* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

Reserved on: 20.11.2019
Date of decision: 22.01.2020

+ W.P. (C) 10098/2018 & CM Nos. 39360/2018 & 26480/2019

EMCURE PHARMACEUTICALS LIMITED & ANR
..... Petitioners

Through: Mr.Amit Sibal, Sr. Adv. with Ms.Archana Sahadeva, Mr.Soham Kumar, Advs.

versus

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

Through: Mr.Kirtiman Singh, CGSC with Mr.Waize Ali Noor, Mr.Rohan Anand, Advs. for UOI.
Ms.Tanya Agarwal, Adv. for the Impleader.

+ W.P. (C) 10114/2018 & CM Nos. 39492/2018 &, 39399/2019

IPCA LABORATORIES LIMITED & ANR ..... Petitioners

Through: Mr.Ajay Bhargava, Mr.Aseem Chaturvedi, Mr.Karan Gupta, Advs.

versus

UNION OF INDIA & ANR ..... Respondents

Through: Mr.Anurag Ahluwalia, CGSC, UOI.

+ W.P. (C) 10919/2018

LUPIN LIMITED AND ANR. ..... Petitioners

Through: Mr.Aseem Chaturvedi, Mr.Karan Gupta, Advs.

versus

UNION OF INDIA & ANR. ..... Respondents

Through: Mr.Ripu Daman Bhardwaj, CGSC with Mr.T.P.Singh, Adv. for UOI.

\+ **W.P. (C) 11067/2018 & CM Nos. 43044-43045/2018**

MANKING PHARMA LIMITED ..... Petitioner

Through: Mr.R.Jawahar Lal, Mr.Siddharth, Mr.Shyamal Anand, Advs.

versus

UNION OF INDIA & ANR. ..... Respondents

Through: Mr.Rakesh Kumar, CGSC with Mr.Raghav Nagar, Adv. for UOI.

\+ **W.P. (C) 11392/2018 & CM Nos. 44076-44077/2018 & 44107/2018**

M/S WINGS PHARMACEUTICALS PVT LTD AND ANR. ..... Petitioners

Through: None.

versus

UNION OF INDIA & ANR. ..... Respondents

Through: Mr.Anurag Ahluwalia, CGSC, UOI.

CORAM:
HON'BLE MR. JUSTICE NAVIN CHAWLA

1. These petitions have been filed challenging the Notification, being SO No. 4706 (E) dated 07.09.2018, issued by the respondent (Union of

India) in exercise of its powers under Section 26A of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the 'Act') prohibiting the manufacture for sale, sale and distribution for human use of Fixed Dose Combination (FDC) Drug of Etodolac + Paracetamol.

2. As the basic challenge in all the petitions is to the Impugned Notification, same are being disposed of by way of this common judgment. At this stage it is important to point out that in WP (C) 10098/2018, the petitioners manufacture FDC of S(+) Etodolac + Paracetamol and therefore, while challenging the Impugned Notification, as an alternative relief, they also seek a clarification that the FDC manufactured by them is not covered within the purview of the Impugned Notification. I shall, therefore, be first dealing with the challenge to the Impugned Notification before considering the alternative prayer made by the petitioners in WP (C) 10098/2018.

3. As noted hereinabove, the Impugned Notification has been issued by the respondent exercising its powers under Section 26A of the Act. Section 26A of the Act is reproduced hereinbelow:-

> *"**26A. Powers of Central Government to prohibit manufacture, etc., of drug and cosmetic in public interest.—** Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by*

notification in the Official Gazette, [regulate, restrict or prohibit] the manufacture, sale or distribution of such drug or cosmetic."

4. By the Notifications dated 10.03.2016, the respondents banned 344 FDCs. By a separate Notification being SO No. 1855 (E) dated 08.06.2017, the respondents banned the FDC of Etodolac + Paracetamol also.

5. As far as the drugs banned by the Notifications dated 10.03.2016, the same were challenged by the manufacturers by way of Writ Petitions, which were allowed by a learned Single Judge of this Court by the judgment dated 01.12.2016.

