IN THE HIGH COURT OF PUNJAB & HARYANA AT CHANDIGARH

CWP-20304-2019 (O&M)
Date of Decision:05.12.2019

Venus Remedies Limited & another ... Petitioners

Versus

Union of India & others ... Respondents

CORAM:- HON'BLE MR.JUSTICE TEJINDER SINGH DHINDSA.

Present:- Mr. Govind Goel, Advocate with
Mr. Rajesh Sethi, Advocate for the petitioners.

Mr. S.P. Jain, Senior Advocate with
Mr. Alok Kumar Jain, Advocate for the respondents.

....

TEJINDER SINGH DHINDSA, J.

CM-11164-2019:

Application is allowed as prayed for. The accompanying affidavit on behalf of the Union of India along with Annexure A-1 is taken on record.

Copies already stands furnished to counsel opposite.

Application is disposed of.

Main case:

Challenge in the instant writ petition is to the Notification dated 11.01.2019 (Annexure P-18) issued by the first respondent i.e. the Secretary, Ministry of Health and Family Welfare, New Delhi, prohibiting the manufacture, sale and distribution of the drug 'Vancoplus' which is a Fixed Dose Combination of Ceftriaxone and Vancomycin (hereinafter called the FDC). A prayer for quashing of recommendation of respondent No.3-Drugs Technical Advisory Board (for short DTAB) dated 16.02.2015 (Annexure

P-15) recommending the prohibition of the said FDC has also been raised.

Counsel has submitted that the Drugs Technical Advisory Board had constituted a Sub-Committee to examine the rationality and safety of the FDC in question. It has been argued that the Sub-Committee has furnished a report in a mechanical fashion and without affording an opportunity of hearing to the petitioner has held the FDC in question to be irrational and placed it as Annexure 'D'. It has been vehemently argued that the Central Government as well as the expert body i.e. the DTAB have directed themselves in taking the impugned decision under Section 26(A) of the Drugs Cosmetics Act, 1940 without even adverting to the material that had been adduced by the petitioner in respect of the FDC.

The instant petition had came up for preliminary hearing before this Court on 25.07.2019 and at that stage, Mr. S.P. Jain, Senior Advocate had entered appearance on behalf of the respondents and had taken a stand that the report of the expert Committee furnished by DTAB as regards rationality and safety of 294 FDCs had been considered by the Apex Court in **Union of India & another Vs. PFizer Limited & others (2018) 2 SCC 39.** It has further been contended that as per report, the list of drugs mentioned in Annexure 'D' were required to be prohibited/withdrawn from the market as these are not rational and that a view was taken by the Apex Court that since an expert body had already deliberated upon the matter, the report be accepted. On 25.07.2019, counsel for the respondents had taken a date to demonstrate that the offending FDC in relation to the instant writ petition falls under Annexure 'D' of the report of the expert Committee of the DTAB which had fallen for consideration before the Apex Court in **PFizer**

Limited (supra).

Subsequently, in terms of moving an application i.e. CM-11164-2019, an affidavit dated 30.07.2019 of Mr. Sushant Sharma, Assistant Drugs Controller (India), Directorate General of Health Sciences, Ministry of Health and Family Welfare, Government of India, Baddi along with Annexure A-1 i.e. FDCs considered as “Not Rational” as per Annexure 'D' was placed on record. As per Annexure A-1, the FDC in question is at Sr. No.8 and the recommendation of the experts in relation thereto is as follows:

> *“Committee opined that this FDC is not rational as it will lead to antibiotic resistance which is a huge concern nowadays. Cetriaxone is most commonly used in common infection where as vancomycin is used in only few specific infection. Therefore, combination is not justified Committee opined that this is not rational as the FDC will lead to development of resistance to antibiotic which is not in the interest of the public.”*

In the affidavit placed on record dated 30.07.2019, it has been deposed that Annexure 'D' had been placed before the Hon'ble Supreme Court of India in the matter of PFizer Limited (supra).

Counsel for the petitioners does not dispute the contents of the affidavit as also of the list at Annexure 'D'.

The Hon'ble Supreme Court had admittedly considered the aforesaid report of the Sub Committee and had accepted the same. Concededly, the FDC in question was specifically listed in Annexure 'D', which was recommended to be prohibited. The Supreme Court unequivocally accepted the said report clearly indicating that the recommendations of the Sub Committee of DTAB were accepted. The

relevant extract of the said decision in **PFizer Limited (supra)** s as follows:

> *"..... the list of 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, be accept the report and accordingly disposed of these petitions in accordance therewith."*

The report submitted by DTAB having been accepted by the Hon'ble Supreme Court, the submissions advanced by counsel assailing notification dated 11.01.2019 (Annexure P-18) prohibiting the FDC in question can possibly have no persuasive value.

In view of the above, no merit is found in the instant petition and the same is dismissed.

Pending applications, if any, shall also stand disposed of.

05.12.2019 **(TEJINDER SINGH DHINDSA)**
harjeet **JUDGE**

i) Whether speaking/reasoned? Yes/No

ii) Whether reportable? Yes/No