IN THE HIGH COURT OF DELHI AT NEW DELHI

% Judgment delivered on: 08.01.2019

+ **W.P.(C) 10403/2018 & CM Nos. 40515-40516/2018**

UNISON PHARAMACEUTICALS PVT. LTD. ..... Petitioner

versus

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

WITH

+ **W.P.(C) 10128/2018 & CM Nos. 39519/2018 & 44752/2018**

ALKEM LABORATORIES LTD. ..... Petitioner

versus

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

WITH

+ **W.P.(C) 10711/2018 & CM Nos. 41727-41728/2018**

M/S EAST WEST PHARMA ..... Petitioner

versus

UNION OF INDIA ..... Respondent

WITH

+ **W.P.(C) 10756/2018 & CM Nos. 41976-41977/2018**

INTAS PHARMACEUTICALS LIMITED ..... Petitioner

versus

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

WITH

\+ **W.P.(C) 10935/2018 & CM Nos. 42603/2018 & 44753/2018**

LUPIN LIMITED & ANR ..... Petitioners

versus

UNION OF INDIA & ANR ..... Respondents

WITH

\+ **W.P.(C) 10966/2018 & CM Nos. 42726-42727/2018**

EAST WEST PHARMA ..... Petitioner

versus

UNION OF INDIA ..... Respondent

WITH

\+ **W.P.(C) 11041/2018 & CM Nos. 42984-42986/2018**

M/S. MICRO LABS LIMITED ..... Petitioner

versus

DRUGS CONTROLLER GENERAL OF INDIA & ANR. ..... Respondents

WITH

\+ **W.P.(C) 11270/2018 & CM Nos.43771-43772/2018**

ERIS LIFESCIENCES LIMITED ..... Petitioner

versus

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

WITH

\+ **W.P.(C) 10916/2018 & CM Nos. 45388/2018**

LUPIN LIMITED & ANR ..... Petitioners

versus

UNION OF INDIA & ANR ..... Respondents

WITH

\+ **W.P.(C) 11273/2018 & CM Nos. 43777-43778/2018**

ERIS LIFESCIENCES LIMITED ..... Petitioner

versus

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

WITH

\+ **W.P.(C) 11493/2018 & CM Nos. 44451-44452/2018**

M/S. FRANCO INDIAN PHARMACEUTICALS PVT. LTD. & ANR. ..... Petitioners

versus

UNION OF INDIA & ORS. ..... Respondents

WITH

\+ **W.P.(C) 11672/2018 & CM No. 45055/2018**

M/S EAST WEST PHARMA **..... Petitioner**

versus

UNION OF INDIA **..... Respondent**

Advocates who appeared in this case:

For the Petitioners: Mr Avinash Tripathi and Mr Rohit Sharma, Advocates in WP(C) No.10403/2018.

Mr Sagar Chandra, Ms Aastha Bhasin and Ms Shubhie Wahi, Advocates in WP(C) No.10128/2018.

Mr Deepak Kumar Mahapatra and Ms Aruni Poddar, Advocates in WP(C) No.10711/2018.

Ms Bitika Sharma, Ms Anusuya Nigam, Mr Lakshay Kaushik and Ms Vrinda Pathak, Advocates in WP (C) No.10756.2018.

Mr Ajay Bhargava, Ms Vanita Bhargava, Mr Aseem Chaturvedi, Mr Arvind Ray adn Mr Karan Gupta, Advocates in WP(C) No.10935/2018.

Mr Deepak Kumar Mahapatra and Ms Aruni Poddar, Advocates in WP(C) No.10966/2018.

Ms Archana Sahadeva, Advocate in WP(C) No.11041/2018.

Mr R. Jawahar Lal, Mr Siddharth Bawa and Mr Shyamal Anand, Advocates in WP(C) No11270/2018.

Mr Ajay Bhargava, Ms Vanita Bhargava, Mr Aseem Chaturvedi, Mr Arvind Ray adn Mr Karan Gupta, Advocates in WP(C) No.10916/2018.