6. The judgment dated 01.12.2016 was challenged by the respondents before the Supreme Court, and the Supreme Court, by its judgment reported as ***Union of India & Anr. vs. Pfizer Limited and Others***, (2018) 2 SCC 39, *inter alia* directed as under:-

"31. *On the facts of these cases, a suggested course of action was stated by learned counsel appearing on behalf of the appellants-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 26-A of the Drugs Act and, accordingly, either maintain the notifications already issued, or modify/substitute them or withdraw them.*

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37. *Insofar as the list of 17 cases handed over by Shri Sibal, in which DCG(I) approvals have allegedly been granted, we are of the view that since the Parliamentary Standing Committee itself refers to DCG(I) approvals and the manner in which they were granted, we do not accede to Mr. Sibal's request that these 17 cases be kept outside the purview of the fresh look that has to be given by the DTAB/sub-committee in these cases."*

7. Pursuant thereto, the FDC of Etodolac + Paracetamol was examined by the Drugs Technical Advisory Board (DTAB)/Sub-

Committee and based on its recommendations, the Impugned Notification has been issued by the respondents.

8. At the outset, the recommendations of the DTAB are reproduced hereinunder:-

> *"Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed.*
> *The Subcommittee noted that FDC of Etodolac 300mg + Paracetamol 500mg film coated tablet is approved by DCGI on 20.10.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. Also, Subcommittee noted that FDC of S (+) Etodolac 150/200/300mg + Paracetamol 500/500/500mg Tablets is approved by DCGI on 25.11.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.*
> *The FDC of Etodolac + Paracetamol was deliberated by NDAC (Analgesics, Anesthetics & Rheumatology) in its meeting held on 19.02.2014. The NDAC commented as under:*
> *"The committee noted the recommendations of the PSC. The committee evaluated the safety and efficacy reports presented by the firm. The committee observed that the product shall not be prescribed more than 10 days as claimed by the firm. The committee opined that FDC is not required for short term use as Paracetamol can be prescribed separately when required and can be tapered off early if need arises. The committee recommended that the FDC is not rationale as present scenario."*
> *The Subcommittee noted the above comments and further noted that:*
> *1. There is only one clinical study with ten day treatment duration, suggesting benefit of Paracetamol and Etodolac FDC over Etodolac alone in knee osteoarthritis. This study used Paracetamol 500mg per tablet in combination with Etodolac 400mg.*

2. There is no published sound/convincing scientific data on various indication mentioned by the appellant. *3. Also, standard treatment guidelines do not recommend use of this combination for the indications mentioned by the appellant.* *4. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects.* *There is no convincing scientific/clinical evidence/justification for the FDC.*			
			xxxxxxx
349	*S.O. 1855(E)*	*Etodolac + Paracetamol*	*Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:* *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 26 A 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."*

9. A reading of the above recommendations would show that the Sub-Committee of the DTAB found that there was no convincing scientific/clinical evidence/justification for the FDC and that the FDC may involve risk to human beings and therefore, recommended a total ban on the manufacture for sale, sale and distribution for human use of the FDC.

10. The learned counsels for the petitioners submit that the Impugned Notification does not comply with the directions issued by the Supreme Court in ***Pfizer Limited and Others*** (Supra). They submit that the reason for discrediting the 'Clinical Study' (*Pareek A et al. Efficacy and Safety of Etodolac-Paracetamol Fixed Dose Combination in Patients With Knee Osteoarthritis Flare-up: A Randomized, Double-blind Comparative Evaluation. Clin J Pain 2010;26:561-566*) is ill founded inasmuch as the Sub-Committee failed to note that by Order dated 23.09.2011, the Directorate General of Health Services (DGHS) had limited the content of Paracetamol to not more than 325 mg per tablet in combination products. Therefore, merely because the Clinical Study was by using Paracetamol of 500 mg, the same could not have been discarded.

