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

% Judgment delivered on: 07.01.2019

\+ **W.P.(C) 9739/2018**

WOCKHARDT LIMITED AND ANR ..... Petitioners

versus

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

**Advocates who appeared in this case:**

For the Petitioner : Mr Parag P. Tripathi, Senior Advocate with Ms Saman Ahsan, Mr Sanjeev K Kapoor.

For the Respondents: Ms Maninder Acharya, ASG, Mr Kirtiman Singh, CGSC and Mr Anil Soni, CGSC with Mr Waize Ali Noor, Mr Prateek Dhanda, Ms Shruti Dutt, Mr Sahil Sood, Mr Viplav Acharya and Mr Harshul Choudhary, Advocates.

**CORAM**
**HON'BLE MR JUSTICE VIBHU BAKHRU**

**JUDGMENT**

**VIBHU BAKHRU, J**

1. The petitioners have filed the present petition impugning the notification No. S.O. 4379 (E) 07.09.2018 (hereafter 'the impugned notification') issued by respondent no.1 (Central Government) under Section 26A of the Drugs and Cosmetics Act, 1940 (hereafter 'the Act'). By the impugned notification, the Central Government has prohibited the manufacture for sale, sale or distribution for human use of the Fixed Dose Combination (FDC) of the formulations Aceclofenac + Paracetamol + Rabeprazol (hereafter referred to as 'the said FDC').

2. The petitioners have challenged the impugned notification on several grounds including : (i) that the same has been issued in violation of principles of natural justice; (ii) that the impugned notification 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 impugned notification has been passed without following the directives issued by the Supreme Court in ***Union of India v. Pfizer Limited and Ors. : 2018 (II) SCC 39***; and (iv) that the said FDC has a sound therapeutic justification and poses no risk to human beings.

3. The respondents dispute the aforesaid grounds. They contend that exercise of power under Section 26A of the Act is legislative in nature and principles of natural justice have no application. It is contended that respondent no.1 (Central Government) is neither obliged to afford the petitioners any hearing nor indicate any reasons for its satisfaction to issue such orders.

4. Briefly stated, the controversy in this case arises in the following factual context:

4.1 Petitioner no.1 distributes and markets a drug under the name 'Aceproxyvon Tablet 10 T'. The said drug combines the dosage of Aceclofenac 100 mg, Paracetamol 325 mg and Rabeprazole 10 mg. Petitioner no. 2 is the manufacturer of the said FDC.

4.2 The petitioners state that the said FDC is typically administered for relief of pain and inflammation associated with Rheumatoid

Arthritis, Osteoarthritis and Ankylosing Spondylitis. It is to be administered twice a day for the aforesaid indication.

4.3 On 15.01.2013, respondent no.2 (the Drug Controller General of India – DCGI) issued a letter to all Drug Controllers of States/Union Territories requesting them to call upon the manufacturers of various FDCs in their respective States/Union Territories to prove the safety and efficacy of FDCs for which licences were issued prior to 01.10.2012 without the approval of DCGI. This was followed by another letter dated 05.07.2013 setting a time line for submission of the applications for establishing efficacy and safety of "New Drugs" not approved by DCGI.

4.4 Pursuant to the above, petitioner no.2 – by way of a letter dated 13.08.2013 – submitted all the details as sought for and further stated that no adverse side effects had been noticed in respect of the FDC.

4.5 Thereafter, with the approval of Ministry of Health and Family Welfare, the Central Drugs Standard Control Organisation (CDSCO) constituted Expert Committee (of ten experts) for examination of the applications received from various manufacturers.

4.6 The Expert Committee, in its third meeting dated 04.06.2014, observed that the said FDC was already approved by DCGI earlier and was being marketed without any adverse drug reaction. It opined that firms manufacturing such drugs should generate data through Phase-4 trials and submit the same to the Expert Committee. The relevant extract of the recommendations is set out below:-

> "The Committee noted that Aceclofenac + Paracetamol and Aceclofenac + Rabeprazole is already approved by DCG(I) earlier. As these are already being marketed and no ADR [adverse drug reaction] has been reported so far, the Committee opined that the firms shall generate data through Phase IV Trial within one year and accordingly protocol shall be submitted before the committee within 3 months....."