Mr R. Jawahar Lal, Mr Siddharth Bawa and Mr Shyamal Anand, Advocates in WP(C) No.11273/2018.

Mr Arunabh Chowdhury, Mr Vaibhav Tomar, Mr Karma Dorjee and Ms Shruti Choudhry, Advocates in WP(C) No.11493/2018.
Mr Deepak Kumar Mahapatra and Ms Aruni Poddar, Advocates in WP(C) No.11672/2018.

For the Respondents: Ms Maninder Acharya, ASG with Mr Kritiman Singh, CGSC, Mr Waize Ali Noor, Mr Prateek Dhanda, Ms Shruti Dutt, Mr Harshul Choudhary, Mr Sahil Sood and Mr Viplav Acharya, Advocates in all abovementioned matters except WP(C) No.10935/2018 and WP(C) No.10916/2018.

Mr Ripu Daman Bhardwaj CGSC with Mr T. P. Singh, Advocate for UOI in WP(C) No.10935/2018 & 10916/2018.

Ms Tanya Agarwal, Advocate for Impleader in WP(C) No.10128/2018 & WP(C) No.10916/2018.

Mr Gaurang Kanth with Ms Eshita Baruah, Advocates for respondents in WP(C) No.11041/2018.

CORAM
HON'BLE MR JUSTICE VIBHU BAKHRU

JUDGMENT

VIBHU BAKHRU, J

1. The petitioners impugn notification nos.S.O.4467(E) and S.O.4470(E) issued by respondent no.1 (the Central Government)

under Section 26A of the Drugs and Cosmetics Act, 1940 (hereafter 'the Act'). The petitioners in W.P.(C) Nos.10403/2018; 10128/2018; 10756/2018; 10935/2018; 10966/2018; 11041/2018 and 11270/2018 impugned the notification no.S.O.4467(E), whereby the Fixed Drug Combinations (FDCs) of the following formulations had been proscribed;

a) Metformin 1000 mg + Pioglitazone 7.5 mg + Glimepiride 1 mg

b) Metformin 1000 mg + Pioglitazone 7.5 mg + Glimepiride 2 mg

c) Metformin 500 mg + Pioglitazone 7.5 mg + Glimepiride 1 mg

d) Metformin 500 mg + Pioglitazone 7.5 mg + Glimepiride 2 mg

2. The petitioners in W.P.(C) 10711/2018 also impugns three other notifications issued under Section 26A of the Act, in addition to the notification S.O.4467(E). However, the petitioners have restricted their challenge in their petition only to impugn SO. 4467(E).

3. The petitioners in W.P.(C) Nos.10916/2018; 11273/2018; 11493/2018 and 11672/2018 impugn notification S.O.(E) 4470(E) issued by the Central Government under Section 26A of the Act, whereby the FDCs of the following formulations have been proscribed.

a) Metformin 500 mg + Pioglitazone 7.5 mg

b) Metformin 1000 mg + Pioglitazone 7.5 mg

4. Admittedly, the manufacture, sale and distribution of the aforesaid FDCs have been proscribed on account of inclusion of the formulation Pioglitazone 7.5 mg. The Sub-Committee constituted to examine the matter of proscribing/restricting the said FDCs had, *inter alia,* found that the evidence for efficacy of 7.5 mg of Pioglitazone is insufficient and, therefore, had recommended prohibition of the said FDCs. Since, the principal issue involved is common, the said petitions were heard together.

5. The aforementioned notifications have been challenged, essentially, on five grounds. First, that the Drug Technical Advisory Board (DTAB) was not properly constituted and, therefore, the constitution of the Sub-Committee, which examined the matter regarding the FDCs in question, was also invalid. Second, that the impugned notifications are based on recommendations, which are unreasoned and made without application of mind. Third, that the conclusion of the Sub-Committee of DTAB that the evidence of efficacy of 7.5 mg Pioglitazone is insufficient is wholly erroneous and contrary to the material on record. Fourth, that the recommendations to prohibit manufacture and sale of the FDCs in question, based on the satisfaction of the Central Government that the FDCs in question be prohibited, is without any material and, therefore, the impugned notifications are liable to be set aside. And fifth, 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 (II) SCC 39***.

