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

\+ W.P.(C) 1071/2019 & CM No. 4870/2019

ALKEM LABORATORIES LTD. ..... Petitioner

Through: Mr Parag P. Tripathi, Sr. Advocate with Mr Sagar Chandra, Ms Shubhie Wahi and Ms Mishika Bajpai, Advocates.

versus

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

Through: Mr Ajay Digpaul, CGSC for UOI. Mr Waize Ali Noor and Ms Shruti Dutta, Advocates for DGI.

CORAM:
HON'BLE MR. JUSTICE VIBHU BAKHRU

O R D E R

% 04.02.2019

1. The petitioner has filed the present petition, *inter alia*, impugning a Notification – S.O.No.215(E) – dated 11.01.2019, whereby the Central Government has proscribed the manufacture and sale of the Fixed Dose Combination (FDC) of Cefixime + Ornidazole with immediate effect.

2. Mr Tripathi, learned senior counsel appearing for the petitioner, contended that the said FDC has been approved by CDSCO. In addition, each of the two constituent formulations are also approved drugs. He also submits that the only ground on which the FDC is banned is that it would be over-prescribed and the same is not a ground for banning a drug under Section 26A of the Drug and Cosmetics Act, 1940 (hereafter 'the Act').

3. The learned counsel appearing for the respondents submitted that

the said drug was proscribed under the provisions of the 26A of the Act, on the basis of a report submitted by the DTAB. A copy of the report of the Sub-Committee of the DTAB has also been handed over in Court by the learned counsel appearing for the respondents, and the relevant extract which relates to the recommendations made in respect of the FDC in question, is reproduced below:-

> "Those selected group who require Anaerobic coverage will develop resistance by the time antibiotics are required if these FDCs are used and will not be in the interest of the public. Combining ornidazole with antibiotics for anaerobic infection will lead to emergence of resistance because there is likely that these drugs will be overprescribed without conducting any laboratory blood test. Hence the committee did not recommend."

4. It is also pointed out that the license for manufacturing the said FDC was cancelled and the said action was challenged by the petitioners before the Madras High Court by writ petitions, which were subsequently transferred to the Supreme Court (TC Nos.308-317/2017 in T.P.(C) Nos.2108-2117/2017). The same were a part of the batch of 294 FDCs that had been proscribed. The said reports which recommended banning the said drugs were also placed before the Supreme Court and considered by the Court in ***Union of India and Anr. v. Pfizer Limited and Ors.: (2018) 2 SCC 39***.

5. It is apparent that the Supreme Court had considered the aforesaid report of the Sub-Committee and had accepted the same. Admittedly, the FDC in question was specifically listed in Annexure – D, which was

recommended to be prohibited. The Supreme Court had unequivocally accepted the said report, clearly indicating that the recommendations of the Subcommittee of DTAB were accepted. The relevant extract of the said decision is set out below:

> ".....The list of the drugs mentioned in Annexure D are required to be prohibited/withdrawn from the market as these are not rational. Considering that an expert body has already deliberated upon and decided these cases, we accept the report, and accordingly dispose of these petitions in accordance therewith."

5. In view of the above, the contentions that the FDC had been approved, or, that the formulations constituting the said FDC are also approved is of no assistance to the petitioner, considering that the recommendations of the Sub-Committee was to proscribe the said FDC and the same was accepted.

6. The contention that the only ground on which the FDC had been proscribed is an apprehension of over-prescription is also unmerited. A plain reading of the report of the Sub-Committee indicates that it was perceived that prohibition of the said drug would lead to resistance of antibiotics for anaerobic infection. It was also apprehended that the said FDC would be prescribed without conducting any laboratory blood test.

7. Mr Tripathi further stated that the entire exercise as required to be conducted under Section 26A of the Act stands vitiated, is also not persuasive. The Central Government has accepted the report submitted by DTAB and the said decision cannot be faulted as the said report was

accepted by the Supreme Court.

8. In view of the above, this Court finds no merit in the present petition. The same is dismissed. The pending application is disposed of.

VIBHU BAKHRU, J

FEBRUARY 04, 2019/MK