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

% ***Judgment reserved on: 18.12.2025***
Judgment pronounced on: 09.01.2026

\+ LPA 671/2019 & CM APPL. 45953/2019 (Delay of 173 days in filing LPA)

ALL INDIA DRUG ACTION NETWORK .....Appellant

Through: Ms. Tanya Agarwal, Mr. Krishna Kumar Keshav and Mr. Ankush Khanna, Advocates.

versus

LUPIN LTD & ORS. .....Respondents

Through: Mr. Raj Sekhar Rao, Senior Advocate with Mr. Ajay Bhargava, Ms.Vanita Bhargava, Mr. Aseem Chaturvedi, Mr. Milind Jain and Mr. Anuj Shrotriya, Advocates.
Mr. Chetan Sharma, ASG for UOI with Mr. P.S. Singh, CGSC with Ms. Shiva Lakshmi, Mr. Amit Gupta, Mr. Madhav Bajaj, Mr. Vivek Mathur, Mr. R.V. Prabhat, Mr. Shubham Sharma, Mr. Vikram Aditya Singh, Mr. Yash Wardhan Sharma, Mr. Naman, Mr. Dinesh Kumar, Advocates, Mr. Deepak Kumar, Mr. Rajneesh K. Sharma, Mr. Ashutosh Bharti, Ms. Minakshi Singh and Mr. Prituysh Kumar, ADC (I) for R-3 & 4

\+ LPA 105/2020, CM APPL. 6860/2020 (Stay), CM APPL. 6862/2020 (Delay of 280 days) & CM APPL. 6863/2020 (Delay of 25 days in re-filing the appeal)

UNION OF INDIA .....Appellant

Through: Mr. Chetan Sharma, ASG with Mr. P.S. Singh, CGSC with Ms. Shiva Lakshmi, Mr. Amit Gupta, Mr. Madhav Bajaj, Mr. Vivek Mathur, Mr. R.V. Prabhat, Mr. Shubham Sharma, Mr. Vikram Aditya Singh, Mr. Yash Wardhan Sharma, Mr. Naman, Mr. Dinesh Kumar, Advocates, Mr. Deepak Kumar, Mr. Rajneesh K. Sharma, Mr. Ashutosh Bharti, Ms. Minakshi Singh and Mr. Prituysh Kumar, ADC (I) for UOI

versus

ERIS LIFESCIENCES LIMITED & ANR. .....Respondents

Through: Mr. R. Jawahar Lal and Mr. Sayyam Maheswari, Advocates.

\+ LPA 106/2020, CM APPL. 6864/2020 (Stay), CM APPL. 6866/2020 (delay of 280 days) & CM APPL. 6867/2020 (Delay of 25 days in re-filing the appeal)

UNION OF INDIA & ANR. .....Appellants

Through: Mr. Chetan Sharma, ASG for UOI with Mr. P.S. Singh, CGSC with Ms. Shiva Lakshmi, Mr. Amit Gupta, Mr.Madhav Bajaj, Mr. Vivek Mathur, Mr. R.V. Prabhat, Mr.Shubham Sharma, Mr. Vikram Aditya Singh, Mr. Yash

Wardhan Sharma, Mr.Naman, Mr. Dinesh Kumar, Advocates, Mr. Deepak Kumar, Mr. Rajneesh K. Sharma, Mr. Ashutosh Bharti, Ms. Minakshi Singh and Mr. Prituysh Kumar, ADC (I)

versus

M/S MICRO LABS LIMITED .....Respondent

Through: Mr. Akhil Sibal, Senior Advocate along with Ms. Archana Sahadeva, Mr. Harshit Bhoi and Ms. Jahnavi Sindhu, Advocates.

CORAM:
HON'BLE MR. JUSTICE ANIL KSHETARPAL
HON'BLE MR. JUSTICE HARISH VAIDYANATHAN SHANKAR

J U D G M E N T

HARISH VAIDYANATHAN SHANKAR, J.

1. The present **Letters Patent Appeals**[1], namely LPA No. 105/2020, LPA No. 106/2020, and LPA No. 671/2019, assails the common **Judgment dated 13.02.2019**[2] passed by the learned Single Judge of this Court in W.P.(C) Nos. 11278/2018, 9978/2018, and 10936/2018, *respectively*. The said writ petitions were instituted challenging two notifications, namely S.O. 4471(E) and S.O. 4472(E), issued by the Central Government in exercise of powers under Section

[1] LPA
[2] Impugned Judgement

26A of the **Drugs and Cosmetics Act, 1940**[3], whereby the manufacture and sale of certain **Fixed Dose Combinations**[4] were prohibited.

2. LPA Nos. 106/2020 and 671/2019 arise from W.P.(C) Nos. 9978/2018 and 10936/2018 and pertain to the challenge to notification S.O. 4471(E), whereas LPA No. 105/2020 arises from W.P.(C) No. 11278/2018 and concerns notification S.O. 4472(E).

3. Notification S.O. 4472(E) proscribed the manufacture and sale of FDCs comprising the formulation "Glimepiride 1 mg/2 mg + Pioglitazone 15 mg/15 mg + Metformin 850 mg/850 mg", while notification S.O. 4471(E) proscribed the manufacture and sale of FDCs comprising the formulation "Glimepiride 1 mg/2 mg/3 mg + Pioglitazone 15 mg/15 mg/15 mg + Metformin 1000 mg/1000 mg".

4. *Vide* the Impugned Judgment, the learned Single Judge, after considering the rival submissions and the material on record, set aside both notifications. Aggrieved thereby, LPA Nos. 105/2020 and 106/2020 have been preferred by the Union of India, while LPA No. 671/2019 has been preferred by the All India Drug Action Network.

5. Since the three appeals arise out of a common Impugned Judgment and involve substantially similar questions of law and fact, they were, with the consent of learned counsel appearing for the parties, heard together and are being disposed of by this common Judgment.

6. The **Union of India**[5], which is the Appellant in LPA No. 105/2020 and LPA No. 106/2020, along with the **All India Drug**

[3] Drugs Act
[4] FDC
[5] UOI

Action Network, which is the Appellant in LPA No. 671/2019, shall hereinafter be collectively referred to as the "Appellants", whereas the pharmaceutical companies, namely M/s Micro Labs Limited, Intas Pharmaceuticals Limited, Lupin Limited, and Eris Lifesciences Limited, who were the writ petitioners before the learned Single Judge, shall be referred to as the "Respondents", unless the context otherwise requires.

BRIEF FACTS:

7. At the cost of some minor repetition, the brief conspectus of the facts, as emerging from the record, is set out hereunder:

7.1 The present appeal arises from the common judgment dated 13.02.2019 passed by the learned Single Judge of this Court, whereby the learned Single Judge set aside notifications S.O. 4471(E) and S.O. 4472(E) dated 07.09.2018, issued by the Central Government in exercise of powers under Section 26A of the Drugs Act, and remanded the matter to the **Drug Technical Advisory Board**[6]/ Sub-Committee for fresh consideration.

7.2 The Respondents/Writ Petitioners, are manufacturers of certain FDCs used in the treatment of Type-II Diabetes Mellitus. By notification S.O. 4471(E) dated 07.09.2018, the Central Government prohibited the manufacture, sale, and distribution of FDCs comprising Glimepiride 1 mg / 2 mg / 3 mg + Pioglitazone 15 mg + Metformin 1000 mg, and by notification S.O. 4472(E) dated 07.09.2018, prohibited FDCs comprising

[6] DTAB

Glimepiride 1 mg / 2 mg + Pioglitazone 15 mg + Metformin 850 mg, on the ground that such FDCs involved risk to human beings and lacked adequate safety justification.

7.3 The issuance of the aforesaid notifications traces its origin to an exercise undertaken by the Central Government on 10.03.2016, whereby 344 FDCs were prohibited on the basis of the recommendations of an Expert Committee chaired by Professor C.K. Kokate. Certain notifications issued in 2016, including S.O. 806(E) and S.O. 807(E), related to FDCs containing Glimepiride, Pioglitazone, and Metformin. Those notifications were challenged before the High Court of Delhi and were set aside by a common judgment dated 01.12.2016, primarily on the ground that consultation with DTAB was mandatory prior to the issuance of notifications under Section 26A of the Drugs Act.