4.7 DCGI considered the aforesaid recommendations and issued a letter dated 08.08.2014 calling upon petitioner no.2 to submit a detailed reply in respect of certain points along with study protocol and other details.

4.8 Petitioner no.2 responded to the aforesaid letter and submitted the details as sought for by DCGI.

4.9 Thereafter, on 16.09.2014, the Central Government (respondent no.1) constituted a Committee under the Chairmanship of Professor C.K. Kokate, Vice-Chancellor of KLE University of Belgaum, Karnataka (hereafter 'the Kokate Committee') for examining the safety and efficacy of various FDCs. The terms of reference, *inter alia*, required the Kokate Committee to categorise the FDCs into four categories : (a) FDCs, which are considered grossly irrational/unsafe based on pharmacokinetic and pharmacodynamic interaction, dosage compatibilities of FDCs vis-a-vis that of single ingredients present in the FDC and available literature/evidence; (b) FDCs that require further deliberations; (c) FDCs, which are considered as safe and effective based on pharmacokinetic and pharmacodynamic interaction,

dosage compatibilities of FDCs present in the FDC, available literature/evidence, clinical experience and other data; (d) FDCs that are considered as rational based on available data and knowledge.

4.10 The petitioners state that the Kokate Committee decided not to evaluate FDCs which had already been approved earlier by the Expert Committee and the same was mentioned in the first assessment report submitted by the Kokate Committee on 19.01.2015. However, the report submitted by the Kokate Committee subsequently included a reference to the said FDC and the same was classified as irrational.

4.11 Thereafter, respondent no.1 proceeded to issue a notification – being SO No. 705(E) on 10.03.2016 – prohibiting the manufacture, distribution and sale of the said FDC.

4.12 The petitioners challenged the a foresaid notification by filing a writ petition – being W.P. (C) No. 2368/2016 – before this Court on several grounds including that the said notification had been issued without consultation with DTAB which, the petitioners contended, was mandatory.

4.13 While the said petition was pending consideration, DCGI withdrew its letter dated 24.08.2014 regarding conducting Phase-IV trials in view of the notification under Section 26A of the Act proscribing the manufacture and sale of the said FDC.

4.14 The said writ petition was considered along with a batch of other petitions challenging several other notifications issued under Section

26A of the Act. This Court accepted the contention that consultation with DTAB was necessary and allowed the said batch of petitions by a common judgment dated 01.12.2016. The notifications impugned in those petitions were set aside. The respondents carried the matter before the Supreme Court (by filing appeals and transfer petitions) impugning the judgment dated 01.12.2016. The said batch of petitions/appeals was disposed of by the Supreme Court by a common judgment. The Supreme Court did not accept the view that consultation with DTAB was mandatory prior to issue of any notification under Section 26A of the Act. However, in the peculiar facts of the case, the Supreme Court remitted the matter to DTAB for examining each case and submitting a report to the Central Government. The Supreme Court also issued certain other directions to DTAB. The relevant extract of the said decision is 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 26A 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 26A 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."

4.15 DTAB considered the matter and recommended constituting the sub-committee under the Chairmanship of Dr Nilima Kshirsagar to review the ban on 344 (+5) Fixed Dose Combination Drugs. In

accordance with the said recommendations, the Sub-committee was constituted by an Office Memorandum dated 19.02.2018.

4.16 On 12.03.2018, a notice was issued on the website of CDSCO requesting the drug manufacturers and other concerned parties to submit information in the prescribed format by 07.04.2018 for further deliberation in compliance with the directions of the Supreme Court.

4.17 The respondents further state that separate letters were also sent to various parties who had challenged the notifications issued under Section 26A of the Act. The said parties were afforded an opportunity of hearing as per the schedule fixed by the Sub-committee.

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

4.19 It is stated that the Sub-committee reviewed the FDC in question on 18.06.2018 and afforded full opportunity to the petitioners to be heard. The Sub-committee, thereafter, submitted its report and recommended the said FDC to be irrational. The reasons for its recommendations, as indicated in the report, are set out below:-

> "1. Pharmacokinetic mismatch: Aceclofenac is given two times a day, Rabeprazole is administered once a day and Paracetamol four times a day.
>
> 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects.

