



EUROPEAN COMMISSION

DG Competition

Case M.9517 – MYLAN / UPJOHN

Only the English text is available and authentic.

**REGULATION (EC) No 139/2004
MERCER PROCEDURE**

Decision on the implementation of the commitments -
Purchaser approval
Date: 14/09/2020



EUROPEAN COMMISSION

Brussels, 14.9.2020
C(2020) 6368 final

PUBLIC VERSION

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus [...]. Where possible the information omitted has been replaced by ranges of figures or a general description.

Mylan NV
Building 4,
Trident Place, Mosquito Way,
AL 10 9UL – Hatfield, Hertfordshire
United Kingdom

Pfizer Inc.
235 East 42nd Street
10017 – New York
United States of America

Dear Sir/Madam,

**Subject: Case M.9517 – Mylan/Upjohn
Approval of Aurobindo as purchaser of the First Divestment Business
following your letter of 03.07.2020 and the Trustee’s opinion of
26.08.2020**

1. FACTS AND PROCEDURE

- (1) By decision of 22 April 2020 (the “Decision”) based on Article 6(1)(b) in conjunction with Article 6(2) of Council Regulation (EC) No 139/2004¹ and Article 57 of the EEA Agreement, the Commission declared the operation by which Mylan N.V. (“Mylan”, the Netherlands) and Upjohn, a business division of Pfizer Inc. (“Pfizer”, the United States of America) intend to merge (the “Transaction”),

¹ OJ L 24, 29.1.2004, p. 1 (the “Merger Regulation”).

compatible with the internal market and the EEA Agreement. Mylan and Upjohn are designated hereinafter as the “Parties” to the Transaction. The Decision is subject to the conditions and obligations laid down in the commitments annexed to the Decision (“the Commitments”).

- (2) In particular, under the Commitments, Mylan undertook to divest to suitable buyers Mylan’s rights, titles and interests together with all associated assets, necessary for the purchaser(s) to be able to operate a viable and competitive business of the following country/molecule combinations in the EEA² (the “Mylan Divestment Business”):

- (i) Mylan's atorvastatin in Norway;
- (ii) Mylan's doxazosin in Czechia;
- (iii) Mylan's doxazosin in France;
- (iv) Mylan's eplerenone in Belgium;
- (v) Mylan's eplerenone in Hungary;
- (vi) Mylan's sildenafil (PAH) in Estonia;
- (vii) Mylan's sildenafil (PAH) in France;
- (viii) Mylan's tadalafil in France;
- (ix) Mylan's sildenafil (PAH) in Latvia;
- (x) Mylan's sildenafil (PAH) in Lithuania;
- (xi) Mylan's sildenafil (PAH) in Romania;
- (xii) Mylan's sildenafil (PAH) in the United Kingdom;
- (xiii) Mylan's eletriptan in Denmark;
- (xiv) Mylan's eletriptan in Finland;
- (xv) Mylan's eletriptan in France;
- (xvi) Mylan's eletriptan in Norway;
- (xvii) Mylan's eletriptan in Sweden;
- (xviii) Mylan's pregabalin in Belgium;
- (xix) Mylan's pregabalin in Czechia;
- (xx) Mylan's pregabalin in Luxembourg;
- (xxi) Mylan's pregabalin in Norway;
- (xxii) Mylan's gabapentin in Ireland;
- (xxiii) Mylan's ziprasidone in Czechia;
- (xxiv) Mylan's alprazolam in Greece;
- (xxv) Mylan's alprazolam in Iceland;
- (xxvi) Mylan's alprazolam in Ireland;
- (xxvii) Mylan's alprazolam in Italy;
- (xxviii) Mylan's alprazolam in Portugal;
- (xxix) Mylan's venlafaxine in Belgium;
- (xxx) Mylan's latanoprost in Belgium;
- (xxxi) Mylan's latanoprost in Luxembourg;
- (xxxii) Mylan's latanoprost/timolol in Belgium;
- (xxxiii) Mylan's latanoprost/timolol in France;
- (xxxiv) Mylan's latanoprost/timolol in Italy;

