



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, 14.09.2020
C(2020) 6370 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 Where possible the information omitted has been replaced by ranges of figures or a general description.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
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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 Towa as purchaser of the Second 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 Towa Pharmaceutical Co, Ltd. ("**Towa**", Japan):

Country	Molecule
Denmark	Eletriptan
Iceland	Alprazolam
Norway	Atorvastatin, Eletriptan
Sweden	Eletriptan
Finland	Eletriptan
Portugal	Alprazolam

- (5) These country/molecule combinations are together referred to as the “Second 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 Second Divestment Business.
- (7) By one of the reasoned submissions dated 3 July June 2020, Mylan proposed Towa for approval by the Commission as purchaser of the Second Divestment Business. Towa specializes in the development, manufacturing and marketing of generic drugs. Worldwide, Towa operates three manufacturing plants with capacity to produce billions of tablets and sells over 760 products. Towa generated over EUR 920 million in annual sales in the financial year 2019. Towa’s generic portfolio covers a wide range of therapeutic areas, such as the gastrointestinal, cardiovascular, central nervous system, respiratory and genito-urinary system.
- (8) On 31 January 2020, Towa acquired Esteve’s generic division, Pensa Pharma ("**Pensa**"). Pensa is engaged in the development, manufacturing and sale of generic pharmaceuticals. It sells over 300 products and is focused on an extensive portfolio of generic medicines in eleven countries, namely Spain, Italy, Portugal, Sweden, Denmark, Norway, Iceland, Germany, the Netherlands, Turkey and the United States. Pensa generated a turnover of approximately EUR [...] in 2019. Towa, after the acquisition of Pensa, therefore, generated annual sales of EUR [...] in the financial year 2019.
- (9) Mylan submitted to the Commission the agreements to be entered into between Mylan and Towa, consisting of the asset sale agreement (the “Asset Sale Agreement”) together with the schedules and exhibits (all together the “Towa Transaction Agreements”) on 12 August 2020.

- (10) 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. Towa fulfils the Purchaser Criteria³ as set out in paragraph 18 of the Commitments and there are no indications that the Second Divestment Business would not be viable after the sale; and
 - b. the Second Divestment Business would be sold in a manner consistent with the Commitments under the Towa 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).

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*

- (13) Towa and Mylan are publicly traded. Towa is listed on the Tokyo 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 Towa. Therefore, Towa is neither owned nor controlled by Mylan, Pfizer or any of their affiliates.⁴
- (14) There are, however, certain minority shareholders of Towa that also hold minority shareholdings in Mylan and/or Pfizer. Five of the largest investors in Mylan also hold interests in Towa (namely, The Vanguard Group, Inc.; FIL Limited; Dimensional Fund Advisors L.P.; Norges Bank Investment Management; and Black Rock, Inc). In addition, five of the largest investors in Pfizer hold interests in Towa (namely, The Vanguard Group, Inc.; Dimensional Fund Advisors L.P.; Norges Bank Investment Management; Teachers Insurance and Annuity Association of America – College Retirement Equities Fund; and Black Rock, Inc;). The Trustee considers, however, that these shareholdings are small (the largest ones, from Towa perspective, are The Vanguard Group, Inc. and FIL Limited, with an 1.5% stake and 1.4% stake respectively in Towa) 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 Towa and Mylan and/or Pfizer.
- (15) No director of Mylan or Upjohn serves on the board of Towa or any of its affiliates and *vice versa*.⁵
- (16) The Trustee also reviewed the existing business relations and contractual relations between Towa and the Parties and concluded that no material agreements exist between the Parties and their Affiliated Undertakings on the one side and Towa on the other side.⁶ Commercial relationships are limited and represent less than [0-5]% of Towa's annual revenues in 2019.⁷
- (17) In light of the above and the Trustee's Reasoned Opinion, the Commission concludes that Towa fulfils the purchaser criterion of being independent of and unconnected to Mylan and Upjohn and their Affiliated Undertakings.⁸

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

- (18) Towa's market capitalisation amounted to EUR 787 million as of July 13, 2020. Towa's turnover in the last financial year amounted to EUR 923 million, representing an increase of [5-10]% on the previous year. Towa acquired Pensa at

⁴ Monitoring Trustee Reasoned Opinion on the acquisition of the Second Divestment Business by Towa 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").

beginning of 2020 and, therefore, Pensa's revenues (EUR [...] in financial year 2019) have only been reflected in Towa's 2019 financial year income statement for the period between acquisition until 31 March 2020. The *pro forma* revenues of Towa for the financial year 2019 after the acquisition of Pensa are approximately EUR [...].