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

5. The said report was accepted and the Central Government issued the impugned notification. Aggrieved by the same, the petitioners have preferred the present petition.

***Submissions***

6. Mr Tripathi, learned Senior Counsel appearing for the petitioners contended that the impugned notification had been issued in violation of principles of natural justice. He submitted that the report of the Sub-committee indicates no reason for recommending why the said FDCs should be proscribed. Although, it is concluded that there is no therapeutic justification for the said FDC, the said conclusion is not supported by any reason. He referred to the detailed submissions made by the petitioners before the Sub-committee for establishing the therapeutic justification for the said FDC. He submitted that the petitioners had also supported its submissions by extensive material. However, the report of the Sub-committee has no reference to either the submissions made by the petitioners or the material furnished by them. He contended that the decision under Section 26A of the Act was administrative and, therefore, the principles of natural justice could not be excluded. He referred to the decision of the Supreme Court in ***Godawat Pan Masala Products I.P. Ltd. & Anr. v. Union of India & Ors.: (2004)7 SCC 68*** and submitted that merely because the impugned notification is of general application does not necessarily mean that it is legislative in nature.

He further submitted that notwithstanding the same, the impugned notification could be challenged on several grounds including that relevant considerations have been excluded; if irrelevant considerations were taken into account and there was credible material for the Central Government to be satisfied as to the conditions specified in Section 26A of the Act.

7. He relied on the decisions of the Supreme Court in ***Systopic Laboratories (Pvt.) Ltd. v. Dr. Prem Gupta: 1994 SCC Supl. (1) 160*;** the decision of the Bombay High Court in ***Roussel Pharmaceuticals (India) Ltd. v. Union of India: 1989 SCC OnLine (Bom) 450***; the decision of the Karnataka High Court in ***Lundbeck India Pvt. Ltd. v. Union of India and Ors.: 2013 SCC OnLine (Kar) 622*** and the decision of this Court in ***E. Merck (India) Ltd. v. Union of India:2001 (90) DLT 60***.

8. Ms Acharya, learned ASG appearing for the respondents countered the submissions made on behalf of the petitioners. She contended that the powers exercised by the Central Government under Section 26A of the Act are legislative powers and, therefore, necessarily exclude the principles of natural justice. She contended that it was not necessary for the Sub-committee or the Central Government to give any reason for banning the said FDC. She submitted that the Sub-committee constituted on 19.02.2018 had, after examining all material, concluded that there was no therapeutic justification for the said FDC. She stated that this was sufficient material for the Central Government to issue the impugned

notification. She also contended that the said conclusion also clearly indicated the reasons for recommending ban on the FDC. Next, she contended that the Sub-committee was constituted by experts in the given subject and the Courts would not re-examine their decision or subject the same to judicial review. She referred to the decision of the Supreme Court in ***Academy of Nutrition Improvement v. Union of India: (2011) 8 SCC 274***; ***Vincent Panikurlangara v. Union of India and Ors. 1987 SCC (2) 165***; and ***Systopic Laboratories (Pvt.) Ltd.*** (*supra*) in support of the aforesaid contention.

***Reasoning and Conclusion***

9. Before proceeding further, it would be relevant to refer to the provisions of Section 26A of the Act, which reads as under:-

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

10. It is clear from the language of Section 26A of the Act that a drug or cosmetic can be banned or restricted only if the Central

Government is satisfied that (i) use of the said drug/cosmetic is likely to involve any risk to human beings or animals; or (ii) the drug does not have the therapeutic value claimed or purported to be claimed; or (iii) contained ingredients and in such quantity for which there is no therapeutic justification. If the Central Government is satisfied that any of the said condition existed and it is not necessary or expedient in the public interest, the Central Government may regulate, restrict or prohibit the sale of such drug or cosmetic.

11. It is clear that the notifications issued in exercise of powers under Section 26A of the Act are of general application and the power exercised by the Central Government under Section 26A of the Act is legislative in nature. In ***E Merck India Ltd*** (*supra*), a Division Bench of this Court had, in the light of the principles laid down by the Supreme Court in ***Cynamide India Ltd***. (*supra*) expressed its *prima facie* view that the powers exercised by the Central Government under Section 26A of the Act, are legislative in nature.