² For the purpose of this Decision, although the United Kingdom withdrew from the European Union as of 1 February 2020, according to the Withdrawal Agreement, Union law continues to apply to the United Kingdom during the transition period. Accordingly, any references made to the EEA in this Decision are meant to also include the United Kingdom

- (xxxv) Mylan's latanoprost/timolol in Luxembourg;
- (xxxvi) Mylan's latanoprost/timolol in the Netherlands; and
- (xxxvii) Mylan's latanoprost/timolol in Portugal.

- (3) By letters of 3 July of 2020, Mylan proposed to divest the Mylan Divestment Business to four purchasers.
- (4) Mylan intends to sell the following country/molecule combinations to Aurobindo Pharma Limited (“Aurobindo”, India):

Country	Molecule	Country	Molecule
Belgium	Eplerenone	Italy	Alprazolam
Belgium	Pregabalin	Italy	Latanoprost/Timolol
Belgium	Venlafaxine	Luxembourg	Latanoprost
Belgium	Latanoprost	Luxembourg	Pregabalin
Czechia	Ziprasidone	The Netherlands	Latanoprost/Timolol
Czechia	Pregabalin	Norway	Pregabalin
France	Latanoprost/Timolol	Portugal	Latanoprost/Timolol
France	Eletriptan	Romania	Sildenafil
Greece	Alprazolam	UK	Sildenafil
Ireland	Alprazolam		
Ireland	Gabapentin		

- (5) These country/molecule combinations are together referred to as the “First Divestment Business”, which is a sub-set of the Mylan Divestment Business.
- (6) This decision only concerns the approval of the proposed purchaser of the First Divestment Business.
- (7) By one of the reasoned submissions dated 3 July 2020, Mylan proposed Aurobindo for approval by the Commission as purchaser of the First Divestment Business. Aurobindo develops, manufactures and markets generic pharmaceuticals and active pharmaceutical ingredients worldwide. The company offers generics formulations primarily in the therapeutic areas of cardiovascular system, central nervous system, antibacterials, cephalosporins, ophthalmics, oral contraceptives, gastroenterologicals, nonsteroidal anti-inflammatory drugs, anti-fungal, anti-emetics, anti-virals, anti-diabetics, anti-allergic, antibiotics and anti-retrovirals. Aurobindo supplies pharmaceutical products to 155 countries across the globe and it has more than 22 000 employees. Aurobindo’s footprint in the EEA has been growing steadily over the last 15 years. Today, the company is active in 22 EEA countries and one of Aurobindo’s manufacturing facilities is located in the EEA, namely in Portugal. Aurobindo has around 25 production plants globally. The company produced over 33 billion doses of different medicines in the financial year 2019 and sourced a large proportion of active pharmaceutical ingredients (“APIs”) internally.
- (8) Mylan submitted to the Commission the agreements to be entered into between Mylan and Aurobindo, consisting of the asset sale agreement (the “Asset Sale

Agreement”) together with the schedules and exhibits (all together the “Aurobindo Transaction Agreements”) on 21 August.

- (9) In its opinion of 26 August 2020 (the “Reasoned Opinion”) pursuant to paragraph 29 of the Commitments, Monitoring Trustee Partners, acting as monitoring trustee (“the Trustee”), concludes that:
- a. Aurobindo fulfils the Purchaser Criteria³ as set out in paragraph 18 of the Commitments and there are no indications that the First Divestment Business would not be viable after the sale; and
 - b. the First Divestment Business would be sold in a manner consistent with the Commitments under the Aurobindo Transaction Agreements.

2. ASSESSMENT OF THE PROPOSAL

- (10) According to paragraphs 18 and 19 of the Commitments, in order for the Commission to approve the purchaser, the purchaser(s) must fulfil(s) the Purchaser Criteria and the divestment businesses should be sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market.

