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***Case No COMP/M.6705 - PROCTER & GAMBLE/ TEVA  
PHARMACEUTICALS OTC II***

Only the English text is available and authentic.

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

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Article 6(1)(b) NON-OPPOSITION  
Date: 09/11/2012

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## EUROPEAN COMMISSION

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

Brussels, 9.11.2012

C(2012) 8211

PUBLIC VERSION

MERGER PROCEDURE

### **To the notifying party:**

**Subject: Case No COMP/M.6705 - PROCTER & GAMBLE/ TEVA  
PHARMACEUTICALS OTC II  
Commission decision pursuant to Article 6(1)(b) of Council Regulation  
No 139/2004<sup>1</sup>**

Dear Sir/Madam,

1. On 9 September 2012, the European Commission received the notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 by which Procter & Gamble (the United States of America) (hereinafter: "P&G") acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of over-the-counter ("OTC") businesses of Teva Pharmaceuticals Industries Ltd. (Israel) (hereafter: "Teva") by way of contributing assets to a newly created entity.

### **I. THE PARTIES**

2. P&G is the parent company of an international group active in a wide range of consumer products, including consumer health.
3. Teva is an international pharmaceutical company headquartered in Israel with a wide portfolio of generics and a limited number of originator pharmaceuticals. It is, according to internal documents, the world's largest manufacturer of pharmaceuticals.

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<sup>1</sup> OJ L24, 29.1.2004, p. 1 ("the Merger Regulation"). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ("TFEU") has introduced certain changes, such as the replacement of "Community" by "Union" and "common market" by "internal market". The terminology of the TFEU will be used throughout this decision.

4. Teva's OTC business consists of the following OTC pharmaceutical businesses: (i) Initial Teva's OTC business acquired by P&G from Teva in 2011<sup>2</sup> and (ii) Teva/Cephalon's OTC business being acquired by P&G by the current transaction.

## **II. THE OPERATION AND THE CONCENTRATION**

5. The present transaction constitutes a second step in the acquisition by P&G of Teva's OTC businesses. The first transaction has been cleared by the Commission on 30 September 2011<sup>3</sup>. It was implemented by way of purchase of shares in a newly created company between P&G and Teva, to which Initial Teva's OTC business was contributed and which is under the sole control of P&G. By the now proposed transaction, P&G will acquire Teva/Cephalon's OTC business<sup>4</sup>, which Teva acquired from Cephalon in the meantime<sup>5</sup>.
6. The proposed acquisition by P&G of Teva/Cephalon's OTC business is taking place between the same parties and within less than two years following the first transaction. It therefore falls under the Commission's jurisdiction under Article 5(2) of the Merger Regulation.

## **III. EU DIMENSION**

7. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million<sup>6</sup> (P&G: EUR 60 523 million; Teva's OTC's business: EUR 525 million<sup>7</sup>). Each of them has an EU-wide turnover in excess of EUR 250 million (P&G: EUR [...] million; Teva's OTC's business: EUR [...] million), but they do not achieve more than two-thirds of their EU-wide turnover within one and the same Member State. The notified operation therefore has an EU dimension.

## **IV. COMPETITIVE ASSESSMENT**

### **IV.1. Relevant Markets**

8. When identifying affected markets in the present case, the notifying party followed the approach adopted in previous Commission decisions<sup>8</sup>. In particular, the notifying party applied the ATC (Anatomical Therapeutic Chemical) classification devised for marketing purposes by EphMRA (European Pharmaceutical Marketing Association) and took the ATC3 level as appropriate starting point, and in line with recent pharmaceutical decisions<sup>9</sup>

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<sup>2</sup> See Case COMP/M.6280 *P&G/Teva OTC Business*, decision of 30.9.2011.

<sup>3</sup> See for example Case COMP/M.6280 *P&G/Teva OTC Business*, decision of 30.9.2011.

<sup>4</sup> In addition to the Cephalon products, P&G will acquire from Teva a product the status of which changed from Rx to OTC ([...]), which belongs to the ATC3 class A2B (antiulcerants), and several pipeline products of Teva's initial OTC business (including [...] and [...], both belonging to ATC3 class R1A (topical nasal preparations)).

