No.4471(E) is not sustainable. Insofar as S.O. No.4472 (E) is concerned, the same proscribes an FDC comprising of Glimepiride 1mg/2mg + Pioglitazone 15mg/15mg + Metformin 850mg/850. As observed above, it is obvious that the said FDC has been proscribed on account of an incremental dosage of Metformin 850mg, considering that the FDC comprising of Glimepiride 1mg/2mg + Pioglitazone 15mg and Metformin 500 mg is approved. The observations made by the Sub- Committee for proscribing this FDC are, essentially,three fold. First, that there is sufficient therapeutic option; second, that increments in the dosage of Metformin are in steps of 500mg as per treatment guidelines; and third, that availability of multiple strengths can lead to medication error of overdosing or under-dosing.

40. Clearly, the reason that there are therapeutic options available is not a ground for prohibiting a drug under Section 26A of the Act. A drug can be proscribed under Section 26A, (i) if it involves any risk to human being or animals; (ii) the drug does not have any therapeutic value purported to be claimed; and (iii) that the drug contains ingredients in such quantity for which there is no therapeutic justification. W.P.(C) 9978/2018 & other connected matters Page 21 of 24 The fact that there are other alternatives available cannot be a 41. ground for proscribing the FDC in question. The second reason that 42. the increments in the dosage of Metformin are in steps of 500mg and, therefore, the FDC which contain the formulation in the

strength of 850 mg ought to be proscribed is also unsustainable. This is so because it is conceded before this Court that Metformin 850mg is an also approved drug. The petitioner has also produced material to indicate that Metformin in the dosage of 850mg is prescribed in certain patients. Plainly, if Metformin 850mg is an approved dosage, the question of proscribing the FDC on the ground that the strength of Metformin is not a multiple of 500mg is not sustainable.

43. It is also relevant to note that the Central Government had also issued a notification under Section 26A of the Act proscribing FDCs comprising of: Metformin 1000 mg + Pioglitazone 7.5 mg + Glimepiride 1 mg; and, Metformin 1000 mg + Pioglitazone 7.5 mg + Glimepiride 2 mg. The said notification S.O4467E) was subject matter of challenge in Unison Pharmaceuticals Pvt. Ltd (supra). It is relevant to note that the said FDCs were proscribed for the reason that Pioglitazone 7.5 mg was not an approved dose; there was no issue with regard to inclusion of Metformin 1000 mg in the said FDCs.

44. The third reason, namely, that availability of multiple strengths can lead to medication error, is also cryptic in the sense that drugs comprising of the FDC are available in multiple strengths. W.P.(C) 9978/2018 & other connected matters Page 22 of 24 It was contended on behalf of the respondents that if the FDC in 45. question is over prescribed or under prescribed, it would entail a serious risk to the patient. In this regard, it is relevant to observe that the rationale for making a FDC is for the convenience of a patient, who is prescribed several drugs (comprising the FDC). There is a compelling argument that an FDC is expedient in cases where a patient is required to take multiple medicines. The risk of over prescription or under prescription is common in all FDCs. The reasons indicated by the Sub-Committee do provide any clarity as to why this reason is relevant for the FDCs in question. In view of the above, the recommendation of the Sub- 46. Committee that there is no therapeutic justification, is difficult to accept. This is also considering that it is not disputed that the contents of the FDC, in the dosage as included, are prescribed to patients to address Type II Diabetes.

47. In view of the above, the impugned notifications are set aside. The matter is remanded to DTAB/Sub-Committee constituted with the direction to examine the issue regarding the FDCs in question in accordance with the directions issued in Pfizer Limited and Ors (supra).

48. The DTAB Sub-Committee shall submit a report to the Central Government clearly providing an explanation for its recommendations along with the material in support thereof. The Central Government is W.P.(C) 9978/2018 & other connected matters Page 23 of 24 required take an informed decision after examining the report of DTAB/Sub-Committee and the material provided along with it. The petitions are disposed of in the aforesaid terms. All pending 49. applications stand disposed of. FEBRUARY13 2019 MK VIBHU BAKHRU, J W.P.(C) 9978/2018 & other connected matters Page 24 of 24