2.1. Assessment of the Purchaser Criteria

- (11) As set out in paragraph 18 of the Commitments, the purchaser(s) of the divestment businesses must fulfil the following criteria:
- (a) The Purchaser shall be independent of and unconnected to the Parties and their Affiliated Undertakings (this being assessed having regard to the situation following the divestiture);
 - (b) The Purchaser shall have the financial resources, proven expertise and incentive to maintain and develop the relevant Divestment Business (or Divestment Businesses) as a viable and active competitive force in competition with the Parties and other competitors;
 - (c) The Purchaser shall be an established generic supplier with presence in the EEA that can market the relevant Divestment Business (or Divestment Businesses) through its own commercial infrastructure or through distributors in the relevant countries where each relevant Divestment Business is currently active; and
 - (d) The acquisition of the relevant Divestment Business (or Divestment Businesses) by the Purchaser must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the Purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business(es).

³ Capitalised terms in this decision will have the meaning as set out in the Commitments, unless indicated otherwise.

2.1.1. Independence from Mylan and Upjohn

- (12) Aurobindo and Mylan are publicly traded. Aurobindo is listed on the National Stock Exchange of India and Bombay Stock Exchange. Mylan is listed on the Nasdaq Stock Market. Upjohn is currently a wholly owned subsidiary by Pfizer Inc. (“Pfizer”). Pfizer is publicly traded. Neither Mylan nor Pfizer holds directly any shareholding in Aurobindo. Therefore, Aurobindo is neither owned nor controlled by Mylan, Pfizer or any of their affiliates.⁴
- (13) There are, however, certain minority shareholders of Aurobindo that also hold minority shareholdings in Mylan and/or Pfizer. Four of the largest investors in Mylan also hold minority shareholdings in Aurobindo (namely, the Vanguard Group, Inc; BlackRock Inc.; AQR Capital Management, LLC; and Pzena Investment Management, Inc). In addition, two of the largest investors in Pfizer hold minority shareholdings in Aurobindo (namely, the Vanguard Group, Inc and BlackRock Inc). The Trustee considers, however, that these minority shareholdings are small (the largest ones, from an Aurobindo perspective, are The Vanguard Group, Inc, and BlackRock Inc., with an 1.7% stake and 1.3% stake respectively in Aurobindo) and, therefore, do not lead to a control situation or the possibility to exercise material influence by any of these minority shareholders holding stock in both Aurobindo and Mylan and/or Pfizer.
- (14) The controlling shareholders of Aurobindo have no shareholding in Mylan or Upjohn.
- (15) No director of Mylan or Upjohn serves on the board of Aurobindo or any of its affiliates and *vice versa*.⁵
- (16) The Trustee also reviewed the existing business relations and contractual relations between Aurobindo and the Parties and concluded that no material agreements exist between the Parties and their Affiliated Undertakings on the one side and Aurobindo on the other side.⁶ Commercial relationships are limited and represent less than [0-5]% of Aurobindo’s annual revenues in 2020.⁷
- (17) In light of the above and in light of the Trustee’s Reasoned Opinion, the Commission concludes that Aurobindo fulfils the purchaser criterion of being independent of and unconnected to Mylan and Upjohn and their Affiliated Undertakings⁸.

⁴ Monitoring Trustee Reasoned Opinion on the acquisition of the First Divestment Business by Aurobindo of 26 August 2020 (“Reasoned Opinion”), Section 4.

⁵ Reasoned Opinion, Section 4.

⁶ Reasoned Opinion, Section 4.

⁷ Reasoned Opinion, Section 4.

⁸ According to the Commitments, Affiliated Undertakings are undertakings controlled by the Parties and/or by the ultimate parents of the Parties, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the “Consolidated Jurisdictional Notice”).