- (19) The Trustee reviewed the financial results of Towa and concluded that Towa 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, Towa has a strong potential to attract further debt financing if and when needed.⁹
- (20) Towa agrees to pay EUR [...] for the Second Divestment Business. Towa will fund the acquisition price of the Second Divestment Business through its existing cash resources, and, therefore, the company does not need to obtain any additional external financing. The Trustee considers that Towa has ample resources to fund the acquisition and subsequent developments of the Second 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.¹⁰
- (21) Based on the information above and the Trustee's Reasoned Opinion on the financial situation of Towa, the Commission concludes that Towa fulfils the criterion of having the financial resources to maintain and develop the Second 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) Towa manufactures and markets generic pharmaceuticals worldwide. Towa operates three manufacturing plants with capacity to produce billions of tablets. Towa's generic portfolio covers a wide range of therapeutic areas, such as the gastrointestinal, cardiovascular, central nervous system, respiratory and genito-urinary system.
- (24) Moreover, on 31 January 2020, Towa acquired Pensa which is engaged in the development, manufacturing and sale of generic pharmaceuticals. Pensa is focused on an extensive portfolio of generic medicines in eleven countries, namely Spain, Italy, Portugal, Sweden, Denmark, Norway, Iceland, Germany, the Netherlands, Turkey and the United States.

⁹ Reasoned Opinion, Section 5.

¹⁰ Reasoned Opinion, Section 5.

- (25) The Second Divestment Business includes molecules in Denmark, Finland, Iceland, Norway, Portugal and Sweden (all together, the “Relevant Countries”).
- (26) Towa has already a significant presence in all Relevant Countries except Finland, either through direct sales forces or distributors. The Second Divestment Business revenues amount, in all Relevant Countries except Finland, to a fraction of Towa’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 in the Relevant Countries except Finland, in which a more detailed assessment is provided below.¹¹
- (27) With regards to Finland the Trustee deems the commercialization of the product to be feasible for the reasons explained below.
- (28) Towa has currently no existing revenues in the country. Towa plans to commercialize eletriptan through a monthly tender process, as Finland is a tender-driven market. The distribution will be performed [information concerning the commercialization of eletriptan in Finland]. The conditions for the [information concerning the commercialization of eletriptan in Finland]. The Trustee considers that Towa will be particularly well suited to entry into the Finnish market with eletriptan. In Finland, the incumbent suppliers who do not win a particular tender have the option to match the winning (i.e. the lowest) price. Given that currently there is no generic competition other than Mylan’s eletriptan which will be divested to Towa, which currently holds a [10-20]% market share, there is no incumbent generics supplier who could price match and thus erode the price or position of Mylan’s eletriptan in Finland. In addition, Towa indicated that it has experience in using multi-language packaging in Nordic countries in order to achieve economies of scale on the production side. These efficiencies, as well the price point at which eletriptan may be tendered in Finland, mean that the product provides for a viable standalone proposition in Finland.¹²
- (29) Moreover, Towa indicated to the Trustee that, independent of the potential transaction with Mylan, it is planning to [Information concerning Towa’s business strategy in Finland]. Towa expects that the acquisition of Eletriptan from Mylan will facilitate the [Information concerning Towa’s business strategy in Finland].¹³
- (30) Based on the information above and the Trustee’s Reasoned Opinion, the Commission considers that Towa is an established generic supplier with presence in the EEA, which can market all the molecule/country combinations included in the Second Divestment Business.

(b) *Manufacturing, Transfer and Regulatory Capabilities*

- (31) Towa has three manufacturing plants globally, out of which one is located in Spain. In the Spanish facility, Towa manufactures a very large number of units of generics a year, including [molecule name] (one of the three molecules included in the Second Divestment Business). In this facility, Towa manufactures a variety of galenic forms, including [information concerning Towa’s manufacturing capabilities]. Towa has sufficient spare capacity in this facility to integrate the production on [molecule

¹¹ Reasoned Opinion, Sections 5 and 7.