12. Having stated the above, it is not necessary for this Court to delve further into the aforesaid issue, essentially, for two reasons. First, that the Supreme Court had – without going into the question as to whether the power under Section 26A of the Act is legislative or not – issued directions for the DTAB/Sub-committee to examine the issue regarding banning of certain FDCs and including the said FDC. Thus, there is no dispute that the issue was to be examined in accordance with the directions issued by the Supreme Court.

13. Second, even if it is expected that the powers to be exercised under Section 26A of the Act are legislative in nature, there is no dispute that such powers can be exercised only on the Central Government is satisfied that it is necessary to exercise the same in larger public interest. Plainly, the Central Government's satisfaction would be required to be based on the relevant considerations; cogent material; and by excluding irrelevant considerations.

14. The controversy involved in the present petition, thus, falls in a very narrow compass. The first and foremost aspect of the controversy is whether the Central Government's decision to proscribe the said FDC is based on relevant material and second, whether the impugned notification has been issued by due compliance of the directions of the Supreme Court.

15. Concededly, the only material considered by the Central Government for issuing the impugned notification was the report of the Sub-committee. The report of the Sub-committee in respect of the said FDC reads as under:-

> "1. Pharmacokinetic mismatch: Aceclofenac is given two times a day, Rebeprazole is administered once a day and Paracetamol four times a day.
>
> 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects.
>
> There is no convincing scientific/clinical evidence /justification for the FDC."

16. This Court is of the view that the said report could not be considered by the Central Government in isolation without reference to the context in which the Sub-committee came to examine the issue. The matter was referred to the Sub-committee pursuant to the directions issued by the Supreme Court in ***Pfizer Ltd***. (*supra*). The operative directions issued by the Supreme Court are 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."

17. It is apparent from the above that the controversy whether FDCs in question were required to be proscribed, was referred to the Sub-committee because the reasons provided by the Kokate Committee for such an action was clear. In the circumstances, the Supreme Court was of the view that analysis was required to be made in greater depth. The Supreme Court had expressly directed that DTAB/Sub-committee to not only hear the appeals before the Supreme Court but also hear submissions from All India Drug Action Network. The Subcommittee was required to deliberate whether any of the parameters as set out in Section 26A of the Act were met. The Supreme Court also expressly directed that the Sub-committee must apply its mind as to whether it

was necessary or expedient in larger public interest to regulate, restrict or proscribe the manufacture, sale and distribution of the FDCs in question. The Subcommittee was also required to clearly indicate in its report as to why any of the three factors as indicated in Section 26A of the Act, were attracted. In addition, the Sub-committee was also required to indicate in its report as to why restriction or regulations were not sufficient to control the manufacture and use of the FDCs in question in case the same were recommended to be proscribed.

18. The Court also directed the Central Government to apply its mind to the parameters set out in Section 26A of the Act having due regard to the report of the Sub-committee or any other relevant information.

19. In view of the above, this Court is unable to accept the contention that the Sub-committee was not required to indicate its reasons for recommending that the said FDC be proscribed. It is clear that the entire exercise of remitting the matter to DTAB/Sub-committee for hearing the parties before the Supreme Court, and submitting a report, was directed to afford the Central Government to take an informed decision.

20. Ms Acharya had contended that since the exercise of powers under Section 26A of the Act are legislative in nature and principles of natural justice are excluded, there was no requirement for the Sub-committee to indicate any elaborate reasons. She had earnestly contended that the Sub-committee was constituted by experts and,

therefore, their conclusions (which she also described as brief reasons) must be accepted.

21. This Court is unable to accept the aforesaid contention. The Central Government may not require indicating its reasons in the notification but surely the material on which the decision is based – in this case the report of the Sub-committee – must provide a clear justification for issuing an order proscribing or manufacture and sale of a drug. Apart from being a part of the principles of natural justice, providing reasons is also necessary to indicate that the authority expressing its conclusion has done so after due application of mind. Thus, notwithstanding whether the principles of natural justice are applicable, the report of the Sub-committee was required to give sufficient reason for its recommendation, as that report was required to be considered by the Central Government for determining the question whether to proscribe or restrict an FDC.