2.1.2. *Financial resources, proven expertise and incentive to maintain and develop the First Divestment Business as a viable and active competitor*

2.1.2.1. Financial resources

- (18) Aurobindo's market capitalisation amounted to EUR 5.9 billion as of 13 July 2020. Aurobindo's turnover in the last financial year amounted to EUR 2 892 million, representing an increase of 18.1% from the previous year.
- (19) The Trustee reviewed the financial results of Aurobindo and concluded that Aurobindo is a healthy and profitable business that has achieved steady growth while maintaining a sound solvency position. The company's net interest-bearing debt position is comfortable and, hence, Aurobindo has a strong potential to attract further debt financing if and when needed.⁹
- (20) Aurobindo agrees to pay EUR [...] for the First Divestment Business. Aurobindo will fund the acquisition price of the First Divestment Business through its existing cash resources, and, therefore, the company does not need to obtain any additional external financing. The Trustee considers that Aurobindo has ample resources to fund the acquisition and subsequent developments of the First Divestment Business considering the company's capability to generate significant positive operating cash flows as evidenced by its EBITDA performance, its current cash position and its additional loan capacity, as evidenced by its strong balance sheet.¹⁰
- (21) Based on the information above and the Trustee's Reasoned Opinion on the financial situation of Aurobindo, the Commission concludes that Aurobindo fulfils the criterion of having the financial resources to maintain and develop the First Divestment Business as a viable and active competitive force in competition with the Parties and other competitors.

2.1.2.2. Proven experience

- (22) According to paragraph 18 of the Commitments, the proposed purchaser(s) must have the proven expertise to maintain and develop the divestment business as a viable and active competitive force in competition with the Parties and other competitors. Moreover, the purchaser(s) shall be an established generic supplier with presence in the EEA that can market the relevant molecule/country combinations through its own commercial infrastructure or through distributors in the relevant countries where each relevant molecule/country combinations is sold.
- (a) *Marketing, Promotion and Distribution of Generic Products in the Relevant Countries*
- (23) Aurobindo, develops, manufactures and markets generic pharmaceuticals and active pharmaceutical ingredients worldwide. Aurobindo supplies pharmaceutical products to 155 countries across the globe and is active in 22 EEA countries. Aurobindo has around 25 production plants globally, including one in Portugal. The company produced over 33 billion doses of different medicines in 2019.

⁹ Reasoned Opinion, Section 5.

¹⁰ Reasoned Opinion, Section 5.

- (24) The First Divestment Business includes molecules in Belgium, Czechia, France, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Romania and the UK (all together, the “Relevant Countries”).
- (25) Aurobindo has already a significant presence in all Relevant Countries, either through direct sales forces or distributors. The First Divestment Business revenues amount, in all Relevant Countries, to a fraction of Aurobindo’s existing revenues in each of the Relevant Countries. Considering this, the Trustee concludes that the integration from a commercial point is deemed to be straightforward.¹¹
- (26) Based on the information above and the Trustee’s Reasoned Opinion, the Commission considers that Aurobindo is an established generic supplier with presence in the EEA, and in particular in all Relevant Countries, that can market the molecule/country combinations included in the First Divestment Business.
- (b) *Manufacturing, Transfer and Regulatory Capabilities*
- (27) Aurobindo has around 25 manufacturing facilities around the globe and is currently commercializing all of the molecules included in the First Divestment Business elsewhere in the EEA. Furthermore, Aurobindo already manufactures a significant number of the molecules included in the First Divestment Business for other EEA countries. The acquisition of the First Divestment Business will therefore generate synergies by enabling Aurobindo to absorb additional molecules in its manufacturing infrastructure or through its established CMO relationships. Aurobindo performed a large number of manufacturing transfers during the last three years.¹²
- (28) Aurobindo has significant experience when dealing with regulatory authorities. In addition to its central regulatory team in India, Aurobindo has a regulatory team in every EEA country where it has a direct market commercialisation. Aurobindo has performed a large number of marketing authorisation transfers during the last three years. Depending on the type of marketing authorisation, Aurobindo expects the transfers for the First Divestment Business to take 3 to 5 months.¹³
- (29) Based on the information above and the Trustee’s Reasoned Opinion, the Commission considers that Aurobindo has proven expertise to maintain and develop the First Divestment Business as a viable and active competitive force.