7.4 The UOI carried the matter to the Hon'ble Supreme Court, which by Judgment dated 15.12.2017 in ***Union of India v. Pfizer Limited & Ors.***[7] rejected the view that consultation with DTAB was mandatory and remanded the matter to DTAB or a Sub-Committee thereof with directions that the re-examination must be undertaken strictly within the parameters of Section 26A the Drugs Act, that the affected manufacturers must be heard, that the Committee must identify whether the FDCs involved risk to human beings, lacked therapeutic value, or contained ingredients without therapeutic justification, and that

[7] 2018 (II) SCC 39.

in cases of proposed prohibition, reasons must be furnished as to why regulation or restriction would not suffice.

7.5 Pursuant to the aforesaid directions, DTAB in its meeting dated 12.02.2018 recommended the constitution of a Sub-Committee under the Chairmanship of Dr. Nilima Kshirsagar, which was formally constituted by Office Memorandum dated 19.02.2018. The Sub-Committee issued notices dated 12.03.2018, called for information from the manufacturers in the prescribed format, afforded hearings to the concerned stakeholders including the AIDAN, and thereafter submitted its report to the Central Government.

7.6 In relation to the FDC containing Glimepiride 1 mg / 2 mg / 3 mg + Pioglitazone 15 mg + Metformin 1000 mg, the Sub-Committee recorded that triple-drug therapy is recognised in standard treatment guidelines for Type-II Diabetes Mellitus, that a large population of patients does not respond adequately to diet, exercise, mono-therapy, or dual therapy, that the DCGI had previously approved an FDC comprising Glimepiride + Pioglitazone 15 mg + Metformin 500 mg, and that the dosages of each ingredient in the impugned FDC were recommended and approved. The Sub-Committee nevertheless recommended prohibition on the ground that the FDC may involve risk of hypoglycaemia and that no safety data pertaining to the FDC was available.

7.7 With respect to the FDC containing Metformin 850 mg, the Sub-Committee recommended prohibition on the grounds that sufficient therapeutic options were available, that increments in

Metformin dosage are ordinarily made in steps of 500 mg, and that availability of multiple strengths could lead to medication errors.

7.8 Accepting the recommendations of the Sub-Committee, the Central Government issued notifications S.O. 4471(E) and S.O. 4472(E) dated 07.09.2018, prohibiting the manufacture, sale, and distribution of the aforesaid FDCs in exercise of powers under Section 26A of the Drugs Act.

7.9 Aggrieved by the said notifications, the manufacturers approached the High Court by way of the aforesaid writ petitions. By the Impugned Judgement, the learned Single Judge held that although the power under Section 26A of the Drugs Act is legislative in nature, it is amenable to judicial review; that the Sub-Committee had itself accepted the therapeutic value and approved dosage of the FDCs; that the reasons recorded for prohibition were cryptic, internally inconsistent, and did not satisfy the parameters laid down by the Supreme Court in ***Pfizer Limited & Ors.*** *(supra)*; that the Sub-Committee failed to explain why regulation or restriction was insufficient; and that the Central Government had relied exclusively on such deficient recommendations. On that reasoning, the learned Single Judge set aside notifications S.O. 4471(E) and S.O. 4472(E) and remanded the matter to DTAB / Sub-Committee for fresh consideration.

8. The present appeals are preferred by the UOI and the AIDAN being aggrieved by the Judgment dated 13.02.2019, contending, *inter alia*, that the learned Single Judge has, while exercising writ

jurisdiction, exceeded the permissible limits of judicial review by re-assessing the adequacy and sufficiency of expert material, failed to accord due deference to the satisfaction of the Central Government formed on the basis of expert recommendations in a matter concerning public health, and has erred in setting aside legislative notifications issued under Section 26A of the Drugs Act thereby necessitating interference by this Hon'ble Court in appeal.

CONTENTIONS OF THE APPELLANT:

9. Mr. Chetan Sharma, learned **Additional Solicitor General**[8]**,** assisted by Mr. P.S. Singh and Ms. Shiva Lakshmi, learned **Central Government Standing Counsel**[9], would articulate the challenge to the Impugned Judgment passed by the learned Single Judge broadly in the following manner:

I. Learned ASG would contend that the Impugned Judgment proceeds on a fundamentally erroneous premise inasmuch as it equates the approval of individual drug components with the approval of those very components when formulated together as a FDC, whereas, in law and regulatory practice, approval of individual active pharmaceutical ingredients cannot *ipso facto* be construed as approval of their combination in a single formulation. He would submit that the learned Single Judge, in transposing the approval of individual constituents to the impugned FDCs, has overlooked the settled principle that each FDC constitutes a distinct drug entity requiring independent evaluation.

[8] ASG
[9] CGSC

II. He would further contend that the FDCs in question were not supported by any dedicated clinical trial data, safety data, or scientific evidence validating their usage, dosage, or risk profile as combinations, and that the absence of such data was a determinative factor weighed by the expert body while recommending prohibition.

III. Learned ASG would submit that the learned Single Judge erred in presuming therapeutic value in the impugned FDCs solely on the basis that the individual components and their respective dosages had received approval, whereas such approval, in the absence of combination-specific evidence, could not form the basis for sustaining the legality of the FDCs or for invalidating the impugned notifications.

IV. He would thus contend that, in the absence of any scientific or clinical evidence pertaining to the safety and efficacy of the combination as such, the UOI was fully justified in invoking its statutory powers under Section 26A of the Drugs Act, to proscribe the manufacture and sale of the impugned FDCs in larger public interest.

V. He would further submit that the statutory standard under Section 26A of the Drugs Act is not the establishment of actual harm but the determination of whether the use of a drug is *likely* to involve risk to human beings, and that the learned Single Judge has erroneously elevated this statutory threshold by requiring a higher degree of proof than what the provision mandates. He would thus submit that mere likelihood would

suffice for the purpose of justifying the proscription of these FDCs.

VI. Learned ASG would further contend that the finding of the learned Single Judge characterising the reasons of the DTAB Sub-Committee as cryptic is unsustainable, as it fails to appreciate the deficiencies expressly recorded by the Sub-Committee, including the absence of clinical data, the lack of approved indications for the combinations, and the admitted absence of acceptance of the impugned FDCs by international regulatory authorities.

VII. Learned counsel for the Appellant would contend that, in exercise of judicial review, this Court does not sit in appeal over the sufficiency, adequacy, or scientific weight of the material considered by an expert body, and its scrutiny is confined to examining whether relevant material existed and whether the decision-making process was lawful. He would submit that once the statutory satisfaction of the Central Government is demonstrably founded on expert evaluation and bears a rational nexus with the object of protecting public health, incidental economic hardship to manufacturers is legally immaterial and cannot vitiate regulatory action, a principle reiterated by the Supreme Court in ***63 Moons Technologies Ltd. v. Union of India***[10], as well as in ***Ugar Sugar Works Ltd.***[11], ***Mohd. Murtaza v. State of Assam***[12], ***Systopic***

[10] (2019) 18 SCC 401
[11] (2001) 3 SCC 635
[12] (2011) 12 SCC 413

Laboratories (P) Ltd. v. Dr. Prem Gupta[13]**,** and ***Hubli Electricity Co. Ltd. v. Province of Bombay***[14]. He would further contend that judicial review does not extend to substituting the Court's view for that of specialised authorities on matters of scientific assessment, policy choice, or regulatory prudence, a position consistently affirmed by constitutional courts.

VIII. Learned ASG would further contend that the DTAB Sub-Committee, constituted pursuant to the directions of the Hon'ble Supreme Court in ***Pfizer Limited & Ors.*** (*supra*), undertook extensive expert deliberations before submitting its report, reflecting a detailed and considered examination of the impugned FDCs.

IX. He would submit that the Sub-Committee comprised experts drawn from diverse medical and scientific disciplines and had, in the course of its deliberative process, co-opted additional experts prior to formulating its recommendations, thereby reinforcing the robustness and technical depth of the decision-making exercise.

X. He would submit that the extensive bibliography appended to the report of the DTAB Sub-Committee, comprising 395 scientific publications and research papers, clearly evidences the depth, breadth, and rigour of the expert deliberation undertaken prior to recommending prohibition of the impugned FDCs.