22. In the case of the said FDC, the principal controversy to be examined by the Sub-committee was whether the said FDC ought to be banned on account of pharmacokinetics incompatibility among the three constituent drugs. The petitioners had disputed the same and had submitted therapeutic justification for the said FDC and also extensive material in this regard. At this stage, it would be relevant to mention that the Kokate Committee had made the following observations with regard to the said FDC:-

> "1. There is pharmacokinetics incompatibility among the three drugs as the dosing intervals are BD for

aceclofenac, OD for rabeprazole and TDS/QID for paracetamol.

2. This FDC is not approved anywhere in the world.

3. The literature regarding safety and efficacy of the combination is not available in Pubmed and Google scholar."

23. As noticed above, the aforesaid reasons were not found to be clear and, therefore, the Supreme Court had directed the Sub-committee to examine the same. Pursuant to the notice dated 12.03.2018, petitioner no.1 made a detailed submission including a therapeutic justification for the said FDC. The relevant extract of the statement indicating the therapeutic justification of the said FDC, as submitted by petitioner no.1, is set out below:-

> "Aceclofenac belongs to the class of Non-steroidal anti-inflammatory drugs (NSAID). Like other nonsteroidal anti-inflammatory drugs (NSAIDS), aceclofenac is a prostaglandin synthetase (cyclooxygenase) inhibitor, which decreases prostaglandin and leukotriene production, therefore inhibiting the inflammatory process. Aceclofenac has been shown to have potent anti-inflammatory, analgesic, and antipyretic properties. The onset of action of Aceclofenac is 30 to 60 minutes after oral administration. The maximum serum concentration is achieved in 1.25-2hours and has a half life of 4 hours. The usually recommended dose is 10mg twice a day. Several studies have proven a superior efficacy and better safety in comparison to Diclofenac, a gold standard NSAID.
>
> Paracetamol belongs to the class of centrally acting analgesic and antipyretic with minimal anti-

inflammatory properties. Paracetamol reduces fever by inhibiting the formulation and release of prostaglandins in the CNS and by inhibition endogenous pyrogens at the hypothalamic thermoregulator center. The maximum serum concentration after oral administration is achieved in 1 hour and has a half life of 2.25 hours. When used alone the recommended dosing is 650 to 1000 mg orally every 4 to 6 hours as needed; maximum 4000 mg/24 hours. However, the purpose of combining pracetamol with NSAIDs is solely to enhance the analgesic effect. Several randomised control trials and a systematic review concluded that a combination of paracetamol and an NSAID may offer superior analgesia compared with either drug alone.

***Rabeprazole*** is a gastric proton pump inhibitor that does not possess anticholinergic or histamine H(2) -receptor antagonist properties. It suppresses gastric acid secretion by inhibiting the gastric H+, K+-ATPase at the secretory surface of pariental cells. The onset of action of Rabeprazole is within 1 hour of oral administration. Rabeprazole absorption is not altered by food and hence can be administered anytime. While the recommended dosing of Rabeprazole is 20 mg once a day, studies have proven either a non-inferiority of dividing the dose to 10mg twice a day, studies have proven either a non-inferiority of dividing the does to 10mg twice a day or superiority of the divided regimen over once daily in night time gastric acid secretion. Accordingly, our proposed FDR, include Rabeprazole in dose of 10 mg.

It is relevant to note that although NSAIDs are the most widely used therapeutic agents in the management of pain, their use is associated with gastrointestinal (GI), cardiovascular, and renal

> adverse events (AEs. One of the commonest side effects reported with NSAID use is gastrointestinal side effects. Owning to this fact, several guidelines such as by National Institute of health and Care Excellence (NICE), UK recommends the use of proton pump inhibitors along with NSAIDs."

24. It was petitioner no.1's case before the FDC that the tablet drug paracetamol would be combined with NSAID (non-steroidal anti-inflammatory drugs) to offer superior analgesia. Petitioner no.1 had also claimed that even though the recommended dose for rabeprazole is 20 mg once a day, the said dose divided into a dose of 10 mg twice a day.

