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

\+ **W.P.(C) 4766/2019**

BESTO CHEM FORMULATIONS
(INDIA) LIMITED ..... Petitioner
Through Mr Surinder Singh, Mr Chander Shekhar Patney, Advocates.

versus

UNION OF INDIA AND ANR. ..... Respondents
Through Mr Akshay Makheeja, Ms Kriti Awasthi, Advocates Ms Bakshi Vinita, G.P. for R1 UOI.

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

**O R D E R**

**% 06.05.2019**

**CM APPL. 21207/2019**

1. Allowed, subject to all just exceptions.

2. The application is disposed of.

**W.P.(C) 4766/2019& CM APPL. 21206/2019**

3. The petitioner has filed the present petition, *inter alia*, impugning a notification – S.O No. 258 (E) dated 11.01.2019 – prohibiting the manufacture and sale of the Fixed Dose Combination of Ondansetron + Omeprazole (hereafter 'the FDC in question') for human use, with immediate effect.

4. The learned counsel appearing for the petitioner contends that the said

notification is arbitrary and unreasonable inasmuch as it is not informed by reason. The petitioner also rests his case on the ground that the drug Omeprazole has similar therapeutic use as the drug Rabeprazole. It is the petitioner's case that since the FDC of Ondansetron and Rabeprazole is permitted, there would be no rationale for not permitting the FDC in question (Ondansetron + Omeprazole).

5. At the outset, it is relevant to mention that the impugned notification has been issued pursuant to a report submitted by a Sub-Committee of experts of the Drugs Technical Advisory Board (DTAB). The meeting of the Sub-Committee of the DTAB was held on 04.01.2014, wherein the rationality and the safety aspect of certain FDCs (294 in number) were considered. This also included review with regard to the FDC in question. The relevant extract of the said minutes, indicating the reason for banning the manufacture and sale of the FDC in question, is set out below:-

> "**Ondansetron + Omeprazole (Sl. No. 258 of DCG(I) list);**
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> The Ondansetron is a 5HT3 receptor blocking antiemetic widely used in chemotherapy & post-operative nausea and vomiting. However, it is also indicated for other vomiting conditions.
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> Ondansetron has no specific indication in vomiting associated with gastritis in which rather prokinetic agents are preferred along with proton pump inhibitors. There is a little justification for giving as FDC, because the pharmacokinetics of both the drugs is not fully compatible as Omeprazole is given once or twice a day, whereas Ondansetron is given 3 times a day.
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> +The committee experts unanimously opined that there is no justification for this FDC and hence the said FDC is not rational."

6. It is seen that the impugned notification has been issued as the Expert Committee had found that there was no justification for the FDC in question and the same could not be considered rational. The Expert Committee had reasoned that Ondansetron is a receptor blocking antiemetic, which is widely used in chemotherapy and post-operative nausea and vomiting. The said drug was not commonly used for the indication of vomiting associated with gastritis. It noted that other medicines were preferred along with proton pump inhibitors for indication of vomiting associated with gastritis. Thus, according to the Expert Committee, the drug Omeprazole should not normally be prescribed along with Ondansetron for post-operative nausea and vomiting.

7. In addition to the above, it was also noticed that the pharmacokinetics of the two constituent drugs of the FDC in question are not compatible. Whereas Omeprazole is given once or twice a day, Ondansetron is given three times a day.

8. Clearly, the opinion of the Expert Committee is not amenable to judicial review on merits in these proceedings. Thus, unless the petitioner establishes that the reasoning is perverse or manifestly arbitrary, no interference by this Court would be warranted.

9. The learned counsel appearing for the petitioner has submitted that the dosage of Omeprazole is based on the indication and there is no hard and fast rule that Omeprazole can be advised only twice a day. The learned counsel appearing for the petitioner has relied upon certain material placed on the internet, in support of his contention. This Court is not persuaded to accept that the said material would warrant any interference from this Court,

as there is no dispute that the pharmacokinetics of both the drugs are not similar. The absorption time for both constituent drugs is different. In any view of the matter, as stated above, the said issue is one which is to be examined by the experts. In this case, the experts have given their opinion as to the incompatibility of the pharmacokinetics of both the constituent drugs and, thus, the decision of the Central Government to accept the same cannot be faulted.

10. The learned counsel appearing for the petitioner also contended that Omeprazole is therapeutically similar to the drug Rabeprazole and since FDC of Ondansetron + Rabeprazole is permitted, there could be no reason to prohibit the FDC in question. This contention is also unpersuasive. Although the therapeutic value of the Rabeprazole and Omeprazole may be similar, however, it is not necessary that the same has to be administered in the same dosage. In addition to the above, the FDC of Ondansetron and Rabeprazole is not identical to the FDC in question. It is contended by the respondents that the effect of the combinations is also different. In view of the above, the petitioner's contention that the FDC in question should be permitted because of the FDC of Ondansetron + Rabeprazole is permitted, cannot be accepted.

11. It is also relevant to note that the Supreme Court in ***Union of India and Anr. v. Pfizer Limited and Ors.*** : ***2018 (2) SCC 39*** had considered the case of 294 FDCs (including the FDC in question). The ban imposed on the said FDCs had been stayed by the Madras High Court.

12. The Supreme Court considered the report of the Expert Committee of DTAB to review the rationality and safety of these FDCs, which was taken on record. The Supreme Court further held that since the expert body has

already deliberated upon and decided these cases, the said report was accepted and the petitions were disposed of.

13. In this view also, the report submitted by the Expert Committee cannot be subject matter of a further review.

14. Indisputably, the impugned notification has been passed by the Central Government on the basis of cogent material – the report of the Sub-Committee of DTAB – and given the limited scope of the present proceedings, this Court is unable to accept that the any interference with the impugned notification is warranted.

15. The petition is, accordingly, dismissed. The pending application is disposed of.

**VIBHU BAKHRU, J**

**MAY 06, 2019**
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