[13] (1994 Supp (1) SCC 160)
[14] 1946 SCC OnLine Bom 58

XI. He would further contend that the proscription of the impugned FDCs was clearly warranted, public health being an integral and inseparable facet of public interest, and that where the use of such FDCs was found to be likely to involve risk to human beings, coupled with the absence of supporting clinical data and the lack of clear therapeutic justification, the Central Government was justified in treating such formulations as inherently injurious to public health.

XII. He would further submit that the statutory mandate as imposed by the Section 26A of the Drugs Act provides only for the Central Government to be "satisfied" and this satisfaction is to be based on relevant considerations. He would submit that this subjective satisfaction, as expressed by the Statute, cannot be subjected to an Appeal by the learned Single Judge in exercise of power under Article 226 of the **Constitution of India**[15].

XIII. He would further submit that in matters concerning prohibition of manufacture and sale of drugs, primacy must necessarily be accorded to considerations of public health and prevention of harm, and that the Court cannot insist upon a standard of proof or justification higher than that contemplated by the statutory scheme itself.

XIV. Learned counsel for the Appellant would contend that the impugned FDC constitute a "new drug" within the meaning of Rule 122E(c) of the **Drugs and Cosmetics Rules, 1945** and Rule 2(w)(iii) of the **New Drugs and Clinical Trials Rules, 2019**, as the combination, ratio, and dosage form had not been

[15] Constitution

previously approved. He would submit that, once so classified, Rule 52 of the 2019 DCT Rules squarely applies, casting a mandatory statutory obligation upon the manufacturer to obtain prior permission of the Central Licensing Authority and to establish safety, efficacy, and therapeutic justification through clinical data strictly conforming to Appendix VI of Schedule Y.

XV. He would further contend that the DTAB Sub-Committee has categorically recorded that the Respondent-manufacturers failed to discharge this statutory onus, having placed no combination-specific clinical trial or safety data, relied upon inadequate and irrelevant literature, and remained unable to specify approved indications. He would submit that the Sub-Committee also noted that the triple-drug FDC of Glimepiride, Pioglitazone, and Metformin lacks approval in any other jurisdiction, thereby underscoring the absence of global regulatory acceptance.

XVI. He would thus contend that, in light of the admitted non-compliance with the statutory threshold, the satisfaction arrived at by the Central Government under Section 26A of the Drugs Act**,** based on expert findings of risk and absence of safety data, is legally unassailable, and that the decision of the Hon'ble Supreme Court in ***Pfizer Limited & Ors.*** (*supra*) authorises and indeed compels prohibition in such circumstances in the paramount interest of public health.

XVII. He would lastly contend that, having regard to the cumulative assessment undertaken by the UOI, the sensitive nature of the drugs involved, and their widespread use by a large segment of the population in a country with a high prevalence of Type-II

Diabetes Mellitus, the prohibition imposed by the Central Government was justified and in larger public interest, and that the impugned judgment of the learned Single Judge warrants interference and deserves to be set aside.

CONTENTIONS OF THE RESPONDENTS:

10. ***Per contra***, learned counsel appearing for the Respondents in the connected appeals would advance submissions broadly on similar lines as follows:

I. They would contend that the Hon'ble Supreme Court, in ***Pfizer Limited & Ors.*** (*supra*), has clearly delineated the contours within which judicial review was to be exercised by the learned Single Judge while examining notifications issued under Section 26A of the Drugs Act.

II. They would further contend that there was a manifest failure on the part of the DTAB Sub-Committee to adhere to the binding directions issued by the Hon'ble Supreme Court, and that such non-compliance vitiates the report itself. In support thereof, they would place reliance upon the relevant findings recorded by the learned Single Judge in the Impugned Judgment.

III. They would submit that Section 26A of the Drugs Act requires the competent authority, before issuing any notification regulating, restricting, or prohibiting a drug, to clearly identify and record which of the statutory conditions is attracted, namely, whether the use of such drug is likely to involve any risk to human beings or animals, whether the drug does not possess the therapeutic value claimed or purported to be claimed for it, or whether it contains ingredients and in such

quantities for which there is no therapeutic justification, and that paragraph nos. 31 to 33 of the Judgment of the Hon'ble Supreme Court in ***Pfizer Limited & Ors.*** (*supra*) reiterate this statutory mandate by requiring the DTAB Sub-Committee to expressly indicate, with reasons, the specific limb or limbs of Section 26A on the basis of which regulatory action is proposed. The relevant portions of the Judgement are reproduced hereinbelow for reference:

> "**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 comittee 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 petitioner-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.
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> **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."

IV. They would further contend that the Hon'ble Supreme Court has *vide* paragraph no. 34 of ***Pfizer Limited & Ors***. (*supra*) additionally required that, after arriving at a conclusion on the aforesaid statutory parameters, the Sub-Committee must specifically examine and indicate whether, in the larger public interest, it was necessary or expedient to regulate, restrict, or prohibit the manufacture, sale, or distribution of the FDCs.

V. They would thereafter submit that the learned Single Judge has clearly held that the deficiencies which were earlier found in the DTAB Sub Committee Report persist in the present Report and taking note of the same, the learned Single Judge has rightly set aside the impugned Notifications.

VI. They would further submit that, in the absence of clear and cogent reasons justifying complete prohibition, the learned

Single Judge was justified in interfering with and setting aside the impugned notifications.

VII. They would contend that, in the present case, the Sub-Committee itself has acknowledged the therapeutic value and therapeutic justification of the impugned FDCs, and that the sole basis for recommending prohibition was that the formulations *"may involve risk to human beings"*.

VIII. They would further submit that such justification, founded merely on a speculative possibility, does not satisfy the statutory threshold prescribed under Section 26A of the Drugs Act, and that the standard applied by the Sub-Committee is neither contemplated by the statute nor sanctioned by the judgment of the Hon'ble Supreme Court in ***Pfizer Limited & Ors***. (*supra*).

IX. They would further contend that the Sub-Committee failed to accord due and meaningful consideration to the material and data submitted by the Respondents in support of the safety, efficacy, and therapeutic justification of their formulations.

11. The above are the broad submissions made by the Respondents, however, there are certain further submissions that have been made which are with respect to the reasoning given by the UOI in support of the two impugned Notifications and which will be dealt with in the analysis portion.

ANALYSIS:

12. We have heard learned ASG appearing for the UOI, assisted by Ms. Shiva Lakshmi, CGSC, and other learned counsel appearing alongside him. We have also heard Mr. Raj Sekhar Rao, learned

Senior Counsel, assisted by Mr. Ajay Bhargava, Advocate, Mr. Akhil Sibal Sr. Adv. Assisted by Ms. Archana Sahadeva, Mr. Jawahar Lal and other learned counsels appearing for the Respondents.

13. With their able assistance, we have had the benefit of perusing the relevant and material portions of the voluminous record placed before us. We place on record our appreciation for the succinct and focused submissions advanced, as well as for the concise manner in which the documents were presented for our consideration.

14. We consider it appropriate to reproduce the relevant extracts of the Impugned Judgment, which are relatable to the Notification being S.O. 4471(E) which deals with FDCs comprised of *"Glimepiride 1 mg/2 mg/3 mg + Pioglitazone 15 mg/15 mg/15 mg + Metformin 1000 mg/1000 mg"* and which read as under:

> "**30.** Thus, the limited question that falls for consideration of this Court is whether the Central Government's decision to ban the manufacture, sale and distribution of the FDCs in question is based on relevant material, and whether the impugned notification has been issued by due compliance of the directions of the Supreme Court in ***Pfizer*** *(supra).*
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> **31.** At the outset, it is relevant to note that the Sub Committee has approved an FDC comprising of Glimepiride 1/2mg + Pioglitazone 15 mg + Metformin 500 mg by a S.O. No. 4711(E) dated 07.09.2018. It is, thus, apparent that the only objection in respect of the FDCs proscribed in terms of S.O. No. 4471(E) and S.O. 4472(E) relate to the increased dosage of Metformin: 1000mg in FDCs proscribed by S.O. 4471(E)and 850 mg in FDCs proscribed by S.O. 4472(E).
>
> **32.** First six paragraph of the reasons indicated by the Sub Committee do not indicate any reason for proscribing the FDC. On the contrary, paragraph 3 of the said reasoning indicates that there is a sufficiently large population of patients that requires a triple drug combination for addressing the chronic disease. It is also noted in paragraph 4 of the said reasons that DCGI has approved the FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg) + Metformin (500 mg ER) uncoated tablet for indication as the third line treatment of Type II diabetes mellitus in cases where diet, exercise and single agents and second line therapy with two drugs, do not result in adequate glycemic control.