25. It does not appear from the report of the Sub-committee that any of the aforesaid contentions were considered. The Sub-committee persisted on the basis that rabeprazole is administered once a day; however, it fails to consider the petitioners' claim that the ordinary dose of 20 mg once a day could be split into two doses of 10 mg.

26. Petitioner no.1 had also stated that two other FDCs, namely, (i) Aceclofenac (100 mg) + Paracetamol (500 mg) and (ii) Aceclofenac 200 mg/200 mg SR + Rabeprazole 10mg/20mg Capsule were already approved. It is not for this Court to consider whether the therapeutic justification as provided by the petitioners was merited or not. Clearly, this Court cannot embark on the said inquiry. The scope of judicial review would not extend supplanting this Court's opinion over of the concerned authorities. However, if the expert Sub-committee had considered the aforesaid justification and rejected the same, no further

interference would be called for. However, it would be important to ascertain whether the Sub-committee had applied its mind to the said justification provided by the petitioners.

27. In this regard, this Court had called upon the respondents to indicate whether there was any material before the Sub-committee to counter such assertions made by the petitioners. In response to the aforesaid direction, the respondents had filed a counter affidavit indicating that the Subcommittee had taken note of the standard text books "Martindale". The said text is a standard text which indicates the ordinary dosages of drug. Thus, it also does not appear that any specific material considered by the Sub-committee on the basis of which it could be assumed that the petitioners' claim for therapeutic justification was rejected. The respondents have also produced the minutes of the meeting of the Sub-committee which also does not indicate whether the petitioners' explanation was considered by the Subcommittee. The minutes of the meeting of the Sub-committee held on 18.06.2018 merely indicates that "*the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide*." Thus, neither the minutes nor the report submitted by the Sub-committee indicates that the explanation provided by the petitioners was considered and was rejected after due application of mind. It was contended by learned ASG that the Sub-committee was not expected to give detailed reasons and elaborate explanation as to why they did not accept the petitioners' contention. This contention is

merited. Surely, the Sub-committee was not expected to provide explanations for rejecting the explanation provided by petitioner no.1. However, it was incumbent on the Sub-committee to indicate that the Sub-committee had considered the petitioners' claim for therapeutic justification and briefly indicate why the same was not acceptable. However, in the present case, it does not appear that the Sub-committee had even considered the presentation made by petitioner no.1. Clearly, the directions given by the Supreme Court to offer parties a hearing cannot be an empty formality. The Sub-committee was required to give reasons for its recommendations and why the claim put up by the petitioner was not acceptable. In this case, the Subcommittee had not even expressly indicated that it did not find any merit that the petitioners' claim. As stated above, the Central Government was required to apply its mind and take an informed decision, and since the sole material on which the Central Government had relied was the report of the Sub-committee, it was necessary that the said report briefly indicate the reasons as to why the claims of the manufacturers of FDCs in question were recommended to be rejected.

28. At this stage, it would also be relevant to refer to the decision of the Supreme Court in ***Cellular Operators Association of India and Ors. v. Telecom Regulatory Authority of India and Ors.: (2016) 7 SCC 703***. In that case, the Court examined the Regulation framed by the Telecom Regulatory Authority of India (TRAI) in exercise of powers under Section 11(4) of the Telecom Regulatory Authority of India Act, 1997. The said Section required the TRAI to ensure

transparency while exercising its powers and discharging its functions. TRAI had held consultations with all the stakeholders and also allowed them to make submissions before the TRAI. The Court found that although the consultations have been held, there was no discussion or reasoning dealing with the arguments put forth by service providers as regards to the reasons for call drops.