6. The respondents countered the aforesaid grounds. It is 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 made by the Sub-Committee were after due application of mind and for cogent reasons; thus, the impugned notifications which are based on the recommendations of the Sub-Committee of 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.

7. The FDCs in question are used for treatment of Type-II diabetes mellitus and to improve the glycemic control as an adjunct to diet and exercise.

8. The Central Drugs Standard Control Organization (CDSCO) had constituted an Expert Committee of comprising of ten experts for examining the efficacy of the FDCs in question. 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 7.5 mg dose Pioglitazone in the FDCs. 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.

9. In view of the recommendations of the Expert Committee, the Central Government had issued a notification – being S.O. No.802 (E)

– which was published in the Gazette of India on 10th March, 2016. In terms of the said notification, the Central Government had prohibited the manufacture and sale of the FDCs comprising of Metformin, Glimepiride and Pioglitazone of 7.5 mg. Similarly, the Central Government had also issued another notification – S.O. 805(E) – prohibiting the FDC comprised of Metformin and Pioglitazone of 7.5 mg. The aforesaid notifications were challenged by the petitioners before this Court on several grounds including 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, which were disposed of by a common judgment dated 01.12.2016. The said notifications – S.O. 802(E) and S.O. 805(E) – were set aside. Aggrieved by the said decision, the respondents had 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."

11. 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 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. 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.

12. The report made by the Sub-Committee in respect of the FDCs comprising of Metformin, Pioglitazone and Glimepiride indicated the following observations in support of their recommendations:

> "The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg) + Metformin (500mg E.R.) uncoated Tablet is approved for the 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 result in adequate glycemic control by CDSCO on 16.08.2005.
>
> The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under:-
>
> "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough o justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further, the committee also noted that the proposed FDC in proposed strength was already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC made on 22.08.2012.
>
> However, the proposal for Pioglitazone HCI 15 mg +Metformin HCI 500 mg (SR) +Glimepiride 1 mg/2 mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.

> The Subcommittee concurred with the recommendations of "10 expert committee". The Subcommittee perused recent publications and concluded that:
>
> 1. The evidence for efficacy of 7.5 mg Pioglitazoneis not sufficient.
>
> 2. Further, Pioglitazone 7.5 mg strength is not approved by DCGI as a simple ingredient for management of Type-2 diabetes as of now.
>
> The Subcommittee considered the strength of Metformin 1000/1000/500/500 mg+ Pioglitazone 7.5/7.5/7.5 mg + Glimepiride 1/2/1/2 mg, as inappropriate.
>
> There is no sound scientific/clinical evidence/justification for the FDC."

13. In view of the aforesaid observations, the Sub-Committee recommended prohibiting the FDCs 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."

14. Similarly, the Sub-Committee also recommended that the FDCs comprising only of Metformin and Pioglitazone 7.5 mg be prohibited. The relevant observations and recommendations made in the report with regard to the said FDCs are set out below:-

> "The Subcommittee perused recent publications and concluded that:
>
> 1. The evidence for efficacy of 7.5 mg Pioglitazone is not sufficient.
>
> 2. Further, Pioglitazone 7.5 mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now.
>
> The Subcommittee considered the strength of Pioglitazone 7.5/7.5 mg + Metformin 500/1000 mg as inappropriate.
>
> There is no sound scientific/clinical evidence/justification for the FDC."
>
> XXXX XXXX XXXX
>
> 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."

Reasons and Conclusion

Whether the impugned notifications are invalid on account of any flaw in constitution of DTAB?

15. It was contended on behalf of the petitioners that in terms of Section 5(2) of the Act, DTAB is to be constituted by sixteen members out of which eight members were ex-officio and the remaining eight are either to be elected or nominated. It was submitted that DTAB is reconstituted every three years and was reconstituted on 29.12.2014. Thus, the term of DTAB ended on 28.12.2017. 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.