33. It is important to note that in paragraph 5 of its report, the Sub Committee expressly noticed that the FDCs in question contain "recommended" and "approved" therapeutic dosage of each ingredient. Thus, there is no dispute that the FDC in question have a therapeutic justification and are prescribed for certain patients. This is also the conclusion drawn by the Sub-Committee, as is apparent from paragraph 6 of their observations quoted above. It is expressly stated that the said FDC has therapeutic value and has the potential to address the need of patients with Type II Diabetes, who are not responding to mono or dual therapy.

34. The only reason provided by the Sub-Committee for proscribing the said FDC is that it can lead to risk of hypoglycemia and there is no safety data pertaining to this FDC. Once it is accepted that the formulations in the dosages, as included in the said FDC, is recommended and approved therapeutic dosages for treatment of Type II Diabetes in certain cases, it is difficult to understand the reason for proscribing the said FDCs on ground of lack of safety data.

35. Insofar as the observation that the said FDC can lead to risk of hypoglycemia is concerned, the petitioners have produced material on record, which indicates that the risk of hypoglycemia in Metformin is minimum. However, this is not an area of controversy which is required to be examined by this Court. The question whether a particular drug has any adverse effects is required to be examined by the experts, and the observation that the FDC can lead to hypoglycemia, must be accepted. However, it is difficult to understand the rationale to proscribe the said FDC on this count, considering that it is accepted that the formulations in that dosage included in the FDC is recommended and approved. Admittedly, the said FDC has therapeutic value in certain cases.

36. The Supreme Court, in the case of ***Pfizer Limited*** *(supra)*, had remanded the matter to DTAB/Sub-Committee for the reason that the reasons given by the Kokate Committee were cryptic. Plainly, the decision of Central Government founded on such reasons could not be sustained. This malady continues to subsist with the observations made by the Sub-Committee, as it provides little clarity for sustaining an action under Section 26A of the Act.

37. It is also conceded that the Central Government had not examined any other material other than the observations/ recommendations of the Sub-Committee for issuing the impugned notification. In absence of clear and cogent reasons, such a decision would be manifestly arbitrary and not sustainable.

38. It is also relevant to note that in ***Pfizer Limited*** (*supra*), the Supreme Court had expressly directed that in case where DTAB/Sub-Committee prohibits a particular FDC, it must also indicate in its report as to why restrictions or regulations are not sufficient to control the manufacture and use of the FDC. The recommendations of the Sub-Committee, read in conjunction with

the risks indicated, do not indicate why regulations or restrictions are insufficient in controlling the use of the FDC."

15. The relevant paragraphs of the Impugned Judgment, insofar as they pertain to Notification S.O. 4472(E), are extracted and reproduced hereinbelow:

> "**39.** In view of the above, the notification S.O. No. 4471(E) is not sustainable. Insofar as S.O. No. 4472 (E) is concerned, the same proscribes an FDC comprising of Glimepiride 1mg/2mg + Pioglitazone 15mg/15mg + Metformin 850mg/850. As observed above, it is obvious that the said FDC has been proscribed on account of an incremental dosage of Metformin 850mg, considering that the FDC comprising of Glimepiride 1mg/2mg + Pioglitazone 15mg and Metformin 500 mg is approved. The observations made by the Sub Committee for proscribing this FDC are, essentially, three fold. First, that there is sufficient therapeutic option; second, that increments in the dosage of Metformin are in steps of 500mg as per treatment guidelines; and third, that availability of multiple strengths can lead to medication error of overdosing or under-dosing.
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> **40.** Clearly, the reason that there are therapeutic options available is not a ground for prohibiting a drug under Section 26A of the Act. A drug can be proscribed under Section 26A, (i) if it involves any risk to human being or animals; (ii) the drug does not have any therapeutic value purported to be claimed; and (iii) that the drug contains ingredients in such quantity for which there is no therapeutic justification.
>
> **41.** The fact that there are other alternatives available cannot be a ground for proscribing the FDC in question.
>
> **42.** The second reason – that the increments in the dosage of Metformin are in steps of 500mg and, therefore, the FDC which contain the formulation in the strength of 850 mg ought to be proscribed – is also unsustainable. This is so because it is conceded before this Court that Metformin 850mg is an also approved drug. The petitioner has also produced material to indicate that Metformin in the dosage of 850mg is prescribed in certain patients. Plainly, if Metformin 850mg is an approved dosage, the question of proscribing the FDC on the ground that the strength of Metformin is not a multiple of 500mg is not sustainable.
>
> **43.** It is also relevant to note that the Central Government had also issued a notification under Section 26A of the Act proscribing FDCs comprising of: Metformin 1000 mg + Pioglitazone 7.5 mg + Glimepiride 1 mg; and, Metformin 1000 mg + Pioglitazone 7.5 mg + Glimepiride 2 mg. The said notification – S.O 4467(E) – was subject matter of challenge in ***Unison Pharmaceuticals Pvt. Ltd***

(supra). It is relevant to note that the said FDCs were proscribed for the reason that Pioglitazone 7.5 mg was not an approved dose; there was no issue with regard to inclusion of Metformin 1000 mg in the said FDCs.

44. The third reason, namely, that availability of multiple strengths can lead to medication error, is also cryptic in the sense that drugs comprising of the FDC are available in multiple strengths.

45. It was contended on behalf of the respondents that if the FDC in question is over prescribed or under prescribed, it would entail a serious risk to the patient. In this regard, it is relevant to observe that the rationale for making a FDC is for the convenience of a patient, who is prescribed several drugs (comprising the FDC). There is a compelling argument that an FDC is expedient in cases where a patient is required to take multiple medicines. The risk of over prescription or under prescription is common in all FDCs. The reasons indicated by the Sub-Committee do provide any clarity as to why this reason is relevant for the FDCs in question.

46. In view of the above, the recommendation of the Sub Committee that there is no therapeutic justification, is difficult to accept. This is also considering that it is not disputed that the contents of the FDC, in the dosage as included, are prescribed to patients to address Type II Diabetes."

16. Upon the aforesaid analysis, the learned Single Judge proceeded to conclude as follows:

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

48. The DTAB Sub-Committee shall submit a report to the Central Government clearly providing an explanation for its recommendations along with the material in support thereof. The Central Government is required take an informed decision after examining the report of DTAB/Sub-Committee and the material provided along with it."

17. In order to appreciate the analysis undertaken and to place the controversy in its proper statutory perspective, it would be apposite to reproduce Section 26A of the DC Act, which reads as follows:

"**26A. Powers of Central Government to [regulate, restrict or 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.]"