29. Since the conclusion was bereft of any reasoning in this regard, the Supreme Court set aside the same. It is relevant to note that there was no dispute that the powers exercised by TRAI were legislative in nature and the Court also noted its earlier decisions in ***Union of India v. Cynamide India Ltd***. (*supra*) and ***MRF Ltd. v. State of Kerala: (1998) 8 SCC 227***, wherein it was held that the principles of natural justice cannot be read into a legislative activity. The Supreme Court held that the definition of "transparency" under Section 13 of the Airports Economic Regulatory Authority of India Act, 2008 provide a good working test of transparency as referred to under Section 11(4) of the TRAI Act, 1997 and applied the same. The Court also referred to the provisions of the US Administrative Procedure Act and observed as under:-

> "74. We find that, subject to certain well defined exceptions, it would be a healthy functioning of our democracy if all subordinate legislation were to be "transparent" in the manner pointed out above. Since it is beyond the scope of this judgment to deal with subordinate legislation generally, and in particular with statutes which provide for Rule making and Regulation making without any added

> requirement of transparency, we would exhort Parliament to take up this issue and frame a legislation along the lines of the U.S. Administrative Procedure Act (with certain well defined exceptions) by which all subordinate legislation is subject to a transparent process by which due consultations with all stakeholders are held, and the Rule or Regulation making power is exercised after due consideration of all stakeholders' submissions, together with an explanatory memorandum which broadly takes into account what they have said and the reasons for agreeing ordisagreeing with them. Not only would such legislation reduce arbitrariness in subordinate legislation making, but it would also conduce to openness in governance. It would also ensure the redressal, partial or otherwise, of grievances of the concerned stakeholders prior to the making of subordinate legislation. This would obviate, in many cases, the need for persons to approach courts to strike down subordinate legislation on the ground of such legislation being manifestly arbitrary or unreasonable."

30. In ***Sitaram Sugar Mills Company v. Union of India: (1990) 3 SCC 223***, the Supreme Court considered the scope of judicial review in the context of *zone-wise fixation of price of levy sugar* under the relevant statutory order in terms of the Essential Commodities Act, 1955 and held as under:-

> "47. Power delegated by statute is limited by its terms and subordinate to its objects. The delegate must act in good faith, reasonably, intra vires the power granted, and on relevant consideration of material facts. All his decisions, whether characterised as legislative or administrative or

> quasi-judicial, must be in harmony with the Constitution and other laws of the land. They must be "reasonably related to the purposes of the enabling legislation". If they are manifestly unjust or oppressive or outrageous or directed to an unauthorised end or do not tend in some degree to the accomplishment of the objects of delegation, court might well say, "Parliament never intended to give authority to make such rules; they are unreasonable and ultra vires.
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> xxxx xxxx xxxx xxxx
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> 51. A repository of power acts ultra vires either when he acts in excess of his power in the narrow sense or when he abuses his power by acting in bad faith or for an inadmissible purpose or on irrelevant grounds or without regard to relevant considerations or with gross unreasonableness."

31. In a recent decision rendered by 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***, the Division Bench of this court examined the scope of judicial review in the context of a notification issued under Section 26A of the Act proscribing the manufacture and sale of the drug Oxytocin. The Court held as under:-

> "90. 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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> xxxx xxxx xxxx xxxx
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> 93. 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."

32. The Court accepted the view that the Courts do not and cannot enter into a "merits review" of an executive decision and observed that the scope of judicial review in determining the validity of the notification in question "*is narrow and confined to examining whether the measure is manifestly arbitrary or vitiated because it did not take into account relevant considerations.*" The Court, thereafter, proceeded to examine whether the notification prohibiting existing licenses from manufacturing Oxytocin was "*justified, legal and a reasonable restriction*".

33. In cases of subordinate legislation, the principal legislation may itself provide certain safeguards requiring the concerned authority to comply with certain conditions. Under Section 26A of the Act, the

Central Government is required to be satisfied as to the parameters set out therein. Although, such satisfaction cannot be questioned on merits, it cannot be disputed that the same must be made on credible and cogent material and after due application of mind.

34. In the present case, the Sub-committee was to provide the comprehensive material for enabling the Central Government to take such decision. Although, the Sub-committee had received the representations from the petitioners and had also afforded the petitioners a hearing, the report does not indicate that any of it was considered and no reason, whatsoever, have been provided for rejecting the explanations provided by the petitioners.

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

36. The petition is disposed of in the above terms.

**VIBHU BAKHRU, J**

**JANUARY 7, 2019**
**RK/pkv/MK**