EUROPEAN COMMISSION
DG Competition

Case M.9517 – MYLAN / UPJOHN

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

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

EUROPEAN COMMISSION

Brussels, 14.9.2020
C(2020) 6372 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 Where possible the information omitted has been replaced by ranges of figures or a general description.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 Substipharm as purchaser of the Fourth Divestment Business following your letter of 03.07.2020 and the Trustee's opinion of 21.08.2020

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 139/2004[1] 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

[1] OJ L 24, 29.1.2004, p. 1 (the "Merger Regulation").

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Inc. (“Pfizer”, the United States of America) intend to merge (the “Transaction”), 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 EEA[2] (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;

[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

(xxxiii) Mylan's latanoprost/timolol in France;
(xxxiv) Mylan's latanoprost/timolol in Italy;
(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 Substipharm SAS ("Substipharm", France):[3]

Country	Molecule
France	Doxazosin
France	Sildenafil (PAH)
France	Tadalafil (PAH)
Belgium	Latanoprost/Timolol
Luxembourg	Latanoprost/Timolol

(5) These country/molecule combinations are together referred to as the "Fourth 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 Fourth Divestment Business.

(7) By one of the reasoned submissions dated 3 July 2020, Mylan proposed Substipharm for approval by the Commission as purchaser of the Fourth Divestment Business. Substipharm develops and commercializes pharmaceuticals in more than 60 countries worldwide.

(8) Substipharm generated a turnover of EUR 120 million in FY 2019 selling over 100 million packs of products worldwide. The company experienced an annual growth rate of around 20% over the last years. Of its total turnover, EUR 78 million was realized in France, its core market, where Substipharm sold 94 million packs.

(9) Mylan submitted to the Commission the agreements to be entered into between Mylan and Substipharm, consisting of the asset sale agreement together with the schedules and exhibits (all together the "Substipharm Transaction Agreements") on 7 August 2020.

3 Substipharm in thie decision covers the Substipharm group of companies, including Gerda. Gerda is a sister company which commercialises a range of originator and generic products, and is to the largest extent, owned by the same private individuals as Substipharm.

(10) In its opinion of 21 August 2020 (the "Reasoned Opinion") pursuant to paragraph 29 of the Commitments, Monitoring Trustee Partners, acting as monitoring trustee ("the Trustee"), concludes that:

a. Substipharm fulfils the Purchaser Criteria[4] as set out in paragraph 18 of the Commitments and there are no indications that the Fourth Divestment Business would not be viable after the sale; and

b. the Fourth Divestment Business would be sold in a manner consistent with the Commitments under the Substipharm Transaction Agreements.

2. ASSESSMENT OF THE PROPOSAL

(11) 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

(12) 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).

[4] 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

(13) Mylan is publicly traded. Mylan is listed on the Nasdaq Stock Market. Upjohn is currently a wholly owned subsidiary by Pfizer Inc. ("Pfizer"). Pfizer is publicly traded. Substipharm is privately owned, ultimately by the Berthier family. Neither Mylan nor Pfizer holds directly any shareholding in Substipharm. Therefore, Substipharm is neither owned nor controlled by Mylan, Pfizer or any of their affiliates.[5] Moreover, there are no investors that hold any shareholdings in both Substipharm and/or Gerda on the one hand and the Parties on the other.

(14) The controlling shareholders of Substipharm, namely the Berthier family members, have no material shareholding in Mylan or Upjohn.

(15) No director of Mylan or Upjohn serves on the board of Substipharm and/or Gerda or any of their affiliates and *vice versa*.[6]

(16) The Trustee also reviewed the existing business relations and contractual relations between Substipharm and/or Gerda and the Parties and concluded that they do not appear to be material to any party.[7]

(17) Regarding commercial relationships between the Parties, Mylan does not sell products or services to Substipharm. Upjohn, does not sell to or purchase from Substipharm any product or service.[8]

(18) However, Substipharm currently [information regarding the commercial relationships between Mylan and Substipharm]. The value of these [commercial relationships between Mylan and Substipharm] amount to around EUR […], which represents […]% of Substipharm's total turnover. In relation to this [information regarding the commercial relationships between Mylan and Substipharm], the Trustee notes that: [9]

(a) […]

(b) Substipharm already competes against Mylan, in particular in the French market.