<sup>5</sup> The acquisition of Cephalon by Teva was cleared by the Commission in Case COMP/M.6258 *Teva/Cephalon*, decision of 13.10.2011.

<sup>6</sup> Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C95, 16.04.2008, p. 1).

<sup>7</sup> This figure comprehends the following: a) Cephalon's products covered by the current transaction: EUR [...] million; b) Teva's initial OTC business: EUR [...] million.

<sup>8</sup> See for example Case COMP/M.5865 *Teva/Ratiopharm*, decision of 3.8.2010, and cases cited therein.

<sup>9</sup> See for example Case COMP/M.5865 *Teva/Ratiopharm*, decision of 3.8.2010.

systematically considered any other plausible narrower market definition (ATC 4 level, "molecule", "API" (active pharmaceutical ingredient) or galenic form)<sup>10</sup>.

9. Given that neither P&G's nor Teva's OTC businesses include prescription pharmaceuticals in the relevant ATC3 categories, the present case concerns exclusively OTC products, and in particular the following categories: antiulcerants (A2B), hepatic protectors (A5B), non-steroidal antirheumatics (M1A), topical antirheumatics and analgesics (M2A), other musculoskeletal (M5X), topical nasal preparations (R1A), throat preparations (R2A), expectorants (R5C) and other cough & cold preparations (R5F).
10. In any event, the exact product market definitions can be left open as the proposed transaction does not raise doubts as to its compatibility with the internal market irrespective of the precise market definition.
11. In the area of finished pharmaceutical products, the Commission has consistently held that the markets for finished pharmaceutical products, including OTC and consumer health care products, are national in scope<sup>11</sup>. This conclusion has generally been reached because of (i) varying regulatory controls for pharmaceutical products; (ii) perceived differences in price setting and purchasing patterns/reimbursement by Member States; (iii) differences in national clinical guidelines, medical views and patient preferences; (iv) differences in brand, pack size and distribution systems; and (v) because competition between pharmaceutical companies generally takes place at the national level<sup>12</sup>. The parties did not challenge this approach and provided market shares on a national basis.

#### **IV.2. Competitive assessment**

12. Given the often large number of affected markets in pharmaceutical cases, and in accordance with case practice<sup>13</sup>, the notifying party was required to group all affected pharmaceuticals markets in three categories. These groupings are:  
Group 1: The parties' joint market share exceeds 35% and the increment exceeds 1%.  
Group 2: The parties' joint market share exceeds 35% but the increment is less than 1%.  
Group 3: The parties' joint market share is between 15% and 35%.
13. In accordance with previous precedents, the Commission focuses only on Group 1 markets and also on instances where one party is planning to enter a market with a new product<sup>14</sup> and the other party (or the parties combined) has a market share of 35% or more on any possible market definition where the pipeline and existing products overlap<sup>15</sup>. This filter is based on the assumption that potential competition would in

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<sup>10</sup> See for example Case COMP/M.5865 *Teva/Ratiopharm*, decision of 3.8.2010.

<sup>11</sup> See for example Case COMP/M.5295 *Teva/Barr*, decision of 19.12.2008; Case COMP/M.5479 *Teva/Lonza*, decision of 14.5.2009; Case COMP/M.5530 *Glaxo Smith Kline/Stiefel Laboratories*, decision of 17.7.2009 and Case COMP/M.6162 *Pfizer/Ferrosan Consumer Healthcare Business*, decision of 9.6.2011.

<sup>12</sup> See Case COMP/M.6280 *P&G/Teva OTC Business*, decision of 30.9.2011.

<sup>13</sup> See for example Case COMP/M.5865 *Teva/Ratiopharm*, decision of 3.8.2010; Case COMP/M.5778 *Novartis/Alcon*, decision of 9.8.2010 and Case COMP/M.5661 *Abbott/Solvay Pharmaceuticals*, decision of 11.2.2010.

<sup>14</sup> A new product is defined based on any aspects considered relevant for market investigation, i.e. a new molecule or a new NFC-1 form of a molecule or a changed Rx/OTC status of a molecule.

