EUROPEAN COMMISSION

DG Competition

Case M.7975 – Mylan / Meda

Only the English text is available and authentic.

REGULATION (EC) No 139/2004

MERGER PROCEDURE

Decision on the implementation of remedies - Art. 6(1)(b) in conjunction with 6(2) - Purchaser approval

Date: 8/3/2017

EUROPEAN COMMISSION

Brussels, 8.3.2017
C(2017) 1699 final

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

To the notifing party:

Dear Sir/Madam,

Subject: **Case M.7975 – Mylan / Meda**
Approval of Teva as purchaser of following your letter of 11 January 2017and the Trustee's opinion of 29 January 2017 and additional information submitted by the Trustee on 3 February 2017.

I. FACTS AND PROCEDURE

1. By decision of 20 July 2016 ("the Decision") based on Article 6(1)(b) in connection with Article 6(2), the Commission declared the operation by which Mylan acquired control of the whole of Meda AB (Meda) by way of purchase of shares ("the Transaction") compatible with the internal market subject to full compliance with the conditions and obligations laid down in the commitments annexed to the Decision ("the Commitments").

2. In particular, the Commitments provide that Mylan will divest the following business ("the Divestment Businesses"):

   (i) Mylan's propafenone business in Belgium, Luxembourg, Ireland, Italy and Spain;

   (ii) Mylan's flecainide business in Belgium and Ireland;

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(iii) Meda's flecainide business in Portugal, United Kingdom and Estonia;

(iv) Mylan's povidone-iodine business in France;

(v) Mylan's diltiazem (Dilfar & Diltiazem) business in Portugal;

(vi) Meda's Dagravit 8 business in Portugal;

(vii) Meda's progesterone business in Austria;

(viii) Meda's amoxicillin business in Norway;

(ix) Mylan's megestrol business in Spain; and

(x) Mylan's nabumetone business in the United Kingdom.

3. By letter of 11 January 2017 Mylan proposed Teva for approval by the Commission as purchaser of all the Divestment Businesses except for Meda's Dagravit 8 business in Portugal and Meda's progesterone business in Austria[1] (hereinafter the businesses to be purchased by Teva are referred to as "the Products"). Mylan submitted the proposed Asset Purchase Agreement and related agreements (the "Proposed Agreement").

4. On 29 January 2017, the Trustee Duff&Phelps ("the Trustee") submitted an assessment of Teva's suitability as a purchaser and, in particular, indicated that it fulfils the criteria of the purchaser requirements set out in section D of the Commitments attached to the Decision. In this assessment, the Trustee also indicated that, on the basis of the Proposed Agreement, the Products would be sold in a manner consistent with the Commitments.

II. ASSESSMENT OF THE PROPOSAL

5. As set out in section D of the Commitments, in order to be approved by the Commission, the purchaser(s) of the Divestment Businesses must fulfil the following criteria:

a. The purchaser shall be independent of and unconnected to the Parties;

b. The purchaser shall have the financial resources, proven expertise and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors;

c. The purchaser shall have an existing marketing and distribution footprint that includes generic pharmaceuticals in the relevant countries in which the Divestment Business is currently active;

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[1] Dagravit 8 (Portugal) and Progesterone (Austria) were also included in the Divestment Businesses. Dagravit 8 is in the process of being acquired by another proposed purchaser. With regard to Progesterone, on 1 September 2016 the licensor of this product decided to terminate the licensing agreement with Mylan with immediate effect, therefore Mylan does not market Progesterone anymore.

d. The acquisition of the Divestment Business 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.

6. This section provides a short description of Teva and an assessment of its suitability in view of these criteria.

(a) Description of the purchaser

7. Teva is a global healthcare company headquartered in Israel. It develops, manufactures, markets and distributes generic medicines and a portfolio of specialty medicines worldwide. Teva is ranked among top 10 pharmaceutical companies in the world with a portfolio of more than 1000 molecules, approximately 58000 employees and 66 manufacturing facilities in 60 countries. The company operates through two business unit. The Generic Medicines unit offers generic products and develops, manufactures and sells active pharmaceutical ingredients, while the Specialty Medicines unit provides branded specialty medicines for use in the central nervous system and respiratory indications, as well as for the women's health, oncology, and other specialty businesses.

(b) Independence from the Parties

8. Teva is listed on the New York Stock Exchange, Teva's main shareholders are institutions that own approximately 61% of all common shares outstanding. Mylan is listed on the NASDAQ and the Tel Aviv stock exchange. Mylan's main shareholders are institutions that own approximately 66% of all common shares outstanding.

