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

\+ W.P.(C) 10791/2018 & CM No. 42049-42050/2018

MEDOPHARM ..... Petitioner

Through: Mr Avinash Tripathi, Mr Rohit Sharma and Mr Ashish, Advocates

versus

UNION OF INDIA & ANR ..... Respondents

Through : Mr Rajesh Kumar and Mr Ravi Rai, Advocates for UOI.

CORAM:
HON'BLE MR. JUSTICE VIBHU BAKHRU

O R D E R

% 09.10.2018

1. The petitioner has filed the present petition impugning the notification dated 07.09.2018 [S.O. 4709(E)], whereby the respondents have restricted the manufacture, sale and distribution of the fixed dose combination (FDC) of Amoxicillin 250mg + Potassium Clavulanate Diluted 62.5 mg. The manufacture and sale of the said FDC is permitted *"subject to the condition that the manufacture, sale or distribution of the said drug shall be for suspension only"*.

2. The petitioner manufactures the said FDC in the form of a dispersible tablet. Concededly, the said notification is based on the report of the Subcommittee. The relevant extracts of the said report are set out below:-

"The Subcommittee noted the recommendations of

the previous committee.

The Subcommittee further noted that following formulations suitable for children are approved by the DCGI:

1. Each 5 ml of reconstituted suspension contains: Amoxycillin Trihydrate IP e.q. to Amoxycillin 200 mg Caluvulanate Potassium e.q. to Clavulanic Acid 28.5 mg

2. Each uncoated dispersible tablet contains: Amoxycillin Trihydrate IP e.q. to anhydrous Amoxycillin 250 mg/ 125 mg Caluvulanate Potassium e.q. to Clavulanic Acid 62.5 mg/31.25 mg

3. Each 5 ml reconstituted syrup contains: Amoxycillin as trihydrate 125 mg + Clavulanic Acid 31.25 mg as potassium salt suspension.

The Subcommittee examined and considered that FDC Amoxillinin 250 mg + Potassium Clavulanate Diluted 62.5 mg for suspension is also acceptable and rational."

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"The Subcommittee examined and considered that FDC Amoxicillin 250 mg + Potassium Clavulanate Diluted 62.5 mg for suspension is acceptable and rational. Therefore, this FDC of Amoxicillin 250 mg + Potassium Clavulante Diluted 62.5 mg (for suspension) should not be prohibited under Section 26A."

5. It is apparent from a plain reading of the report of the Sub-committee that it had not recommended any prohibition of FDC in question under Section 26A of the Drugs and Cosmetics Act, 1940. It is not disputed that the impugned notification has been issued only on the basis of the above report of the Sub committee.

6. In view of the above, the impugned notification cannot be sustained. It is, accordingly, set aside. It is clarified that this would not preclude the respondents from issuing a fresh notification in

accordance with law.

7. The petition is disposed of. All pending applications are also stand disposed of.

VIBHU BAKHRU, J

OCTOBER 09, 2018
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