2.1.2.3. Incentives to maintain and develop the Divestment Business

- (30) The Trustee’s Reasoned Opinion concludes that the purchase of the First Divestment Business represents an opportunity for Aurobindo to expand the geographic footprint of its product portfolio and strengthen its presence in numerous EEA countries. Moreover, since Aurobindo already commercialises all of the relevant molecules in other EEA countries, the acquisition of the First Divestment Business will enable Aurobindo to generate synergies with respect to both manufacturing and

¹¹ Reasoned Opinion, Sections 5 and 7.

¹² Reasoned Opinion, Section 5.

¹³ Reasoned Opinion, Section 5.

distribution.¹⁴ Indeed, after the Aurobindo Transaction, Aurobindo will be able to offer a broader range of generics drugs in the Relevant Countries.¹⁵

- (31) Based on the information above and the Trustee's Reasoned Opinion, the Commission considers that Aurobindo has the incentives to maintain and develop the First Divestment Business.¹⁶

2.1.3. Absence of *prima facie* competition concerns

- (32) The acquisition of the First Divestment Business by Aurobindo is *prima facie* not likely to give rise to competition concerns.

- (33) The acquisition of the First Divestment Business by Aurobindo does not give rise to any vertically affected markets.

- (34) With regards to horizontal overlaps, the acquisition of the First Divestment Business by Aurobindo gives rise to three affected markets.¹⁷ In particular, the Aurobindo Transaction creates three Group 3¹⁸ overlaps:¹⁹ eletriptan in France, pregabalin in Czechia and venlafaxine in Belgium. The combined market shares are moderate in the three affected markets with a very limited increment. Moreover, there remain in all cases more than three competitors with market shares above 5% or above the increment.

- (35) With regards to eletriptan in France in 2019, the acquisition of the First Divestment Business by Aurobindo would result in a moderate combined market share at the molecule level ([20-30]% both value and volume), with a negligible increment brought by Aurobindo ([0-5]%). Moreover, five competitors will remain active on the market, of which four, including the originator Upjohn/Viatris, have shares well above the increment (Servier: [30-40]%, Upjohn/Viatris: [30-40]%, Zentiva: [0-5]%, Stada: [0-5]%; Zydus Cadila: [0-5]%).²⁰

- (36) With regards to pregabalin in Czechia in 2019, the acquisition of the First Divestment Business by Aurobindo would result in a limited combined market share which exceeds 20% at the molecule level only by value ([30-40]%). Aurobindo will bring a limited increment ([0-5]% by volume, [0-5]% by value). Over 15 competitors will remain active after the Aurobindo Transaction with market shares that are the same as, or higher than the increment created by the Aurobindo Transaction. Moreover, three of them have market shares of at least 5% (both in volume and

¹⁴ In the countries in which Aurobindo already commercializes the same molecule, the Aurobindo Transaction represents an opportunity to grow its limited position and gain market shares that will lead to synergies in terms of commercialization, marketing, distribution and/or production.

¹⁵ Reasoned Opinion, Section 5.

¹⁶ Reasoned Opinion, Section 5.

¹⁷ For nine of the molecule/country combinations included in the First Divestment Business, there is no horizontal overlap with the molecules currently commercialized by Aurobindo, while for eight of the molecule/country combinations, overlaps with the molecules currently commercialized by Aurobindo result in a combined market share of less than 20% at any level.

¹⁸ In paragraph 33 of the Decision, the Commission concluded that Group 3 markets arising from the transaction do not raise serious doubts as to their compatibility with the internal market due to the limited market shares of Mylan and Upjohn and the presence of significant competitors remaining on the market post-Transaction.

¹⁹ In line with the Commission precedents, in the pharmaceutical sector, Group 3 markets arise where the parties' combined market share is between 20% and 35%.

