COMPETITION COMMISSION OF INDIA

(Combination Registration No. C-2020/01/720)

23rd March, 2020

Notice under Section 6 (2) of the Competition Act, 2002 filed by Mylan N.V. and Upjohn Inc.

CORAM:

Mr. Ashok Kumar Gupta
Chairperson

Ms. Sangeeta Verma
Member

Mr. Bhagwant Singh Bishnoi
Member

Order under Section 31(1) of the Competition Act, 2002

1. On 27th January, 2020, Competition Commission of India ("**Commission"**) received a notice under Section 6(2) of the Competition Act, 2002 ("**Act**"), jointly filed by Mylan N.V. ("**Mylan**") and Upjohn Inc. ("**Upjohn**"). The notice has been filed pursuant to the execution of (i) Separation & Distribution Agreement ("**SDA**") entered into between Pfizer Inc. ("**Pfizer**") and Upjohn and (ii) Business Combination Agreement ("**BCA**") entered into by and among Mylan, Upjohn and Pfizer, both dated 29th July, 2019. [Hereinafter, Mylan and Upjohn are together referred to as "**Parties**".]

2. The Proposed Combination entails the following steps:
   (i) Upjohn Business will be separated from Pfizer and contributed to Upjohn, currently a wholly-owned subsidiary of Pfizer.

(ii) Upjohn and Mylan will combine by implementing a merger or asset sale, resulting in the transfer of all of Mylan's assets and liabilities to Upjohn. Upon completion of the Combination, the Upjohn Business and Mylan's business will be wholly-owned by Upjohn, which will be renamed "**Viatris**".

3. Post the Proposed Combination, the current shareholders of Mylan and Pfizer will account for 43% and 57% of Viatris' stock capital on a proforma basis, respectively.

4. The Commission *vide* its letter dated 11th February, 2020 issued under Regulation 14(3) of the Competition Commission of India (Procedure in regard to transaction of business relating to combinations) Regulations, 2011 ("**Combination Regulations**") sought certain information from the Parties, *inter alia*, regarding overlaps, market shares and shareholding structure. The Parties submitted the response on 18th February, 2020, 2nd March, 2020 and submitted certain revised figures for assets and turnover *vide* their letter dated 18th February, 2020.

5. Mylan, incorporated in Netherlands, is a global pharmaceutical company having a broad portfolio of generic and brand name products which are sold in over 165 countries. Mylan has 19 manufacturing facilities located in India and these facilities include eight Active Pharmaceutical Ingredient ("**API**") facilities, six Oral Solid Dosage ("**OSD**") facilities and five injectable facilities, which manufacture medicines for markets all over the world. It has three registered entities in India namely Mylan Laboratories Limited ("**MLL**"), Mylan Pharmaceuticals Private Limited ("**MPPL**") and Mylan Laboratories India Private Limited ("**MLIPL**").

6. Upjohn Business, a division of Pfizer and headquartered in China, is engaged in operating Pfizer's off-patent branded and generic (non-sterile injectables) established medicines business. At present, Upjohn Business is an integrated part of the Pfizer business in India but does not have dedicated legal entity or Research & Development or manufacturing facilities. It distributes and markets its products via two local Pfizer entities - Pfizer Limited and Pfizer Products India Private Limited.

7. Upjohn Inc., a Delaware (USA) corporation, is currently a wholly-owned subsidiary of Pfizer and was created in 2019 for the purpose of its separation from Pfizer and subsequent combination with Mylan.

8. Both the Parties are engaged in the business of supply of APIs and Finished Dosage Products (**FDPs**), mainly prescription drugs, in India. The Parties have categorized their products on the basis of hierarchy of therapeutic area and/or molecule. It is submitted that the activities of the Parties do not exhibit any horizontal overlaps at the molecule level or based on ATC[1] classifications (at level 3 and 4[2]).

9. Based on the pipeline products, the Parties have identified two potential horizontal overlaps. Upjohn is already present in two therapeutic categories in which Mylan intends to launch a product. The presence of Upjohn in these therapeutic categories may not raise any competition concerns and there are other players selling similar products in India.

10. It was submitted that there are no existing vertical or complementary relationships between the Parties. The Upjohn Business currently does not supply API to third parties within India and Mylan does not market any FDPs based on Upjohn's molecules in India.

11. However, it was submitted that Mylan sells certain APIs (upstream market) which could potentially be used by Upjohn in the manufacture of its FDPs (downstream market) in India. Mylan sells three APIs namely Amlodipine, Sildenafil Citrate and Sertraline, which could potentially be used by Upjohn Business to manufacture Amlogard (or Norvasc), Viagra and Daxid (or Zoloft), respectively, in India.

[1] Anatomical Therapeutic Chemical or "**ATC**" is a form of classification of medicinal/pharmaceutical products based on the particular medicine's indications, therapeutic use, composition and mode of actions, maintained by the European Pharmaceutical Marketing Research Association (**EphMRA**) and IQVIA (formerly Intercontinental Medical Statistics (**IMS**)).

[2] It is submitted that level 1 or **ATC1** is the anatomical main group; level 2 or **ATC2** is the therapeutic main group; level 3 or **ATC3** is pharmacological/therapeutic subgroup; and level 4 or **ATC4** is chemical/ pharmacological/therapeutic subgroup.

12. It was submitted that Mylan's market share in the upstream market in India is [0-5%] for Amlodipine and Sildenafil Citrate and in the range of [5-10%] for Sertraline. It is submitted that key players in the upstream market include Dr. Reddy's Laboratories, Hetero Drugs Limited, Cadila Healthcare Limited, Aurobindo Pharma and Teva Pharmaceuticals.

13. In the downstream market, Upjohn's market share is as follows: (i) for Norvasc - in the range of [0-5%] in terms of both volume and value at ATC3, ATC4 and molecule level; (ii) for Viagra - in the range of [0-5%] in terms of volume (at ATC3, ATC4 and molecule level and [3-8%] in terms of value at ATC3, ATC4 and molecule level; (iii) for Daxid - in the range of [0-5%] in terms of volume and value at ATC3 level and [5-10%] in terms of volume and value at ATC4 level. The market shares for Daxid at molecule level appears to be in the range of [20-25%] and [30-35%] in terms of volume and value respectively. But there are other large players present in the market such as Mankind Pharma, Zydus Cadila, Dr. Reddy's Laboratories and Ranbaxy.

14. Based on the above, it appears that there are some large players present in both upstream and downstream markets in India and it appears that merged entity (Viatris) is not likely to have ability or incentive to foreclose competition in any market.

15. Considering the material on record including the details provided in the Notice and the assessment of the Proposed Combination based on the factors stated in Section 20(4) of the Act, the Commission is of the opinion that the Proposed Combination is not likely to have any appreciable adverse effect on competition in India. Therefore, the Commission approves the Proposed Combination under Section 31(1) of the Act.

16. This order shall stand revoked if, at any time, the information provided by the Parties is found to be incorrect.

17. The information provided by the Parties shall be treated as confidential in terms of and subject to provisions of Section 57 of the Act.

18. The Secretary is directed to communicate to the Parties accordingly.