9. There are no institutional investors that hold a material stake (i.e. an ownership stake of more than 5%) in both Teva and Mylan for which reason none of the shareholders is able to exercise material influence on both Teva's and Mylan's strategic decisions. Furthermore, all mutual investors are large mutual funds that have broad portfolios with many investments.

10. Teva has a direct ownership stake of 4.2% of Mylan's outstanding shares, but this stake is too small to exercise material influence on Mylan.

11. There are no joint ventures or alliances between Teva and Mylan, it is thus considered that also in this respect Teva is independent from Mylan.

12. It is noted that there exist business relationships between Mylan and Teva, based on which both companies sell/purchase finished goods as well as active pharmaceutical ingredients one from another. Such business relationships are very common among pharmaceutical companies and the value of the transaction concerns are not material to any of the Parties and therefore do not impede their independence.

13. The two companies have no common directors or members of the Management or Supervisory Boards of the respective companies.

14. In view of the above, the Commission considers that Teva is independent of and unconnected to Mylan.

(c) Financial resources, proven expertise, incentive and ability to maintain and develop the Divested Businesses as a viable and active competitor

15. In 2015, Teva generated revenue of USD 19.7 billion. Teva's assets grew by approximately 14% annually between 2013 and 2015 and its EBIT margin grew from 8.1% in 2013 to 167.1% in 2016. Clearly Teva has sufficient financial resources to maintain and develop the Products as a viable and active competitor, which was also confirmed by the Trustee.

16. According to the Commitments, the purchaser must have the proven expertise to maintain and develop the Divestment Business as a viable and active competitive force in competition with other suppliers. It shall also have an existing marketing and distribution footprint that includes generic pharmaceuticals in the relevant countries in which the Divestment Business is currently active.

17. Teva already has substantial operations in all countries in which the Products are sold. Furthermore, Teva confirmed that it is able to integrate the Divestment Products in these existing operations and does not need to hire additional employees. Teva presented a business strategy for each of the Products, which is summarized below:

a. Propafenone

18. Propafenone belongs to the cardio vascular therapeutic area and thus it falls in Teva's strategic categories. In all the countries where Teva acquires Propafenone i.e. Belgium, Ireland, Italy, Luxembourg, and Spain, Teva employs significant number of people which will be marketing and distributing the product.[2]

19. In Belgium Teva has a market share of just over [5-10]% (based on volume) in the cardio vascular therapeutic area. After the acquisition Teva aims to promote Propafenone through both its specialist sales force (that is promoting cardiologic molecules to cardiologists and general practitioners) and its pharmacy sales force. On the pharmacy side Teva's sale force will promote the product [Information concerning Teva's business plan for the Product].

20. In Ireland Teva is the main company in Ireland for cardiologic medicines dispensing and markets 26 products in this therapeutic area. The inclusion of antiarrhythmic molecules (also Flecainide) in its portfolio is seen by Teva as strengthening its commercial position since this broadens its cardio vascular portfolio. Teva will communicate the availability of the product to all commercial stakeholders and [Information concerning Teva's business plan for the Product][3]. Furthermore, the product will be offered by the team of retail sales representatives and will be promoted.

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2 In Luxembourg Teva [Information concerning Teva's presence in Luxembourg].

3 Teva is [Information concerning Teva's sales strategy in Ireland].

21. In Italy Teva markets 50 molecules in the same therapeutic area as Propafenone and the product of the Divestment Business will be promoted as part of that portfolio to cardiologists and general practitioners through Teva's […] sales force and pharmacies through its […] sales force. In Italy, Teva introduced in [Information concerning Teva's sales policy in Italy] Teva's presence around the customers by focusing on physicians, pharmacies and wholesalers and patients. Propafenone will be included in Teva's broad cardio product portfolio and will follow the same approach, which proved to be effective.

22. In Luxembourg currently Teva markets 20 products in the same therapeutic area as Propafenone, which will be added to this portfolio. Teva's strategy for this product is in line with the one it applies for the Belgian market [Information concerning Teva's presence in Luxembourg].

23. In Spain currently Teva markets 298 products in the same therapeutic area as Propafenone, which will be added to this portfolio. Teva intends to keep the current commercial and communication strategy to doctors in place. Teva's presence in the pharmacy and hospital channel will ensure that the availability of the product of the Divestment Business to patients will not be disrupted.

b. Flecainide

24. Flecainide also belongs to the cardio vascular area, one of the strategic categories of Teva.

25. In Belgium Teva already owns Flecainide molecule but in a different dosage form (i.e. in the "extended release form" whereas the Product purchased is in the "immediate release form"). Teva indicates that these two dosage forms are used in different circumstances and that, having these two alternatives will enhance both products.