²⁰ Reasoned Proposal Aurobindo from Mylan of 3 July 2020.

value) and will remain important competitive constraints in the market, including the originator of pregabalin, Upjohn/Viatris ([40-50]% volume, [10-20]% value), as well as Novartis ([10-20]% volume, [10-20]% value) and Krka ([10-20]% volume, [5-10]% value).²¹

- (37) With regards to Venlafaxine in Belgium in 2019, the acquisition of the First Divestment Business by Aurobindo would result in a limited combined market share ([20-30]% volume and [10-20]% value) with a moderate increment brought by Aurobindo of [5-10]% in terms of volume and [5-10]% value. Five competitors will remain active after the Aurobindo Transaction, three of them having market shares well exceeding 5% in both volume and value: Upjohn/Viatris ([40-50]% volume and [40-50]% value), Stada ([20-30]% volume and value) and Novartis ([10-20]% volume and [10-20]% value).²²
- (38) Moreover, the proposed Aurobindo Transaction does not require any merger control filings.
- (39) Lastly, the controlling shareholders of Aurobindo, have no controlling interest in other companies active in the relevant markets, that is molecule/country pairs covered by the First Divestment Business
- (40) In light of the above and the Trustee's Reasoned Opinion, the Commission considers that the acquisition of the First Divestment Business by Aurobindo is neither likely to create *prima facie* competition concerns, nor to give rise to a risk that the implementation of the Commitments will be delayed.

2.1.4. Conclusion

- (41) In view of the above, the Commission considers that Aurobindo meets the Purchaser Criteria.

2.2. The Divestment business is being sold in a manner consistent with the Commitments

- (42) The Commission has reviewed the Aurobindo Transaction Agreements and considers that the Aurobindo Transaction Agreements reflect the Parties' obligations set out in the Commitments. The Trustee observed no deviations between the Commitments and the Aurobindo Transaction Agreements with the exception of the one described below. Moreover, Aurobindo confirmed that it is satisfied with the manner the Commitments are reflected in the Aurobindo Transaction Agreements.²³
- (43) As per the Commitments, the purchaser also acquires the full rights to develop the molecule outside of the territory for which it acquired the marketing authorisation and for which competition concerns were identified. As per the License Agreement, schedule 3, however, the Trustee observed that this right is limited, such that the purchaser can only develop the molecule in territories for which there were no further marketing authorisations included in the Mylan Divestment Business. Although this inclusion in the License Agreement may be regarded as a limitation with regards to the rights to develop the molecule in other territories as envisaged in

²¹ Reasoned Proposal Aurobindo from Mylan of 3 July 2020.

²² Reasoned Proposal Aurobindo from Mylan of 3 July 2020.

²³ Reasoned Opinion, Section 6.

the Commitments, the Trustee considers that this limitation is helpful to protect the future viability of the other purchasers of parts of the Mylan Divestment Business. The Commission shares the views of the Trustee, as this limitation is justified to preserve the viability and value of the other molecule/country combinations included in the Mylan Divestment Business. Moreover, this limitation will not negatively affect the viability of the First Divestment Business.²⁴

- (44) Therefore, based on the information above and the Trustee's Reasoned Opinion the Commission concludes that the First Divestment Business is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market.

3. CONCLUSION

- (45) Based on the above assessment, the Commission approves Aurobindo as a suitable purchaser of the First Divestment Business.
- (46) Based on the Aurobindo Transaction Agreements, the Commission further concludes that the First Divestment Business is being sold in a manner consistent with the Commitments.
- (47) This Decision only constitutes approval of the Proposed Purchaser identified herein and of the Aurobindo Transaction Agreements. This decision does not constitute a confirmation that the Parties have complied with the Commitments.
- (48) This Decision is based on paragraphs 18 and 19 of the Commitments attached to the Decision.

For the Commission

(Signed)
Olivier GUERSENT
Director-General

²⁴ Reasoned Opinion, Section 6.