¹² Reasoned Opinion, Section 7.

¹³ Reasoned Opinion, Section 7.

name] and [molecule name].¹⁴ With regards to [molecule name], Towa has already identified a CMO that already manufactures the product for other customers. Given that Towa already commercializes two out of the three molecules included in the Second Divestment Business in other countries, the acquisition of the Second Divestment Business will therefore generate synergies by enabling Towa to absorb additional molecules in its manufacturing infrastructure or through its established CMO relationships. Towa has an established track record in integrating acquired products and businesses into its organization. In fact, Towa performed a significant number of manufacturing transfers since the beginning of 2018. Furthermore, Towa acquired Pensa in the beginning of 2020.¹⁵

- (32) Moreover, Towa has significant experience when dealing with regulatory authorities. Its regulatory team in the EEA consists of a large number of individuals and the company has performed a large number of marketing authorization transfers since 2016. Based on its experience, it expects the transfer to take approximately three to eight months.¹⁶
- (33) Based on the information above and the Trustee's Reasoned Opinion, the Commission considers that Towa has proven expertise to maintain and develop the Second Divestment Business as a viable and active competitive force.

2.1.2.3. Incentives to maintain and develop the Divestment Business

- (34) The Trustee's Reasoned Opinion concludes that the purchase of the Second Divestment Business represents for Towa an opportunity to broadening its portfolio offering in the Relevant Countries, as well as further optimizing its current manufacturing capacity by increasing the production in its Spanish facility. Furthermore, Towa indicated that the Second Divestment Business provides it with a unique opportunity to enter the Finnish tender market, given the characteristics of the product. Therefore, through the acquisition of the Second Divestment Business, Towa will expand its geographic and strengthen its presence in numerous EEA countries, at the same time that it generates synergies with respect to manufacturing.¹⁷
- (35) Based on the information above and the Trustee's Reasoned Opinion, the Commission considers that Towa has the incentives to maintain and develop the Second Divestment Business.¹⁸

2.1.3. Absence of *prima facie* competition concerns

- (36) The acquisition of the Second Divestment Business by Towa is *prima facie* not likely to give rise to competition concerns.
- (37) The acquisition of the Second Divestment Business by Towa does not give rise to any horizontal or vertical overlaps between the Second Divestment Business and the

¹⁴ While Towa has confirmed it will produce in-house [molecule name]. Regarding [molecule name], Towa is contemplating two options depending on the outcomes of a cost-benefit analysis it will be performing shortly after Closing once it had access to the dossier: (i) Towa's current CMO supplier for [molecule name] in Spain, Italy and Portugal, or (ii) in-house.

¹⁵ Reasoned Opinion, Sections 5 and 7.

¹⁶ Reasoned Opinion, Sections 5 and 7.

¹⁷ Reasoned Opinion, Section 5.

¹⁸ Reasoned Opinion, Section 5.

molecules/country combinations currently commercialized by Towa in the Relevant Countries.

- (38) Moreover, the proposed Towa Transaction does not require any merger control filings.
- (39) In light of the above and the Trustee's Reasoned Opinion, the Commission considers that the acquisition of the Second Divestment Business by Towa 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

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

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

- (41) The Commission has reviewed the Towa Transaction Agreements and considers that the Towa Transaction Agreements reflect the Parties' obligations set out in the Commitments. The Trustee observed no deviations between the Commitments and the Towa Transaction Agreements with the exception described below. Moreover, Towa confirmed that it is satisfied with the manner the Commitments are reflected in the Towa Transaction Agreements.¹⁹
- (42) 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 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 Second Divestment Business.²⁰
- (43) Therefore, based on the information above and the Trustee's Reasoned Opinion the Commission concludes that the Second 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.

¹⁹ Reasoned Opinion, Section 6.

²⁰ Reasoned Opinion, Section 6.

3. CONCLUSION

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

For the Commission

(Signed)
Olivier GUERSENT
Director-Genera