26. In Ireland, as explained above Teva has a strong position in the cardio vascular area, Flecaininde will be added to its already broad portfolio and [Information concerning Teva's business plan for the Product].

27. In Portugal Currently Teva markets 39 products in the same therapeutic area as Flecainide, making the company the largest cardiological medicines provider. Flecainide will be added to this portfolio. Teva intends to use its strong position in the generics market in general and its strong position as a cardiological medicines provider in particular to increase the product sales. Since Portugal [Information concerning Teva's business plan for the Product].

28. In the United Kingdom Teva markets 57 products in the same therapeutic area as Flecainide, which will be added to this portfolio. Since Teva is the market leader in this very competitive market it has developed an integrated commercial approach. Firstly, Teva will include Flecainide in its UK portfolio which will thereafter contain the two largest molecules within the cardio vascular therapeutic area. Secondly, after introduction, Teva's sales force will start a campaign to create

awareness to customers about its ownership of Flecainide. Also in the UK [Information concerning Teva's business plan for the Product].[4]

29. In Estonia Teva markets currently 45 products in the same therapeutic area as Flecainide. The product will be added to this portfolio. The product is part of one of Teva's focus therapeutic areas and will be pushed through the retail channel by focusing on physicians. Furthermore, all commercial stakeholders will be informed about the addition of the Divestment Product to the overall portfolio.

c. Povidone Iodine, France

30. Povidone Iodine belongs to a broad category of products comprising all dermatological antiseptic preparations for humans, including soaps and shampoos with antiseptic/disinfectant properties. Currently Teva markets 11 products in this therapeutic area; Povidone Iodine and will be added to this portfolio. Teva plans to integrate Povidone Iodine into its generics and OTC portfolio and will use its regular distribution channels to ensure product continuity towards pharmacists who currently purchase the product. Finally, Teva intends to [Information concerning Teva's business plan for the Product].

d. Dilitazem, Portugal

31. Dilitazem is a calcium channel blocker. It is primarily used for the treatment of high blood pressure and angina thus it belongs to the cardio vascular area, one of the strategic categories of Teva. Currently Teva markets 28 products in the same therapeutic area as Diltiazem. The product will be added to this portfolio. The product of the Divestment Business has been declining over the last few years in terms of sales. Teva aims to leverage its strong position in the Portuguese generics market in general and its position as a cardiological medicines provider in particular. Moreover, the product will be included in the promotion basket of Teva's sales force. Teva's target is to [Information concerning to Teva's business plan for the Divestment Product].

e. Amoxicillin, Norway

32. Amoxicilin is a product in the category of broad spectrum penicillins which are systemic anti-bacterials of penicillin derivatives. The product is not included in one of Teva's top 7 focus areas; however Norway is [Information concerning Teva's business plan in Norway]. Acquiring Amoxicillin Norway will give Teva the opportunity to strengthen its position in that country. Currently Teva markets 21 products in the same therapeutic areas as Amoxicillin. Amoxicillin will be added to this portfolio. Teva intends to leverage the relationship it has with the ([Information concerning Teva's relationships with the wholesalers in Norway]) wholesalers and the pharmacy chains by offering competitive prices and reliable services. Although the product has been in decline for a number of years and this trend is expected to continue, Teva considers Amoxicillin to be an essential addition to its portfolio to broaden its offer to its customers.

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4 As explained above [Information concerning Teva's sales strategy in the UK].

f. Megestrol, Spain

33. Megestrol is in the category of cytostatic hormones, which are hormones that are often used to treat cancer, it is branded as Megefren. It falls in Teva's two strategic categories, namely women's health and oncology. Megefren is one of the three brands in the Spanish market and prescriptions are done on an INN level (international nonproprietary name, i.e. generic name). Therefore, the pharmacy determines the brand choice. Teva intends to leverage its strong relationship with the pharmacies and its overall generics portfolio ([Information concerning Teva's business plan for the Product]) in order to increase the sales of Megefren. Moreover, Teva has a very broad network of strong relationships with gynaecologists ([Information concerning Teva's relationship with the gynaecologists in Spain]) which can be used to promote the product.

g. Nabumetone, United Kingdom

34. Nabumetone is a product in the category of non-steroidal anti-rheumatics, which covers non-hormonal anti-inflammatory products for systemic treatment of musculoskeletal inflammation. It falls in Teva's strategic category: pain area. Nabumetone will be added to Teva's portfolio in the relevant area (currently comprising 21 products) thereby increasing the relevant Teva's generics offering. The introduction of the product will be followed by a campaign to create awareness to customers. Teva believes that its position in the UK market ([Information concerning Teva's sales strategy in the UK]) will help driving the market share of Nabumetone.