<sup>15</sup> See Case COMP/M.5865 *Teva/Ratiopharm*, decision of 3.8.2010 and Case COMP/M.6258 *Teva/Cephalon*, decision of 13.10.2011.

particular raise issues if the party already present on the market had market power, i.e. if it might already not have been subject to a significant competitive pressure from existing competitors. Further, according to the Commission's criteria, the contemplated launch date of said product should be within 2 years.

14. The present transaction entails only five horizontally affected markets. All five markets are Group 3 markets. Although these overlaps between Teva and Cephalon have already been cleared in 2011<sup>16</sup>, the parties provided updated market data showing that no significant changes in the markets have occurred. These five markets are briefly described below.
15. As regards potential competition, the parties have also confirmed that there are no pipeline products to be launched in any market where the other party or both parties together would have a market share of over 35% and for which the contemplated launch date is within 2 years. The Commission, therefore, will not further assess such instances.

#### *IV.2.2. M2A – Topical antirheumatics and analgesics (Latvia)*

16. The ATC3 category M2A consists of ointments, creams and sprays for the treatment of injuries, sprains, muscular tension, etc. In previous decisions<sup>17</sup>, the Commission considered that assessing all ATC3 products classified under M2A together was appropriate for market definition.
17. The affected markets would arise only under ATC3 class M2A comprising OTC products in Latvia. There the parties' combined market share would not exceed 30% and P&G would be facing several strong generic competitors such as Novartis ([20-30]%), Grindex ([5-10]%), Valeant Pharma ([5-10]%), Silvanols ([0-5]%) and others. The competitive conditions in these markets have not materially changed since the clearance of the acquisition of Cephalon by Teva in 2011.
18. In view of this, the Commission considers that the transaction does not raise serious doubts in the market for topical antirheumatics and analgesics in Latvia.

#### *IV.2.3. R5C – Expectorants (Latvia, Lithuania, Estonia)*

19. The ATC3 class R5C includes cough preparations (in all galenic forms) with an expectorant as the main ingredient (e.g. guaiacol, sponin, ammonium chloride). These may also include antihistamines and bronchodilators. There is no ATC4 level. In *Teva/Ratiopharm*<sup>18</sup> the Commission further segmented the market according to the product's specific molecule and galenic form (with reference to the first letter of the typology of form codes (the so-called "New Form Code or NFC) used by IMS/EphMRA)<sup>19</sup>. The products in ATC3 class R5C are mostly classified either as NFC1 A (oral solid ordinary) or NFC1 D (oral liquid ordinary).
20. The affected market would arise only at ATC3 level. At an overall ATC3 level the operation leads to one affected market in Latvia, where the parties achieve a combined market share of [10-20]%. At the ATC3 level and galenic form D the proposed transaction results in three Group 3 markets, namely in Estonia, Lithuania and Latvia. However, the

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<sup>16</sup> See Case COMP/M.6258 *Teva/Cephalon*, decision of 13.10.2011.

<sup>17</sup> See for example Case COMP/M.3751 *Novartis/Hexal*, decision of 27.5.2005.

<sup>18</sup> See Case COMP/M.5865 *Teva/Ratiopharm*, decision of 3.8.2010.

<sup>19</sup> See Case COMP/M.5865 *Teva/Ratiopharm*, decision of 3.8.2010, para. 16.

parties' combined market shares in these markets would only amount to [10-20]% in Estonia, [20-30]% in Latvia and [10-20]% in Lithuania. In Latvia, where the aggregated market share is highest, the parties' would face other strong players such as Novartis ([20-30]%) and Bionorica ([10-20]%) and several smaller competitors. The competitive conditions in these markets have not materially changed since their clearance in the acquisition of Cephalon by Teva in 2011.

21. In view of this, the Commission considers that the transaction does not raise serious doubts in a market for expectorants in Estonia, Latvia or Lithuania under any market definition.

## **V. CONCLUSION**

22. For the above reasons, the European Commission has decided not to oppose the notified operation and to declare it compatible with the internal market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of the Merger Regulation.

*For the Commission*  
*(signed)*  
*Joaquín ALMUNIA*  
*Vice-President*