16. The petitioners contended that it is necessary that all nominated members and elected members be appointed in order for DTAB to be validly constituted in terms of Section 5 of the Act. They submit that DTAB was reconstituted on 15.05.2018 when the vacancies were filled up and, therefore, during the period 28.12.2017 to 15.05.2018, there was no validly constituted body.

17. The aforesaid contention is unmerited. The notification dated 29.12.2014, whereby the DTAB was reconstituted does not specify the term of DTAB. Paragraph 3 of the said notification clearly states that it would come into force on the date of publication in the official gazette. Thus, with effect from the said date, DTAB was reconstituted by the eighteen members mentioned in the said notification. The said body, obviously, would continue till it was reconstituted.

18. At this stage, it is relevant to refer to Section 5 of the Act, which provides for constitution of the DTAB.The said section is set out below:-

> "**5. The Drugs Technical Advisory Board.—**
>
> (1) The Central Government shall, as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act.
>
> (2) The Board shall consist of the following members, namely:—
>
> (i) the Director General of Health Services, ex officio, who shall be Chairman;
>
> (ii) the Drugs Controller, India, ex officio;
>
> (iii) the Director of the Central Drugs Laboratory, Calcutta, ex officio;
>
> (iv) the Director of the Central Research Institute, Kasauli, ex officio;
>
> (v) the Director of the Indian Veterinary Research Institute, Izatnagar, ex officio;
>
> (vi) the President of the Medical Council of India, ex officio;
>
> (vii) the President of the Pharmacy Council of India, ex officio;
>
> (viii) the Director of the Central Drug Research Institute, Lucknow, ex officio;
>
> (ix) two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States;

(x) one person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian University or a college affiliated thereto;

(xi) one person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian University or a college affiliated thereto;

(xii) one person to be nominated by the Central Government from the pharmaceutical industry;

(xiii) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;

(xiv) one person to be elected by the Central Council of the Indian Medical Association;

(xv) one person to be elected by the Council of the Indian Pharmaceutical Association;

(xvi) two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government.]

(3) The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election:

Provided that the person nominated or elected, as the case may be, under clause (ix) or clause (x) or clause (xi) or clause (xvi) of sub-section (2) shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the Board.

(4) The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.

(5) The Board may constitute sub-committees and may appoint to such sub-committees for such periods, not

exceeding three years, as it may decide, or temporarily for the consideration of particular matters, persons who are not members of the Board.

(6) The functions of the Board may be exercised notwithstanding any vacancy therein.

(7) The Central Government shall appoint a person to be Secretary of the Board and shall provide the Board with such clerical and other staff as the Central Government considers necessary."

19. It is relevant to note that Section 5 of the Act also does not limit the term of DTAB and, therefore, there is no reason to assume that the term of DTAB would expire after three years of its constitution.

20. Sub-section (3) of Section 5 expressly provides that the elected and the nominated members of the DTAB shall hold office for a period of three years but would be eligible for nomination and re-election. The ex-officio members would continue to hold office as per their tenure. The petitioners may be correct that with the expiry of three years, the term of some of the members may have come to an end. However, that does not mean that the term of DTAB had expired or that it was rendered nonfunctional. Sub-section (6) of Section 5 of the Act expressly provides that the functions of the Board may be exercised notwithstanding any vacancy therein. Thus, notwithstanding the vacancy caused due to expiry of the term of some of the members, the DTAB would continue to function and there is no flaw in constitution of the Sub-Committee.

21. It was submitted on behalf of the petitioners that the term 'vacancy' as referred to in Sub-section (6) of Section 5 of the Act

would only mean casual vacancy that may be caused on account of reasons such as resignation and demise of any member. The said contention is unpersuasive. This Court is unable to read the term 'vacancy' as used in Sub-section (6) in a narrow sense. There is no reason to limit the import of the said expression. A vacancy may be caused due to several reasons including expiry of the term of some of its members. There is no ground to accept that the vacancies caused by expiry of the terms of members are not contemplated as vacancies under Section 5(6) of the Act.