18. We also deem it appropriate, for the purposes of the present analysis, to extract the relevant paragraphs from the Judgment of the Hon'ble Supreme Court in ***Pfizer Limited & Ors.*** (*supra*), which are reproduced hereunder:

> "**1.** Leave granted. The present appeals and transfer petitions relate to the interpretation of Section 26-A of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as "the Drugs Act"). By the impugned judgment of the learned Single Judge of the Delhi High Court dated 1-12-2016, the learned Single Judge has held that the mandatory condition precedent for the exercise of the power by the Central Government under Section 26-A of the Drugs Act is the prior consultation of the Drugs Technical Advisory Board (DTAB) set up under Section 5 of the said Act. It must be stated that the learned Single Judge differed from the judgments of the Karnataka and the Madras High Courts in this regard, wherein two other learned Single Judges of two other High Courts have held that such consultation with the DTAB is not mandatory before exercise of such power under Section 26-A. Since we are concerned only with this narrow question that has been decided by the learned Single Judge of the Delhi High Court, we are not going into any other contentions that have been raised by the learned counsel for the parties.
>
> **2.** The issue regarding the prevalence of many fixed dose combinations (hereinafter referred to as "FDCs") that were flooding the Indian market and had not been tested for efficacy or safety was considered by the Parliamentary Standing Committee on Health and Family Welfare in its 59th Report in May 2012. The Standing Committee observed that some of the State Licensing Authorities have issued manufacturing licences for a very large number of FDCs without prior clearance from the Central Drugs Standard Control Organization (CDSCO). Such FDCs can pose significant risks to persons and need to be withdrawn immediately in that human lives can be at risk. The Committee recommended that a clear and transparent policy may be framed for approving FDCs based on scientific principles, and that, at present, Section

26-A of the Drugs Act is adequate to deal with the problem of FDCs not cleared by the Cdsco. Pursuant to the aforesaid report, the Ministry of Health in October 2012 issued directions to the States and Union Territories under Section 33-P of the Drugs Act not to grant licences to FDCs falling under the definition of "new drugs" and not approved by the Drug Controller General of India [DCG(I)]. The DCG(I), in turn, had requested all States/Union Territories Drug Controllers to ask the manufacturers concerned in their respective States/Union Territories to prove the safety and efficacy of such FDC licences issued prior to 1-10-2012, without due approval of the DCG(I), within a period of 18 months, failing which such FDCs would be considered for being prohibited, both qua manufacture and marketing in the country. On 5-7-2013, the DCG(I) vide its communication to the State Drug Controllers asked manufacturers to make applications as per the procedure prescribed within this 18 month period. We have been informed that a large number of applications were received from the manufacturers within the 18 month period for 2911 products, which had to be subjected to examination.

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14. Having heard the learned counsel for the parties, it is clear that Section 26-A has been introduced by an amendment in 1982. A bare reading of this provision would show, firstly, that it is without prejudice to any other provision contained in this Chapter (meaning thereby Chapter IV). This expression only means that apart from the Central Government's other powers contained in Chapter IV, Section 26-A is an additional power which must be governed by its own terms. Under Section 26-A, the Central Government must be "satisfied" that any drug or cosmetic is likely to involve (i) any risk to human beings or families; or (ii) that any drug does not have the therapeutic value claimed or purported to be claimed for it; or (iii) contains ingredients in such quantity for which there is no therapeutic justification. Obviously, the Central Government has to apply its mind to any or all of these three factors which has to be based upon its "satisfaction" as to the existence of any or all of these factors. The power exercised under Section 26-A must further be exercised only if it is found necessary or expedient to do so in public interest. When the power is so exercised, it may regulate, restrict or prohibit manufacture, sale or distribution of any drug or cosmetic.

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16. As has been stated hereinabove, Section 26-A was brought in by an amendment in 1982. The amendment specifically made changes in Sections 33 and 33-N in which it added the words "on the recommendation of the Board". From this, it is clear that

Parliament in the very Amendment Act which introduced Section 26-A made certain changes which involved the DTAB under Section 5 of the said Act. It is clear that the additional power that is given to the Central Government under Section 26-A does not refer to and, therefore, mandate any previous consultation with the DTAB. On the contrary, the Central Government may be "satisfied" on any relevant material that a drug is likely to involve any risk to human beings, etc. as a result of which it is necessary in public interest to regulate, restrict or prohibit manufacture, sale or distribution thereof. So long as the Central Government's satisfaction can be said to be based on relevant material, it is not possible to say that not having consulted the DTAB, the power exercised under the said section would be non est. Take the case of an FDC that is banned in 50 countries of the world owing to the fact that the said FDC involved significant risk to human beings. Assuming that the Central Government is satisfied based on this fact alone, which in turn is based on Expert Committee Reports in various nations which pointed out the deleterious effects of the said drug, can it be said that without consulting the DTAB set up under Section 5, the exercise of the power under Section 26-A to prohibit the manufacture or sale or distribution of a drug that is banned in 50 countries would be bad only because the DTAB has not been consulted? The obvious answer is no inasmuch as the Central Government's satisfaction is based upon relevant material, namely, the fact that 50 nations have banned the aforesaid drug, which in turn is based on Expert Committee Reports taken in each of those nations. Take another example. Suppose the Central Government were to ban an FDC on the ground that, in the recent past, it has been apprised of the fact that the FDCs taken over a short period of time would lead to loss of life, which has come to the notice of the Central Government through reports from various district authorities, in let us say, a majority of districts in which the said FDC has been consumed. Could not the Central Government then base its ban order on material collected from district authorities which state that this particular drug leads to human mortality and ought, therefore, to be prohibited? The obvious answer again is yes for the reason that the Central Government has been satisfied on relevant material that it is necessary in public interest to ban such drug. Examples of this nature can be multiplied to show that the width of the power granted under Section 26-A cannot be cut down by artificially cutting down the language of Section 26-A.

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22. It was also argued that Section 26-A had no non obstante clause to keep Section 5 out of harm's way. On our construction of Section 26-A, it is clear that no such non obstante clause was necessary in that the width of the expression "is satisfied"

contained in Section 26-A cannot be cut down by reference to Section 5. As has been stated by us hereinabove, the expression "without prejudice" makes it clear that Section 26-A is an additional power given to the Central Government which must be exercised on its own terms.

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24. If the power under Section 26-A is exercised on the basis of irrelevant material or on the basis of no material, the satisfaction itself that is contemplated by Section 26-A would not be there and the exercise of the power would be struck down on this ground. Further, it is argued that the provision may be read down to make it constitutionally valid, but in so doing, words cannot be added as a matter of constitutional doctrine.

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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 petitioner-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."

19. A careful reading of the Judgment of the Hon'ble Supreme Court in ***Pfizer Limited & Ors.*** (*supra*) indicates that the Court was primarily concerned with examining the limited and specific issue as to whether, prior to the exercise of powers by the Central Government under Section 26A of the Drugs Act, there existed a mandatory requirement of consultation with the DTAB constituted under Section 5 of the Drugs Act. This question arose in the backdrop of serious

regulatory concerns regarding the proliferation of FDCs in the Indian market which had not been subjected to adequate evaluation for safety and efficacy, an issue that had also engaged the attention of the Parliamentary Standing Committee on Health and Family Welfare in its 59th Report.

20. The Hon'ble Supreme Court thereafter traced the course of action adopted by the Central Government in addressing the aforesaid concerns, including the adoption of various regulatory measures such as the prohibition of manufacture and sale of certain drugs. In paragraph no. 5 of the said judgment, the Hon'ble Supreme Court delineated the categorisation of FDCs and the corresponding recommendations of the expert committees constituted for that purpose, the FDCs involved in the present matter falling within Category 'A'.

21. While answering the question placed before it, the Hon'ble Supreme Court unequivocally held that Section 26A of the Drugs Act does not mandate prior consultation with the DTAB before the Central Government proceeds to regulate, restrict, or prohibit the manufacture, sale, or distribution of drugs. The Court thus construed Section 26A of the Drugs Act as an enabling provision which sets out the circumstances under which such regulatory power may be exercised by the Central Government. The relevant portion the aforesaid Judgement is reproduced hereinbelow for reference:

> "**5.** On 16-4-2015, a detailed report in this regard was submitted by the Kokate Committee to the Ministry stating the reasons for declaring FDCs as irrational. We have been informed that for the FDCs which were considered as irrational by the Committee, the Committee wrote to various manufacturers/associations calling upon them to submit material to establish the therapeutic justification/rationality of the FDCs. Replies received from such associations were examined by the Expert Committee and final

recommendations therein were given only on 10-2-2016. In Category A, following the final recommendations of the Expert Committee, the Central Government has banned 344 FDCs. In Category B, 944 FDCs needed to be considered/deliberated upon further, which meant that they would be referred to the respective Expert Committees out of the 10 Expert Committees already constituted for further examination. In Category C, 1493 FDCs have been declared "rational" and we are informed that approvals have since been issued by the DCG(I) in respect of these FDCs. In Category D, 126 FDCs have to be considered for further generation of data by the prospective applicants. It is only after carrying out of this exercise, that by Notifications dated 10-3-2016 issued under Section 26-A, the Central Government banned manufacture and sale of 344 FDCs."