(c) Mylan extended […] for an additional period of […] years.

(d) Furthermore, Substipharm benefits […]. In particular, Mylan can only […].

(19) The Commission notes that […] between competitors are relatively standard in the pharmaceutical industry. Furthermore, the Commission notes that Substipharm, besides being a direct competitor to Mylan for the relevant molecules, also […] for the same molecules.

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5 Monitoring Trustee Reasoned Opinion on the acquisition of the Fourth Divestment Business by Substipharm of 21 August 2020 ("Reasoned Opinion"), Section 4.

6 Reasoned Opinion, Section 4.

7 Reasoned Opinion, Section 4.

8 Reasoned Opinion, Section 4.

9 Reasoned Opinion, Section 4.

(20) In light of the above and the Trustee's Reasoned Opinion, the Commission concludes that Substipharm fulfils the purchaser criterion of being independent of and unconnected to Mylan and Upjohn and their Affiliated Undertakings[10].

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

2.1.2.1. Financial resources

(21) Substipharm's turnover in the last financial year amounted to EUR 107 million, representing an increase of over 20% on the previous year.

(22) The Trustee reviewed the financial results of Substipharm and concluded that Substipharm is a healthy and profitable business that has achieved steady growth while maintaining a sound solvency position.[11]

(23) Substipharm agrees to pay EUR […] for the Fourth Divestment Business. Substipharm will fund the acquisition price of the Fourth Divestment Business through its existing cash resources, and, therefore, the company does not need to obtain any additional external financing. The Trustee considers that Substipharm has resources to fund the acquisition and subsequent developments of the Fourth 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.[12]

(24) Based on the information above and the Trustee's Reasoned Opinion on the financial situation of Substipharm, the Commission concludes that Substipharm fulfils the criterion of having the financial resources to maintain and develop the Fourth Divestment Business as a viable and active competitive force in competition with the Parties and other competitors.

2.1.2.2. Proven experience

(25) 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.

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10 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").

11 Reasoned Opinion, Section 5.

12 Reasoned Opinion, Section 5.

(a) *Marketing, Promotion and Distribution of Generic Products in the Relevant Countries*

(26) Substipharm commercializes pharmaceuticals on a worldwide scale, with a focus on France. The company generates sales in around 60 countries globally, including France, Belgium and Luxembourg (all together, the "Relevant Countries"). The portfolio of Substipharm covers primarily the sales of finished dose pharmaceuticals, primarily to other pharmaceutical companies ("B2B"), but also to hospitals and wholesalers ("B2C").

(27) The Fourth Divestment Business includes molecules in the Relevant Countries, sold primarily B2C.

(28) Substipharm has already a presence in all Relevant Countries, particularly in France, where it has a direct presence, and makes B2C sales. In Belgium and Luxembourg, Substipharm has an agreement with a third party distributor for B2C products.

(29) The Fourth Divestment Business revenues amount, in all Relevant Countries, to a fraction of Substipharm and Gerda'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 straight-forward.[13]

(30) Based on the information above and the Trustee's Reasoned Opinion, the Commission considers that Substipharm is an established generic supplier with presence in the EEA and in particular in all Relevant Countries, that can market all the molecule/country combinations included in the Fourth Divestment Business.

(b) *Manufacturing, Transfer and Regulatory Capabilities*

(31) Substipharm's business model is based on outsourcing the manufacturing of the pharmaceutical products it develops or acquires. Substipharm currently uses more than 20 different contract manufacturing organizations ("CMOs") for its products.

(32) Substipharm is planning to transfer the manufacturing of Sildenafil (PAH) and Tadalafil (PAH) to a new CMO. The Trustee understands that Substipharm has identified two CMOs that already manufacture these molecules for other generic companies in the same dosage and that it will start negotiating contracts with them after it acquires the products. The production of Doxazosin and Latanoprost/Timolol will continue to be performed by the existing CMOs, [name of a CMO] and [name of a CMO].