22. It was also pointed out on behalf of the respondents that in terms of Sub-section (4) of Section 5 of the Act, DTAB is empowered to make bye-laws for fixing a quorum and regulating its own procedure. In exercise of such powers, DTAB had framed bye-laws wherein quorum was fixed as eight members. Indisputably, in terms of the said bye-laws, the quorum so fixed was present and, therefore, recommendations made by DTAB cannot be questioned on that ground as well.

23. There is yet another aspect of the matter that puts the controversy at rest. The petitioners had participated before the Sub-Committee without any reservation or objection as to their constitution. In this view also, it is not open for the petitioners to now question the constitution of the said Committee. This contention is, obviously, an afterthought, and merits rejection on this ground as well.

Whether the recommendations of the Sub-Committee are unreasoned and vitiated on the ground of non application of mind?

24. It was contended on behalf of the petitioners that the Sub-Committee had not applied its own mind and simply relied upon the report of the Expert Committee constituted earlier. This contention is also bereft on any merit. The Sub-Committee had noticed the observations made by the earlier Committee and had expressed their concurrence. In addition to noticing the observations made by the Expert Committee constituted earlier, the Sub- Committee had expressly concluded that the (i) the evidence for efficacy of 7.5 mg Pioglitazone is not sufficient, and (ii) that Pioglitazone 7.5 mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. Thus, the reasons that weigh with the Sub-Committee for recommending that the FDCs in question be prohibited, are clear and unambiguous.

25. The fact that the Sub-Committee had concurred with the findings of the earlier Expert Committee cannot possibly lead to the conclusion that they had not applied their mind.

26. Next, it was contended that a Sub-Committee had proceeded on an erroneous premise that the drug Pioglitazone 7.5 mg was not approved for use in the country. In this regard, it was contended by Ms Archana Sachdeva, learned counsel who appeared for the petitioner in W.P.(C) 11041/2018 that (i) Pioglitazone 7.5 mg was manufactured and marketed in this country since 2002 and, therefore,

cannot be considered as not approved for use in this country. She further contended that M/s Micro Labs Ltd, the petitioner in W.P.(C) 11041/2018, had a valid and subsisting license for manufacturing and marketing Pioglitazone 7.5 mg. She also referred to a notification dated 10.07.2014 issued by the National Pharmaceutical Pricing Authority (NPPA), whereby NPPA had fixed the maximum retail price of Pioglitazone 7.5 mg at ₹5.31 in terms of paragraph 19 of the Drug (Prices Control) Order, 2013. She also pointed out the manufacture and sale of Pioglitazone had been suspended with effect from 18.06.2013. However, the said ban was revoked by a notification dated 31.07.2013 on the recommendations of the DTAB. The DTAB had further imposed certain conditions, however, no restriction was placed with regard to the manufacture and sale of the Pioglitazone in the strength of 7.5 mg. She further submitted that no specific approval under the Act for manufacturing and sale of Pioglitazone 7.5 mg was required since the said formulation of the strength of 15 mg and 30 mg, was approved.

27. Mr Kirtiman Singh, learned counsel who appears for the respondents had countered the aforesaid statement. He had referred to the definition of 'New Drug' as defined under Rule 122E of the Drugs and Cosmetics Rules, 1945 and submitted that if a drug which is already approved is proposed to be marketed/modified for new claims – namely, indication, dosage form and route of administration – the same would qualify as a 'New Drug'. He submitted that in terms of Rule 122E of the Drugs and Cosmetics Rules, 1945, no new drug

could be manufactured unless it is approved by the Licensing Authority as defined in Rule 21(b) of the Drugs and Cosmetics Rules, 1945. He submitted that an application for permission was required to be made in Form-44 and approval for the same is to be granted in Form-46, which also specifies the composition of the drug. Ms Sachdeva, countered the aforesaid submissions and submitted that the State Licensing Authority could grant license for manufacture and sale of drug which had been approved in different strengths. She also submitted that Rule 2(b) had been introduced in 2002. However, prior to the said inclusion, the State Licensing Authority also had the power to approve drugs for indigenous manufacture.