11. The learned counsels for the petitioners, further placing reliance on paragraph 34 of the judgment of the Supreme Court in ***Pfizer Limited and Others*** (Supra), submit that the DTAB/Sub-Committee did not consider as to why prohibition alone of the FDC in question is to be recommended and as to why restriction or regulation of the same is not sufficient to meet the public interest. They submit that even one Clinical Study showing the benefit in treatment of knee osteoarthritis would be sufficient to show that the FDC in question, instead of being prohibited, could only have been restricted/regulated. They place reliance on the judgment dated 7.01.2019 passed by this Court in WP(C) 9739/2018, titled ***Wockhardt Limited and Anr. vs. Union of India and Anr.,*** and the judgment dated 08.01.2019 passed by this Court in WP (C) 10403/2018, titled ***Unison Pharmaceuticals Pvt. Ltd. vs. Union of India and Anr.***

12. On the other hand, the learned counsels for the respondents submits that the Parliamentary Standing Committee on Health and Family Welfare in its 59th Report had adversely commented on the FDC in question by observing that the same does not have permission in any of the major developed countries nor has any special or specific relevance to the medical needs of India. The Clinical Study relied upon by the petitioners was also adversely commented upon by observing that the same was conducted just in Maharashtra (Nagpur, Pune and Mumbai) and, therefore, does not serve the purpose of Phase III trials. He submits that in the subsequent 66th Report, the Standing Committee again adversely commented upon the inaction of the Ministry to ban such FDC.

13. As far as the Clinical Study is concerned, the learned counsels for the respondents submits that the same having been adversely commented upon by the Parliamentary Standing Committee in its 59th Report, it was incumbent upon the petitioners to have placed further material on record to show the efficacy and safety of the FDC in question. He submits that even otherwise, the said Clinical Study cannot be relied upon as the same was sponsored by IPCA Laboratories Limited, that is, the petitioner in WP (C) 10114/2018.

14. As far as the decision to prohibit the said FDC, the learned counsels for the respondents submits that the DTAB/Sub-Committee had found that while there was no convincing scientific/clinical evidence/justification for the FDC, at the same time, patients may not need both the ingredients of the FDC simultaneously and use of the FDC in question may lead to unnecessary exposure to other ingredients and its

side effects. The DTAB further found that the FDC may involve risk to human beings. He submits that therefore, DTAB has specifically considered the question of prohibition versus regulation/restriction for the FDC in question and found that prohibition was the answer. This being a report of experts cannot be faulted by this Court.

15. I have considered the submissions made by the learned counsels for the parties. In ***Wockhardt Limited and Anr.*** (Supra), this Court while holding that the power exercised by the Central Government under Section 26A of the Act is legislative in nature, at the same time held that such power can be exercised only on the satisfaction of the Central Government that it is necessary to do so in larger public interest. Such satisfaction would be required to be based on the relevant considerations; cogent material; and by excluding irrelevant considerations. This Court further held that in view of the direction of the Supreme Court in ***Pfizer Limited and Others*** (Supra), the Sub-Committee was required to indicate its reasons for recommending that the particular FDC be proscribed. It was held that while the Sub-Committee was not expected to give reasons like a judgment of a Court, it was incumbent on the Sub-Committee to indicate that it had considered the claims for therapeutic justification and briefly indicate as to why the same was not acceptable.

16. In ***Unison Pharmaceuticals Pvt. Ltd.(Supra),*** it was held that this Court cannot be called to re-examine and re-appreciate the view of the experts on merits. It was further held that a drug, which is used to address the ailment but fails to do so, itself presents a significant risk for the obvious reason that the patient continues to suffer with the ailment,

which ought to have been addressed. Lack of therapeutic justification would also, in certain circumstance, present an element of risk to human beings. Where the drug lacks efficacy but presents risk in certain situation, the same can be prohibited.

17. In ***Lupin Limited and Anr. vs. Union of India and Anr.*** (judgment dated 22.02.2019 in WP (C) 10917/2018), this Court held that mere risk of overdose of a particular drug in FDC cannot itself justify its prohibition instead of restriction/regulation.