22. The Hon'ble Supreme Court, in the context of the matters under consideration, issued specific directions for the manner in which the DTAB was to conduct the exercise of consideration, in paragraph nos. 32, 33 and 34 of the Judgment, which are reproduced hereunder:

"**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."

23. The aforesaid paragraphs constitute the foundational basis of the submissions advanced on behalf of the Respondents, who contend that the DTAB Sub-Committee failed to adhere to the directions so enunciated by the Hon'ble Supreme Court.

24. We find it apposite to note that, in addition to delineating the parameters which the Committee was required to address and the manner in which its conclusions were to be articulated in the report, the Hon'ble Supreme Court, in paragraph no. 34, also issued an express and specific direction, which reads as follows:

> "34. …..We may indicate that the Central Government thereafter must have due regard to the Report of the DTAB Sub Committee 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."

25. A careful analysis of the aforesaid directions reveals that the Hon'ble Supreme Court, in the prefatory paragraph nos. 32 and 33, while prescribing the manner in which the DTAB Sub-Committee was to undertake its examination and structure its report, did not, in any manner, curtail or dilute the statutory autonomy, independence, or discretion vested in the Central Government under Section 26A of the Drugs Act. On the contrary, the judgment preserves the primacy of the Central Government's role in arriving at the requisite statutory satisfaction, making it clear that the report of the Sub-Committee was

intended to operate as a relevant and informed input, and not as a binding determination. The Hon'ble Supreme Court consciously left it to the Central Government to assess the Sub-Committee's report, along with any other relevant material, and to thereafter independently apply its mind to the conditions expressly enumerated under Section 26A of the Drugs Act before deciding whether regulation, restriction, or prohibition was warranted in public interest.

26. In that view of the matter, even assuming, *arguendo*, that the Sub-Committee did not submit its report in strict conformity with the manner indicated by the Judgment of the Hon'ble Supreme Court, the determinative factor remains the subsequent and independent exercise undertaken by the Central Government in arriving at its statutory satisfaction. Since what is under challenge in the present proceedings is the latter act of the Central Government in exercising its powers under Section 26A of the Drugs Act, the issue as to whether the Sub-Committee's report, *per se*, adhered in all respects to the directions of the Hon'ble Supreme Court does not, in our considered view, assume decisive significance.

27. Before proceeding further, it is apposite to emphasise that, while exercising jurisdiction under Article 226 of the Constitution, courts are required to exercise restraint and circumspection while reviewing reports and recommendations of expert committees, particularly in matters involving technical and scientific domains such as pharmaceuticals. In this context, the Hon'ble Supreme Court, in ***Systopic Laboratories (Pvt.) Ltd. v. Dr. Prem Gupta and Ors.*** [16], has held as follows:

[16] AIR 1994 SC 205

> "**19.** Having considered the submissions made by the learned counsel for the petitioners and the learned Additional Solicitor General in this regard, we must express our inability to make an assessment about the relative merits of the various studies and reports which have been placed before us. Such an evaluation is required to be done by the Central Government while exercising its powers under Section 26A of the Act on the basis of expert advice and the Act makes provision for obtaining such advice through the Board and the DCC."

28. To further reinforce the aforesaid principle, the Co-Ordinate Bench of this Court, while placing reliance on ***Systopic Laboratories (Pvt.) Ltd.*** (*supra*), in ***E. Merck (India) Ltd. and Ors. v. Union of India and Ors.***[17]**,** elucidated and clarified the scope and limits of judicial review in matters involving expert committee reports, and held as follows:

> "29. By now it is also well settled that the matters which are to be decided by experts, are to be left for them to decide and once such expert bodies take decisions in technical and scientific matters, it is not for the Court to interfere with the evaluation made by these expert bodies. In fact the argument which is advanced by the petitioners on the basis of the reports of DTAB and the arguments raised before Supreme Court and was considered by the Supreme Court in the case of ***Systopic Laboratories (Pvt.) Ltd. v. Dr. Prem Gupta*** (AIR 1994 SC 205) (*supra*) and other connected petitions reported in the said judgment. That was a case where validity of the notification issued by the Government of India prohibiting completely the manufacture and sale of fixed dose combination of corticosteroids with any other drug for internal use was challenged. In the said notification it was stated that Central Government was satisfied that long term use of steroids in fixed dose combinations for treatment of asthma is likely to involve risk to human beings and such formulations do not have therapeutic justification and further that it was necessary and expedient in public interest to prohibit the manufacture and sale of the said drugs. On behalf of the petitioners, scientific data in the form of published papers in the various medical journals had been filed to show that fixed dose combination of a corticosteroid and an antihistamine is highly beneficial for the treatment of asthma. Relying upon such studies, it was sought to be argued that the decision of the Central

[17] 2001 AIR Del 326.

Government in prohibiting the manufacture and sale of the drug in question was not proper. While rejecting the contention of the petitioners, the Court observed as under:

> "*19.* Having considered the submissions made by the learned counsel for the petitioners and the learned Additional Solicitor General in this regard, we must express our inability to make an assessment about the relative merits of the various studies and reports which have been placed before us. Such an evaluation is required to be done by the Central Government while exercising its powers under Section 26-A of the Act on the basis of expert advice and the Act makes provision for obtaining such advice through the Board and the Drugs Consultative Committee (DCC).""
>
> ***(emphasis added)***

29. To augment the aforesaid position, and as a reiteration of the settled principles governing the scope of judicial review in matters involving expert evaluation, it would be apposite to extract the following observations of this Court in ***Wockhardt Limited and Anr v. Union of India and Anr.***[18]**,** which also delineate the role, remit, and scope of consideration of an expert Sub-Committee, and which bear direct relevance to the controversy at hand and are reproduced hereunder:

> "**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."
>
> ***(emphasis added)***

[18] 2019:DHC:3

30. In light of the foregoing discussion and the settled position of law, the scope of challenge in the present proceedings necessarily stands confined to the validity of the impugned notifications themselves. In that regard, we find merit in the submissions advanced by the learned ASG that, in exercise of judicial review, this Court does not ordinarily sit in appeal over the sufficiency or adequacy of the material placed before the authority. This approach is wholly consistent with the conclusion reached earlier, particularly having regard to the fact that the Hon'ble Supreme Court has unequivocally posited that the Central Government is required to apply its mind to the parameters expressly enumerated under Section 26A of the Drugs Act. Consequently, any alleged deviation or infirmity in the manner in which the Sub-Committee structured or articulated its report would, at the highest, relate to the sufficiency or depth of the material considered, and cannot, by itself, vitiate the subsequent exercise of statutory power by the Central Government in issuing the impugned notifications.

31. It is not in dispute, nor has it been the case of any of the parties, that there was a complete absence of material before the Central Government while arriving at its subjective satisfaction with reference to the parameters enumerated under the Drugs Act.

32. A plain reading of Section 26A of the Drugs Act, would, in our considered view, indicate that the statutory parameters prescribed for the Central Government to arrive at its requisite satisfaction are, first, whether (i) the use of the drug is likely to involve any risk to human beings or animals, (ii) the drug does not possess the therapeutic value claimed or purported to be claimed for it, or (iii) the drug contains

ingredients and in such quantities for which there exists no therapeutic justification. These contingencies constitute the *first limb* of the statutory framework governing the exercise of power under Section 26A of the Drugs Act.

33. The *second limb* of the provision contemplates that, upon the existence of any one or more of the aforesaid contingencies, the Central Government must further be satisfied that, in the larger public interest, it is necessary or expedient to regulate, restrict, or prohibit the manufacture, sale, or distribution of such drug by issuance of a notification. Thus, the statutory scheme makes it clear that regulatory action under Section 26A of the Drugs Act is premised upon the concurrence of one or more of the specified contingencies with an overarching determination of public interest warranting such intervention.

34. We are of the considered opinion that the statutory standard prescribed under Section 26A of the Drugs Act does not require the establishment of actual or proven harm to human beings. The legislative intent underlying the provision is clearly precautionary in nature and is satisfied once it is shown that the use of a drug is *likely* to involve risk to human health. The focus of the inquiry, therefore, is not on demonstrable injury but on the potential or foreseeable risk arising from continued use of the drug. In this context, the learned Single Judge committed error while elevating the statutory threshold and insisting upon a higher degree of proof than what Section 26A of the Drugs Act contemplates. Such an approach defeats the preventive object of the provision, which is designed to enable timely regulatory intervention in the interest of public health.