28. This Court is not inclined to examine this controversy whether a State Licensing Authority could issue a license for manufacturing of Pioglitazone 7.5 mg on standalone basis, as it is not necessary to do so. The Sub-Committee had noticed that in fact the Drug Controller General of India (DCGI) had not approved Pioglitazone 7.5 mg. Admittedly, this observation is not incorrect, as DCGI has not approved Pioglitazone 7.5 mg. It is relevant to note that the approval of a new drug requires submission of extensive data and also clinical trials as specified in Schedule 'Y' of the Drugs and Cosmetics Rules, 1945. Thus, insofar as Pioglitazone 7.5 mg is concerned, it is not disputed that DCGI has not examined any data or clinical trials relating to the said drug in that strength. Thus, the reason cited by the Sub-Committee for recommending prohibition of the FDCs in question cannot be faulted.

29. Coupled with the reason that DGCI had not approved Pioglitazone, the Sub-Committee also found that the evidence for efficacy of 7.5 mg Pioglitazone was not sufficient. Plainly, no further reasons were required to be given by the Sub-Committee in support of the recommendations made by it.

30. The learned counsel appearing for the petitioners also endeavored to persuade this issue that there was ample material and reports to establish the efficacy of Pioglitazone 7.5 mg. Mr Gopal Jain, learned senior counsel appearing for the petitioner in W.P.(C) 10935/2018 had referred to the bibliography mentioned in the report of the Sub-Committee and referred to certain passages from those articles in support of his contention that Pioglitazone 7.5 mg could be used in certain circumstances. He also referred to an article authored by Dr Nilima Kshirsagar, (the Chairman of the Sub-Committee), which reported that Pioglitazone in the strength of 7.5 mg was useful. Plainly, this Court cannot be called to re-examine and re-appraise the view of the experts on merit. The fact that certain articles also formed a part of the bibliography referred to in the Sub-Committee's report clearly indicates that the Sub-Committee had examined the said articles and yet had concluded that the evidence of efficacy of Pioglitazone 7.5 mg was not sufficient. A plain reading of the said articles also indicate that the sample size of subjects, on which the findings are based, is small and no extensive studies have been conducted on data pertaining to a wider sample. It is well settled that this Court cannot enter into merits review of an expert opinion. This

Court is not competent to decide whether the material indicated in the articles is sufficient to establish the efficacy of Pioglitazone 7.5 mg. The Sub-Committee, which is an expert committee constituted to examine the same, has found the same to be insufficient and this Court must let it rest at that.

31. It was also submitted on behalf of the respondents that Pioglitazone 7.5 mg is not approved as a standalone drug anywhere in the world. This statement also remains uncontroverted.

32. In view of the above, this Court is unable to accept that the report submitted by the Sub-Committee could not form the basis for the Central Government to be satisfied that it was necessary to proscribe the manufacture and sale of the FDCs in question and to issue a notification to the aforesaid effect, under Section 26A of the Act.

33. Mr Gopal Jain had emphatically contended that the pharmaco vigilance programme had been put in place by the Government of India, which required any Adverse Drug Reaction (ADR) to be reported. He submitted that the said programme is in operation for several years and no ADR has been reported in respect of the FDCs in question or the use of Pioglitazone 7.5 mg. He submitted that in view of the above, there was no material for the Sub-Committee to recommend that the FDCs in question may involve risks to human beings. This Court finds the said contention to be unmerited as well. "Risks to human beings" is not synonymous to ADR. A drug, which

is used to address ailment but fails to do so itself presents a significant risk for the obvious reason that patient continues to suffer with ailment, which ought to have been addressed. A lack of therapeutic justification (although also stated as a separate ground under Section 26A of the Act) would also in certain circumstances present an element of risk to human beings. As pointed out by the learned counsel, the manufacture and sale of Pioglitazone had been suspended by a notification issued on 18.06.2013. DTAB had examined the issue of suspension of said drug and had recommended that the same be revoked and the drug be marketed only with certain conditions. The said drug had adverse affects in certain patients and the use of the said drug in certain patients was considered risky. Thus, the Central Government had directed that all formulations containing Pioglitazone be distributed subject to a package insert mentioning certain warnings. Plainly, Pioglitazone is not a formulation that could be permitted to be used without due therapeutic justification. Thus, notwithstanding that no ADR are reported regarding the use of Pioglitazone 7.5 mg, the decision of the Sub-Committee that it does present a risk to humans as is efficacy has not been established, cannot be faulted.