18. Applying the above principles of law to the facts of the present case, it is evident that the petitioners had placed reliance only on one Clinical Study in support of their claim of therapeutic justification for the FDC in question. The said Clinical Study had been adversely commented upon by the Parliamentary Standing Committee in its 59th Report. In spite of this, the petitioners did not choose to produce before the DTAB any further evidence of therapeutic justification for the FDC in question. It is also of some significance to note that the FDC has not been granted approval by other major developed countries. The DTAB also found that the Standard Treatment Guidelines did not recommend use of combination in the present FDC for the indication mentioned by the petitioners and use of FDC may lead to unnecessary exposure to other ingredients of the FDC and its side effects. The DTAB, therefore, found that the FDC in question may involve risk to human beings and recommended prohibition of the same instead of mere restriction/regulation. This was the opinion of the National Drug Advisory Committee as well.

19. As held by this Court in ***Unison Pharmaceuticals Pvt. Ltd.*** (Supra) as also by the Supreme Court in ***Union of India and Others vs. Cipla Limited and Another***, (2017) 5 SCC 262, this Court cannot sit in appeal over the opinion of experts and therefore, once it is found that the Expert Committee has kept all relevant considerations in mind, this Court, in exercise of its powers of judicial review, will not seek to substitute the opinion of such experts.

20. The learned senior counsel for the petitioner in WP(C) 10098/2018 sought to contend that the Clinical Study taken note of by the DTAB/Sub-Committee may not be the same which had been adversely commented upon by the Parliamentary Standing Committee.

21. I find no merit in the above submission. It was for the petitioners to have shown that there was some other Clinical Study placed by them before the DTAB/Sub-Committee in support of their claim for therapeutic justification of the FDC. In fact, this submission was not supported by the counsel appearing for the other petitioners.

22. The learned counsels for the petitioners further contended that the Parliamentary Standing Committee is not an expert body and therefore, its reports cannot be given weightage by this Court.

23. I do not find any merit in the above submission. In paragraph 37 of the judgment of the Supreme Court in ***Pfizer Limited and Others*** (Supra), the Supreme Court had taken cognizance of the report of the Parliamentary Standing Committee, while referring the matter to the

DTAB/Sub-Committee. Paragraph 37 of the judgment is reproduced herein below:-

> *"**37.** Insofar as the list of 17 cases handed over by Shri Sibal, in which DCG(I) approvals have allegedly been granted, we are of the view that since the Parliamentary Standing Committee itself refers to DCG(I) approvals and the manner in which they were granted, we do not accede to Mr. Sibal's request that these 17 cases be kept outside the purview of the fresh look that has to be given by the DTAB/sub-committee in these cases."*

24. The onus was therefore, on the petitioners to show to the DTAB/Sub-Committee that the Parliamentary Standing Committee reports were incorrect or should not be relied upon.

25. The learned counsels for the petitioners further submit that merely because the Parliamentary Standing Committee adversely commented on the Clinical Study, the same could not have been disregarded by the DTAB/Sub-Committee.

26. I find no merit in the above submission. The DTAB/Sub-Committee has given its independent reasons as well for not accepting the Clinical Study. They found that this was the only study with ten day treatment duration and suggesting benefit of the FDC over Etodalac alone in knee osteoarthritis. The Study had used the combination with different usage strength. The reasons for not placing reliance on such Clinical Study were therefore, different from the Parliamentary Standing Committee and are not found to be unreasonable or arbitrary so as to warrant any interference by this Court.

27. The learned counsels for the petitioners have further submitted that Etodolac and Paracetamol have been approved not only as standalone drugs but also as part of various FDCs. They submit that therefore, there was no reason to prohibit the particular FDC; the same could have been restricted/regulated.

28. I again find no merit in the above submission. Merely because Etodolac and Paracetamol have been approved as standalone drugs or as part of other FDCs, it cannot be a justification for allowing a particular FDC even though it may have been found, as in this case, to have no therapeutic justification and, in fact, as involving risk to human beings. It was for the petitioners to have shown the therapeutic justification, efficacy and safety of the FDC in question, which they failed to do.

29. I therefore find no merit in WP (C) 10114/2018, titled ***IPCA Pharmaceuticals Limited & Anr vs. Union of India & Anr;*** WP (C) 10919/2018, titled ***Lupin Limited and Anr. vs. Union of India and Anr.***; WP (C) 11067/2018, titled ***Mankind Pharma Limited vs. Union of India & Anr.;*** and WP (C) 11392/2018, titled ***M/s Wings Pharmaceuticals Pvt Ltd and Anr. vs. Union of India and Anr.*** and the same are accordingly dismissed. The pending applications shall stand disposed of. There shall be no order as to cost.