(33) According to the Trustee, Substipharm has a limited track record in integrating acquired products into its organization. However, the company has a strong track record when it comes to performing manufacturing transfers and obtaining marketing authorizations. Substipharm performed over 100 marketing authorization transfers since the beginning of 2017.

(34) Substipharm has significant experience when dealing with regulatory authorities. Substipharm has a large regulatory team that has significant experience when dealing with regulatory authorities. Based on its experience, it expects the transfer of

13 Reasoned Opinion, Sections 5 and 7.

marketing authorisation to take approximately transfers to last approximately 3 to 5 months. [14]

(35) Based on the information above and the Trustee's Reasoned Opinion, the Commission considers that Substipharm has proven expertise to maintain and develop the Fourth Divestment Business as a viable and active competitive force.

2.1.2.3. Incentives to maintain and develop the Divestment Business

(36) The Trustee's Reasoned Opinion concludes that the purchase of the Fourth Divestment Business represents for Substipharm an opportunity to broadening its portfolio offering in the Relevant Countries, in particular by expanding its current (limited) B2C product portfolio, and more in particular, to strengthen its existing footprint in France, and to accelerate its transition to the B2C segment in Belgium and Luxembourg. Therefore, through the acquisition of the Fourth Divestment Business, Substipharm will strengthen its presence in the Relevant Countries.[15]

(37) Based on the information above and the Trustee's Reasoned Opinion, the Commission considers that Substipharm has the incentives to maintain and develop the Fourth Divestment Business.[16]

2.1.3. Absence of prima facie competition concerns

(38) The acquisition of the Fourth Divestment Business by Substipharm is *prima facie* not likely to give rise to competition concerns.

(39) The acquisition of the Fourth Divestment Business by Substipharm does not give rise to any horizontal or vertical overlaps between the Fourth Divestment Business and the molecules/country combinations currently commercialized by Substipharm and/or Gerda, in the Relevant Countries.

(40) Moreover, the proposed Substipharm Transaction does not require any merger control filings.

(41) Lastly, the controlling shareholders of Substipharm, namely the Berthier family members, have no controlling interest in other companies active in the relevant markets, that is molecule/country pairs covered by the Third Divestment Business.

(42) In light of the above and the Trustee's Reasoned Opinion, the Commission considers that the acquisition of the Fourth Divestment Business by Substipharm 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.

14 Reasoned Opinion, Sections 5 and 7.

15 Reasoned Opinion, Section 5.

16 Reasoned Opinion, Section 5.

2.1.4. Conclusion

(43) In view of the above, the Commission considers that Substipharm meets the Purchaser Criteria.

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

(44) The Commission has reviewed the Substipharm Transaction Agreements and considers that the Substipharm Transaction Agreements reflect the Parties' obligations set out in the Commitments. The Trustee observed no deviations between the Commitments and the Substipharm Transaction Agreements with the exception described below. Moreover, Substipharm confirmed that it is satisfied with the manner the Commitments are reflected in the Substipharm Transaction Agreements.[17]

(45) 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 authorization 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 authorizations 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 the Commitments, the Trustee considers that this limitation is helpful to protect the future viability of 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 Fourth Divestment Business.[18]

(46) Therefore, based on the information above and the Trustee's Reasoned Opinion the Commission concludes that the Fourth 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

(47) Based on the above assessment, the Commission approves Substipharm as a suitable purchaser of the Fourth Divestment Business.

(48) Based on the Substipharm Transaction Agreements, the Commission further concludes that the Fourth Divestment Business is being sold in a manner consistent with the Commitments.

17 Reasoned Opinion, Section 6.

18 Reasoned Opinion, Section 6.

(49) This Decision only constitutes approval of the Proposed Purchaser identified herein and of the Substipharm Transaction Agreements. This decision does not constitute a confirmation that the Parties have complied with the Commitments.

(50) This Decision is based on paragraphs 18 and 19 of the Commitments attached to the Decision.

For the Commission

(Signed)
Olivier GUERSENT
Director-General