Whether the Sub-Committee had conducted its proceedings in conformity with the directions issued by the Supreme Court in Pfizer Limited?

34. It is contended on behalf of the petitioners that the Supreme Court had directed that the Sub-Committee also indicate in its report as to why restrictions or regulations were sufficient to control the

manufacture and use of FDCs in cases where prohibition was recommended. It was contended that in the present case, the Sub-Committee had not given any such indication why the restriction or regulation of the FDCs would be insufficient. Next, it was contended that the reasons that persuaded Kokate Committee to arrive at its conclusion were not clear. It was submitted that the present Sub-Committee's report suffered from the same defect.

35. The aforesaid contentions are unpersuasive. The Sub-Committee had clearly indicated that there was insufficient evidence of efficacy of Pioglitazone 7.5 mg. Thus, the Pioglitazone 7.5 mg as a standalone drug could not be recommended for use. It is obvious that in this view, the said drug could not be permitted to be used as a part of the said FDC. Therefore, the question of permitting the manufacture and sale of FDC subject to any restriction did not arise. The question of restricting or regulating the manufacture would arise only in cases where it is found that the drug has some efficacy but presents risks in certain situations. In this case, the manufacture and sale could be restricted or regulated to ensure that the drug is not sold and used in certain patients or in certain indications. Certain safeguards relating sale of such drug could also be put in place. However, there is no scope for regulating or restricting a drug, which does not have any therapeutic justification and its efficacy is not established.

36. The contention that the reasons given by the Sub-Committee are unclear is also unmerited. This Court finds no ambiguity in the reasons articulated by the Sub-Committee.

37. It is also contended on behalf of the respondents that notifications under Section 26A of the Act were issued in exercise of legislative powers and principles of natural justice are not applicable. It was further submitted that said notifications were not open to judicial review. 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.*** The scope of judicial review in the context of Section 26A of the Act has also been extensively considered by the Division Bench of this Court 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***, wherein, the Court 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….."

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> 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."

38. Section 26A of the Act 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.]"

39. It is apparent that a notification under Section 26A of the Act can only be issued if the Central Government is satisfied as to the conditions set out therein, namely, (i) that the drug is likely to involve any risks to human beings or animals, or (ii) that the drug does not

have any therapeutic value, or (iii) that it contains ingredients in such quantity for which there is no therapeutic justification.

40. Undisputedly, if there is no material for the Central Government to be satisfied that the conditions as mentioned in Section 26A of the Act are met, the notifications issued in this regard would be susceptible to challenge as being manifestly arbitrary. Similarly, in cases where a material on which such satisfaction is based is not credible and does not present sufficient justification, it would be wholly insufficient for the Central Government to form any satisfaction at all. A recommendation which does not indicate any reasons or any justification would present little material for the Central Government to be satisfied as to the stipulated conditions. Plainly, in such circumstances, notifications issued under Section 26A of the Act would be amenable to challenge on the ground of being arbitrary, unreasonable or without any justification.

41. In this case, the Court is unable to accept that the report submitted by the Sub-Committee is unreasoned. The reasons indicated are brief but there is no ambiguity as to why the Sub-Committee has recommended prohibiting the FDCs in question. This is also not a case where the parties had presented any material, which has not been considered by the Sub-Committee. The articles relied upon by the petitioners were duly considered and reference to the same is found in bibliography of the report of the Sub-Committee.

42. In view of the above, this Court finds no ground to interference with the impugned notifications. The petitions are, accordingly, dismissed. All pending applications stand disposed of.

VIBHU BAKHRU, J

JANUARY 08, 2019
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