WP (C) 10098/2018

30. As noted hereinabove, the petitioner in WP (C) 10098/2018 claims to be manufacturing FDC of S (+) Etodolac + Paracetamol.

31. The petitioners submit that 'S' in the Petitioners' FDC stands for Chiral, that is pure form. S (+) Etodolac is a pharmacologically active component of racemate Etodolac. The anti-inflammatory, analgesic and antipyretic activities of S (+) Etodolac have been observed to be due to inhibition of cyclooxygenase-2 (COX-2) resulting in inhibition of prostaglandin synthesis. In this regard, the learned senior counsel for the petitioners has placed reliance on various Articles in support of his submission that S (+) Etodolac has various advantages over Etodolac.

32. The petitioners further claim that the DGHS vide its communication dated 18.09.2009 granted permission to the petitioner no. 1 for conducting Phase III clinical trial for the said FDC using comparator drug of Diclofenac Sodium 50 mg +Paracetamol Tablets. It is further claimed that the petitioner no. 1 carried out such clinical trial and submitted its report dated November, 2009. The said clinical trial concluded as under:-

> *"This multi-centric, randomized, clinical trial to assess and compare the efficacy and safety of the fixed dose combination of S-etodolac and Paracetamol (test group) versus the fixed dose combination of Diclofenac and Paracetamol (comparator group) showed that both the products provide similar analgesic efficacy, with better tolerability and lesser adverse events with the fixed dose combination of S-etodolac and Paracetamol. This study confirms the safe and effective use of fixed dose combination of S-etodolac and Paracetamol in Indian patients."*

33. The petitioners further assert that based on the said clinical test, the Central Drugs Standard Control Organization (CDSCO) granted

permission/approval dated 25.11.2009 for the manufacture of the FDC in question.

34. It is further asserted by the petitioners that Diclofenac + Paracetamol, which was the comparator drug in the clinical trial, has been approved by the DTAB to be administered in tablet form and therefore, there is no reason for banning the FDC in question.

35. The learned senior counsel for the petitioners further submits that in any case, S (+) Etodolac as a standalone drug as also as a part of an FDC with other drugs has always been separately approved by the respondents in contradistinction with Etodolac standalone or Etodolac as part of an FDC, therefore, the DTAB/Sub-Committee not having separately considered the claims of the petitioners for S (+) Etodolac + Paracetamol, the Impugned Notification does not operate against the said FDC/Petitioners. Further, placing reliance on the report of the Core Committee constituted by the Government to revise the National List of Essential Medicines (NLEM), he submits that different isomers/analogues/derivatives of one active moiety have to be considered as separate entities and approved as different medicines. He submits that the same is the effect of the definition of "New Drug" under Rule 122 E of the Drugs and Cosmetics Rules, 1945(hereinafter referred to as 'Rules').

36. On the other hand, the learned counsel for the respondents, placing reliance on the additional affidavit dated 28.05.2019 filed by the respondents, submits that the isomers having the same therapeutic value in terms of safety and efficacy are included in the Notification and as

there is no difference in therapeutic value of Etodolac and S (+) Etodolac, the FDC of such isomers, that is S (+) Etodolac with Paracetamol is included in the Impugned Notification.

37. The learned counsel for the respondents further submits that before the DTAB, the petitioners had relied upon the same Clinical Study (*Pareek A et al*) in support of its claim for therapeutic justification; dosage justification (rational); as also for its claim of advantages of S(+) Etodolac over Etodolac. He submits that the claim of the petitioners before the DTAB was not that the FDC of the petitioners is different from the FDC of Etodolac + Paracetamol; the claim was that it is more potent.

38. As far as the clinical trial conducted by the petitioners in 2009 is concerned, he submits that as the therapeutic rationale and dosage for combining the two drugs are the same as for the FDC of Etodolac + Paracetamol, no relevance can be placed on the said clinical trial. He submits that the FDC in question would, in fact, continue to suffer from the same prejudicial effect on human beings as the FDC of Etodolac + Paracetamol.