35. In the present case, a perusal of the report of the DTAB Sub-Committee would reveal that it expressly recorded its conclusion that the Impugned FDCs were likely to lead to a risk of *hypoglycaemia* and that there was an absence of safety data pertaining to the combinations. The learned Single Judge has, in fact, accepted the expert observation that the FDCs may lead to *hypoglycaemia*. Having done so, the learned Single Judge nevertheless proceeded to question the rationale behind the proscription of the FDCs, primarily on the reasoning that the individual components, in the dosages employed, were separately recommended and approved, and that the FDCs were perceived to possess therapeutic value in certain cases.

36. In our considered view, neither of the aforesaid considerations lay within the permissible domain of judicial scrutiny. The DTAB Sub-Committee was an expert body constituted pursuant to the directions of the Hon'ble Supreme Court, comprising specialists drawn from diverse disciplines, which had co-opted additional experts, examined a vast body of scientific material, and engaged in extensive deliberations prior to formulating its recommendations. Once such an expert body recorded its conclusions on matters of safety and risk, it was not open to the learned Single Judge to substitute such expert assessment with judicial reasoning grounded on assumptions dehors the expert material.

37. The second ground on which the learned Single Judge interfered with Notification S.O. 4471(E), namely, that the individual components of the FDCs were themselves approved and recommended therapeutic dosages, is equally untenable. It cannot be presumed, as a matter of law or science, that individual drug

components would behave, interact, or manifest identical safety profiles when administered in combination, as opposed to being administered independently. Such a presumption is antithetical to the regulatory framework governing FDCs and cannot obviate the statutory requirement of safety data for the combination as a distinct drug entity.

38. The reasoning adopted by the learned Single Judge that the existence of approved dosages of individual components dispensed with the necessity of safety data for the FDCs, therefore, cannot be sustained. The requirement of safety data is intrinsic to the regulatory evaluation of FDCs and flows directly from the statutory mandate underlying Section 26A of the Drugs Act.

39. The mere fact that the individual components of a FDC are approved and in use cannot, by itself, dispense with the statutory rigour of Section 26A of the Drugs Act. Each FDC is required to be independently assessed under Section 26A, as the pharmacological impact of a combination may differ from that of its individual constituents. This position stands reinforced by the decision of this Court in ***Alkem Laboratories Ltd. v. Union of India***[19], wherein the proscription of an FDC comprising individually approved drugs was upheld, recognising that an FDC constitutes a distinct therapeutic entity warranting separate evaluation. The relevant portions of the said Judgement are reproduced hereinbelow for reference:

> "**20**. I shall now proceed to examine the challenge to the Notification in the present case applying the law laid down by this Court in the above referred judgments.

[19] 2019 SCC OnLine Del 11058

21. The reasons given by the DTAB for proscribing the FDC in question are re-extracted herein below:

> "1. Nimesulide in combination has potential of misuse and safety concern. It's use in children below 12 years is already banned in India and it's use is limited to 15 days in adults in Europe.
> 2. Pharmacodynamically inappropriate FDC as both have similar mechanism of action (both drugs acting on the same enzyme). However, adverse effects of the two drugs (such as Gastrointestinal, ulceration, nephrotoxicity and hepatoxicity) add up. Thus, combining two NSAIDs may not improve the efficacy of treatment but may increase the risk.
> 3. Further, Diclofenac poses specific risk to animals (vultures).
> 4. This combination is not as per the standard therapeutic guidelines.
> There is no convincing scientific/clinical evidence/justification for the FDC."

22. As far as the 1st and 3rd reasons are concerned, clearly the same could not have independently formed the basis for proscribing the FDC in question, inasmuch as it is not denied that Nimesulide and Diclofenac have been independently approved for manufacture and sale.

23. At the same time, both the Kokate Committee Report as also the DTAB have opined that the FDC in question is pharmacodynamically inappropriate as both Nimesulide and Diclofenac have similar mechanism of action and therefore, their combination, though cannot improve efficacy of treatment, but may add up to the adverse effects of the two drugs thereby increasing the risk. It was further observed that there is no convincing scientific/clinical evidence/justification for the FDC.

24. In the present case, barring relying upon certain general Articles, which I shall deal with in the latter part of this judgment, the petitioners have not been able to place any material on record to show how the above opinion of the Expert Committee as also the DTAB can be found to be arbitrary or unreasonable.

25. Admittedly, the petitioners have not taken the approval for the FDC under Rule 122B of the Rules. Rule 122E(c), includes within definition of a "New Drug", a Fixed Dose Combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, which is, indications, dosage, dosage form (including sustained release dosage form) and route of administration.

26. Appendix VI to Schedule Y of the Rules and specifically Clause (d) thereof, on which reliance was also placed by the learned counsel for the petitioners, is reproduced herein below:

> "(d) The fourth group of FDC includes those whose individual active ingredients (or drugs from the same class) have been widely used in a particular indication(s) for years, their concomitant use is often necessary and no claim is proposed to be made other than convenience. It will have to be demonstrated that the proposed dosage form is stable and the ingredients are unlikely to have significant interaction of a pharmacodynamic or pharmacokinetic nature."

27. A reading of the above would show that even where the claim of FDC is based on convenience, the applicant has to demonstrate that the individual active ingredients of the FDC have been widely used in a particular indication for years and their concomitant use is often necessary, but also that the proposed dosage form is stable and the ingredients are unlikely to have significant interaction of a pharmacodynamic or pharmacokinetic nature. Therefore, the burden of proving the same has to be on the applicant, herein the petitioners. As noted hereinabove, barring making of a reference of a few general Articles, the petitioners have been unable to place before this Court any material that may have even remotely satisfied the above conditions.

28. As far as the submissions of the learned counsels for the petitioners that both Nimesulide and Diclofenac are also available in combination with acetaminophen (Paracetamol), learned counsel for the respondent submits that the same is irrelevant inasmuch as paracetamol is not considered as an NSAID.

29. As far as the submissions of the petitioners that Nimesulide and Diclofenac are also been prescribed in combination, barring making a bald statement in this regard in the petitions, there was no other material placed on record by the petitioners before the DTAB or the Kokate Expert Committee or even in this petition. During the course of the arguments, learned counsels for the petitioners handed over a chart showing that the data published by IQVIA demonstrates prescription and sale of Diclofenac and Nimesulide simultaneously and that the sale of around 30,640 units was reported in July, 2019 as compared to 46,070 units in July, 2018. In my view, the same cannot be read as evidence to show a substantial use of the two drugs in combination being prescribed by the Doctors."

(*Emphasis supplied)*

40. There are various pharmacological reasons for manufacturing FDCs. The combination may result in synergy, enhancing the effects of the drug or maybe purely for convenience. It is further apposite to note that Rule 122E of the Drugs Rules, 1945 define a "new drug" and expressly include FDCs within that category. In particular, Appendix VI to Schedule Y of categorises various FDCs into four categories and enlist the additional data required for their approval for marketing. It is thus clear that a bald reference to the approved status of the ingredients of an FDCs, even if no claim is proposed to be made other than convenience with regards to the FDC, is inadequate to establish if a particular FDC has been proscribed in contravention with Section 26A of the Drugs Act.

41. The further reason which weighed with the learned Single Judge in setting aside the impugned notifications was the perceived non-conformity of the DTAB with the directions issued by the Hon'ble Supreme Court in ***Pfizer Limited & Ors.*** (*supra*). This aspect has already been dealt with at length hereinabove. As noticed earlier, the directions of the Hon'ble Supreme Court did not curtail the statutory discretion vested in the Central Government under Section 26A of the Drugs Act, but merely required the DTAB Sub-Committee's report to operate as a relevant input in the decision-making process. The ultimate obligation to apply its mind to the statutory parameters and to arrive at the requisite satisfaction was left to the Central Government. The learned Single Judge, therefore, erred in treating the alleged non-adherence to the Supreme Court's directions as a determinative factor for invalidating the impugned notifications.