35. In general, for all the Products Teva has broad portfolios of products in corresponding therapeutic areas in the relevant countries, therefore adding the Products and subsequently promoting them can be done without significant additional promotional cost.

36. For each of the Products Teva presented projections of sales until 2020 which were reviewed by the Trustee and were considered realistic, while showing Teva's intention to develop the businesses. In most cases the forecasts envisage increase in sales while for the declining products Teva's intention is to reduce the negative trends, stabilize sales level and ideally to outperform the overall decrease of the relevant product market.

37. Teva performs between 60 and 90 technology transfers annually, it has a dedicated and experienced team to manage such transfers and already has an established procedure which it can apply to the technology transfers related to the Products. It is therefore clear that it has adequate manufacturing and technology capabilities to take over the Products. Teva has also indicated that it has sufficient spare capacity to transfer the production of the Products to its production facilities.

38. In general, the acquisition of the Products is in line with Teva's strategy to grow faster than the overall generic market by focusing on limited of therapeutic areas worldwide. The Products will complement Teva's existing portfolio in these areas.

39. In view of the above, the Commission considers that Teva has proven expertise, incentive and ability to maintain and develop the Products as viable and active competitor on the relevant markets.

(d) Absence of prima facie competition problems

40. Teva is not active in most of the product markets in the countries concerned by the transaction. The only exceptions are Teva's presence in the Flecainide market in Belgium with a market share below [0-5]%; and Teva's presence in the Propafenone market in Italy with the market share of less than [0-5]%.

41. The Commission notes that as explained in the Decision on the Belgium market for Flecainide, apart from Mylan and Teva there will be other competitors present, in particular Stada with a market share of [0-5]% and Novartis with a market share of [0-5]%.[5] As regards the market for Propafenone in Italy, apart from Mylan and Teva, other suppliers are present in the market, including Novartis with [5-10]% market share, as well as Bruno Faramceutici with a market share below [5-10]%.[6]

42. Furthermore, the Commission notes that there exist vertical links between Teva and the Products, since Teva produces the active pharmaceutical ingredients (APIs) for amoxicillin, diltiazem, megestrol and nabumetone. **I**n none of the upstream markets concerned Teva's market share reaches 30%.

43. The transaction leads to one theoretically affected market in Norway, since the purchased Product, amoxicillin, has a market share of approximately [40-50]% (downstream market), while Teva is currently active on the upstream market producing the API: amoxicillin. The link, however does not lead to competition concerns, since Teva's market share on the upstream market is negligible (significantly below [0-5]%), Therefore, Teva will have no ability or incentive to engage in any foreclosure strategy, in particular in view of the fact that the quantities of the relevant API sold in Norway are very small compared to the corresponding total worldwide APIs volumes.

44. Thus, the Commission considers that the purchase of the Products will not give Teva either the ability or the incentive to engage in any vertical foreclosure strategy.

45. Regarding potential conglomerate effects, it is noted that the acquisition by Teva of the Products will not confer on Teva a significant degree of market power in any of the relevant markets. Moreover, the products offered by Teva and the Products acquired are usually dedicated to different groups of patients therefore any tying or bundling practices could not be pursued. Alternatively, even if products are dedicated to the same patient group, patients do not purchase two products together, since they use either one or the other, depending on their prescription or needs. More generally, in all the relevant countries patients and prescribers will have various strong alternatives to Teva's products. Thus the Commission considers that the Transaction will not lead to any conglomerate effects.

46. Based on the above elements the Commission considers that the approval of Teva as the purchaser of the Products would not create prima facie competition concerns.

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5 The Decision, recital 54.

6 The Decision, recital 82.

III. CONCLUSION

47. On the basis of the above assessment, the Commission approves Teva as a suitable purchaser for the above-mentioned reasons.

48. On the basis of the Proposed Agreement, the Commission further concludes that the Products are being sold in a manner consistent with the Commitments.

49. This decision only constitutes approval of the proposed purchaser identified herein and of the Proposed Agreement. This decision does not constitute a confirmation that Mylan has complied with its Commitments.

50. This decision is based on Section D of the Commitments attached to the Commission Decision of 20 July 2016.

For the Commission

(Signed)

Johannes LAITENBERGER
Director-General