39. As far as the difference between the S (+) Etodolac and Etodolac is concerned, he submits that S (+) Etodolac is merely claimed to be more potent in nature without having any other therapeutic value and therefore, reliance of the petitioner on NLEM Report or on Rule 122E of the Rules is ill founded.

40. I have considered the submissions made by the learned counsels for the parties. A reading of the recommendations of DTAB/Sub-

Committee would show that while the Sub-Committee noted that the FDC of Etodolac + Paracetamol had been approved by DCGI on 20.10.2009 and the FDC of S (+) Etodolac + Paracetamol had been approved on 25.11.2009, the sub-committee, however, made no recommendation for FDC of S (+) Etodolac + Paracetamol. It is further evident that the Sub-Committee considered only the Clinical Study (*Pareek A et al)* and not the clinical trial of the petitioners conducted in the year 2009. The Sub-Committee also did not consider the effect of Diclofenac + Paracetamol, which was a comparator drug for the clinical trial for the FDC in question, to have been approved by the DTAB.

41. The submission of the learned counsel for the respondents that S (+) Etodolac being merely claimed to be more potent in nature and its therapeutic and dosage justification as also Pharmacokinetic/ pharmacodynamic rationality being same as that of Etodolac, the adverse effect of Etodolac + Paracetamol would equally apply to the FDC in question, cannot be accepted at this stage inasmuch as it could not be shown from the record that this issue has been considered by the DTAB/Sub-Committee. The recommendations of the DTAB/Sub-Committee clearly show that only FDC of Etodolac + Paracetamol was considered by it.

42. These recommendations alone being acted upon by the Central Government for issuance of the Impugned Notification and it not having been shown that the Central Government relied upon any other material, the Impugned Notification cannot be supported by way of additional affidavit or explanation by the learned counsel in his oral submission.

Reference in this regard can be made to the judgment of the Supreme Court in ***Mohinder Singh Gill & Anr. vs. The Chief Election Commissioner, New Delhi & Ors.***, (1978) 1 SCC 405.

43. As held by this Court in ***Wockhardt Limited and Anr.*** (Supra), this Court can interfere with the Impugned Notification where it finds the same to have been issued by excluding relevant consideration or without giving any reasons on the submissions made by the manufacturers. The present case would fall within this limited exception. It was for the DTAB/Sub-Committee to have considered and given reasons whether there is no difference between FDC of S (+) Etodolac + Paracetamol and FDC of Etodolac + Paracetamol. This Court cannot, in exercise of its power of Writ Jurisdiction, examine this aspect as it is no expert on the same.

44. Equally, the Sub-Committee not having considered the clinical trial conducted by the petitioners for the FDC in question, its report, if it is to be extended to the FDC in question, would clearly have ignored a relevant material, thereby making it susceptible to challenge.

45. Even otherwise, S(+) Etodolac, in a standalone form and as part of different FDCs, having been separately approved in contradistinction with Etodolac in a standalone form or as part of FDCs having similar other drug in combination, the submission of the learned counsel for the respondents of there being no difference in the same, cannot be *prima facie* accepted. In any case, this will be a question to be determined by DTAB/Sub-Committee in the first instance.

46. In view of the above, this Court is of the view that the Impugned Notification, insofar as it is stated to be applicable to the FDC of S (+) Etodolac + Paracetamol, cannot be sustained. The same is set aside. The matter is remanded back to DTAB/Sub-Committee constituted by it to examine the issue regarding the said FDC in accordance with the directions issued by the Supreme Court in ***Pfizer Limited and Others*** (Supra). The DTAB/Sub-Committee shall submit its report to the Central Government who may act thereon in accordance with law.

47. WP (C) 10098/2018, titled ***Emcure Pharmaceuticals Limited & Anr. vs. Drugs Controller General of India & Anr.,*** is allowed in the above terms. There shall be no order as to cost.

NAVIN CHAWLA, J

JANUARY 22, 2020/*rv*