42. Viewed thus, the Impugned Judgment in so far as regard to Notification S.O. 4471(E), in our considered opinion, traverses beyond the permissible contours of judicial review in matters concerning the Statutory satisfaction expressed by the Central Government, in conjunction with the inputs from the expert regulatory assessment and also public health considerations, thereby warranting appellate interference.

43. Turning next to the challenge concerning the proscription of the FDCs by Notification S.O. 4472(E); having already dealt with the general submissions common to both notifications, it becomes necessary to address the specific reasoning which weighed with the learned Single Judge in relation to the said formulation.

44. The relevant extracts of the Judgment dealing with the said Notification have already been extracted hereinbefore and are articulated in paragraph nos. 39-46 of the Impugned Judgment.

45. The learned Single Judge held that the reasoning of the DTAB Sub-Committee, namely that sufficient therapeutic options were available, could not by itself constitute a valid ground for prohibition under Section 26A of the Drugs Act, and on that basis proceeded to discount the recommendation of the expert body. In our considered view, such an approach reads Section 26A of the Drugs Act in an unduly constricted manner. The statutory threshold under Section 26A is the satisfaction of the Central Government, founded upon relevant considerations, and not a rigid or compartmentalised inquiry divorced from the overall regulatory context. The observation regarding availability of therapeutic alternatives cannot be examined in isolation, particularly when viewed in conjunction with the undisputed

position that only general data had been provided by the Respondents and no specific data was made available in respect of the said FDCs as also the fact that the impugned FDCs are not approved or marketed in other jurisdictions, a factor which bears directly upon the regulatory assessment undertaken in public interest.

46. Equally, the said reasoning cannot be severed from the other grounds recorded by the Sub-Committee, namely, that increments in the dosage of Metformin are ordinarily prescribed in steps of 500 mg in accordance with treatment guidelines, and that the availability of multiple strengths in a single FDC may lead to medication errors, including over-dosing or under-dosing. The learned Single Judge, however, approached each of these considerations in isolation rather than examining their cumulative effect, thereby fragmenting what was, in essence, a holistic expert assessment.

47. It also bears emphasis that Section 26A of the Drugs Act, expressly empowers the Central Government to prohibit a drug where it contains ingredients and in such quantities for which there exists no therapeutic justification. The statutory framework does not mandate the establishment of actual or demonstrable harm in every case; the absence of therapeutic justification, when assessed in the light of expert opinion and overarching public health considerations, by itself constitutes a sufficient statutory trigger for regulatory intervention. This position stands reinforced by the decision of this Court in ***E. Merck (India) Ltd.*** *(supra)*, which reads as under:

> "**23.** The arguments of the petitioners that the entire basis of the decision is the opinion of two Members of the Core Group namely, Dr. Antia and Dr. Naresh Banerjee who had personal bias is also without any merit. It is totally untenable on the part of the petitioners to argue that the decision lacks fairness or is arbitrary. Under Section 26-A of the Act, manufacture of a drug can be

banned if the Central Government is satisfied that the drug does not have any thereapeutic value. It can also be banned if the Central Government is satisfied that it does not have therapeutic justification. If a particular FDC has no therapeutic justification it would be in public interest to prohibit the manufacture, sale or distribution of such a drug. One has to keep in mind the ground realities prevailing in a poor country like India. If the drug in question did not have any therapeutic justification and doctors prescribe this drug as a matter of routine, it would be unnecessary and unjust burden on the pockets of poor people in this country to have such a drug. It was rightly argued by the respondents that with the change in times, now the emphasis is on therapeutic rationality for continuing the drug i.e. whether a drug is really required at all. **If it does not have any rationale or therapeutic justification that would also be one of the relevant factors mentioned in Section 26-A of the Act which may permit the Central Government to issue Notification prohibiting the manufacture etc. of such a drug. Therefore, it is not necessary that a drug has to be only hazardous before it is banned. It is also not necessary that sufficient material is not available to show that a particular drug lacks therapeutic value. Once it is found that the drug in question lacks therapeutic justification that would be sufficient for the satisfaction of the Central Government under Section 26-A of the Act.** It is not disputed that Vitamins B1, B6 and B12 are available separately. It is not a case of the respondents that these vitamins taken individually do not have therapeutic value. What is prohibited by the impugned Notification is the fixed dose combination of the three Vitamins. If a patient/person requires either vitamin B1 or B6 or B12, what is the justification in giving him vitamin B-Complex which contains fixed dose combination of Vitamins B1, B6 and B12 thereby administering other two vitamins not needed. After all these tablets or injections of vitamins contain chemicals and unnecessary chemicals are being administered by giving FDC of banned Drug which are not required. Therefore, when the opinion of Dr. Antia or Dr. Naresh Banerjee suggested that FDC does not have therapeutic value/justification and there was no material available in the Text Books or National Formularies to support it, that would also be a relevant consideration. In any case the Core Group had discussed the entire matter before accepting such opinion and did not blindly follow the opinion of these doctors. Same exercise was done by DTAB and thereafter by the Central Government. Therefore, the argument that Notification was result of personal bias of two doctors, cannot be accepted."

(Emphasis supplied)

48. In dealing with the second reason, relating to dosage increments of Metformin, the learned Single Judge placed emphasis on the fact that Metformin 850 mg is independently marketed as an approved drug and, relying upon material produced by the writ petitioners, concluded that the prescription of such dosage in certain patients rendered the Sub-Committee's concern untenable. In our view, this line of reasoning is fundamentally flawed. *First*, there was no occasion for the learned Single Judge to enter upon an evaluation of scientific or clinical material to arrive at conclusions regarding appropriate dosages, as courts are institutionally ill-equipped to adjudicate upon specialised pharmacological determinations. *Secondly*, and more importantly, the mere fact that an individual drug component is approved or prescribed at a particular dosage does not ipso facto justify its inclusion in a FDC at that dosage, the combination being a distinct therapeutic entity requiring independent assessment of safety and risk.

49. The learned Single Judge thereafter examined the third reason recorded by the Sub-Committee, namely, the possibility of medication errors arising from multiple strengths, and characterised the same as cryptic. Proceeding on that premise, the learned Single Judge observed that FDCs are often expedient where patients are required to consume multiple medicines, and that such convenience constitutes a compelling argument against prohibition. With respect, this reasoning overlooks the fundamental regulatory concern that convenience cannot supplant considerations of safety. The fact that individual components may be prescribed separately cannot, without more,

sustain an assumption that their combined administration would operate in an identical or benign manner.

50. We also find ourselves unable to appreciate the reasoning of the learned Single Judge in observing that "*the risk of over-prescription or under-prescription is common in all FDCs*." The expert Sub-Committee had expressly recorded that over-prescription or under-prescription of the impugned FDCs could entail serious risk to patients. The learned Single Judge, however, appears to have neutralised this expert concern by treating such risk as commonplace across all FDCs, without disclosing any scientific or evidentiary basis for such an assumption. In matters of drug regulation, where expert bodies have identified specific risks associated with particular formulations, it is impermissible for the Court to dilute those concerns on the basis of broad generalisations unsupported by technical material.

51. Viewed thus, the approach adopted by the learned Single Judge in relation to Notification S.O. 4472(E) traverses beyond the permissible contours of judicial review, substitutes expert assessment with judicial inference, and fails to accord due deference to the composite and precautionary evaluation undertaken by the statutory authorities in exercise of powers under Section 26A of the Drugs Act.

DECISION:

52. In view of the afore-mentioned discussion, analysis, and conclusions arrived at by us, we find merit in the contentions advanced on behalf of the Appellants and are of the considered view that the learned Single Judge erred in interfering with the Notifications bearing no. S.O. 4471(E) and S.O. 4472(E), issued by the Central

Government in exercise of powers under Section 26A of the Drugs Act, thereby warranting appellate interference by this Court.

53. For the aforesaid reasons, we are of the opinion that the present appeals, namely ***LPA No. 105/2020, LPA No. 106/2020,*** and ***LPA No. 671/2019***, deserve to be allowed, and accordingly, the Impugned Judgment dated 13.02.2019 passed by the learned Single Judge is set aside.

54. The present appeals, along with pending application(s), if any, stand disposed of in the above terms.

55. No Order as to costs.

ANIL KSHETARPAL, J.

HARISH VAIDYANATHAN SHANKAR, J.

JANUARY 09, 2026/rk/kr