

***Case No COMP/M.7276 - GLAXOSMITHKLINE/
NOVARTIS VACCINES BUSINESS (EXCL.
INFLUENZA)/ NOVARTIS CONSUMER HEALTH
BUSINESS***

Only the English text is available and authentic.

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

Article 6(1)(b) in conjunction with Art 6(2)

Date: 28/01/2015



EUROPEAN COMMISSION

Brussels, 28.1.2015
C(2015) 539 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 Where possible the information omitted has been replaced by ranges of figures or a general description.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

MERGER PROCEDURE

To the Notifying Party:

Dear Madam(s) and/or Sir(s),

Subject: Case M.7276 – GLAXOSMITHKLINE/ NOVARTIS VACCINES BUSINESS (EXCL. INFLUENZA)/ NOVARTIS CONSUMER HEALTH BUSINESS Commission decision pursuant to Article 6(1)(b) in conjunction with Article 6(2) of Council Regulation No 139/2004¹

- (1) On 28 November 2014, the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which GlaxoSmithKline plc ("GSK") acquires the global human vaccines business (the "Novartis Vaccines business") of Novartis AG ("Novartis"), with the exception of Novartis' human flu vaccine business (the "Influenza business"), by way of purchase of assets. GSK and Novartis are also creating a new venture, under the sole control of GSK, combining their non-prescription (over the counter – "OTC" – or "consumer health") activities. GSK is hereinafter referred to as the "Notifying Party". GSK and Novartis are referred to as the "Parties". Novartis' contributed OTC activities are referred to as the "Novartis Consumer Health business", and the new venture is referred to as "the OTC JV". The Vaccines and OTC operations are together referred to as the "Transaction".²

¹ OJ L 24, 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.

² Publication in the Official Journal of the European Union No C 248, 30.07.2014, p. 7.

I. THE PARTIES

- (2) **GSK** is a global pharmaceutical company headquartered in the UK. It is active in research, development, manufacturing and marketing in four general product areas: prescription pharmaceuticals and vaccines, consumer healthcare products, dermatological products (through its subsidiary Stiefel), and HIV/Aids pharmaceuticals (through the ViiV joint venture with Pfizer).
- (3) **Novartis** is a global pharmaceutical company headquartered in Switzerland. It is active in research, development, manufacturing and marketing of pharmaceuticals, generic pharmaceuticals (via its subsidiary Sandoz), vaccines and consumer health products.
- (4) The **Novartis Vaccines business** comprises vaccines that treat adult tickborne and Japanese encephalitis, rabies and meningococcal diseases. Novartis has also sales in monovalent and combination tetanus and diphtheria vaccines. In addition, Novartis currently has three pipeline products in the early stage of development, targeting five meningococcal serogroups (MenABCWY) for adolescents, group B streptococcus for adults and adolescents, and *Pseudomonas Aeruginosa*.
- (5) The **Novartis Consumer Health business** includes branded products in several segments such as cold and flu, pain management, cold sore management and smoking cessation. In cold sore management, Novartis supplies antiviral creams containing the active substance *penciclovir* under the brands *Fenivir*, *Pencivir*, *Vectavir*, *Vectatone* and *Fenistil*. As regards smoking cessation, Novartis markets under the *Nicorette* brand a range of NRT products in the form of patches, gums, and lozenges in the majority of the EEA countries. Novartis also offers a range of different cold and flu treatments, with a particular focus on topical nasal preparations (*Otrivin*). Its product selection also includes multi-symptom cold and flu treatments (*Theraflu*), throat preparations (*Orofar*), cough treatments (*Sinecod*), and chest rubs (*Pulmex*). In pain management, Novartis supplies *Voltaren* across the EEA.

II. THE OPERATION AND CONCENTRATION

The Transaction

- (6) On 22 April 2014, the Parties signed an agreement, further amended by several agreements on 29 May 2014, foreseeing a three steps transaction:
 - (a) GSK is acquiring Novartis' global human Vaccines business, excluding the Influenza business.³
 - (b) GSK and Novartis are combining in a new venture their global activities in Consumer Health (i.e. their non-prescription business, also called over the counter or OTC),⁴ over which GSK will be the one exercising decisive influence; Novartis rights are limited to minority protection rights.

³ On 26 October 2014, Novartis announced divestiture of its influenza vaccines business to CSL. According to the Parties, the transaction is subject to regulatory approvals and is expected to close in the second half of 2015.

⁴ Prescription medicines will overall remain outside the scope of the OTC JV, as well as some OTC activities of GSK and Novartis. GSK will not transfer to the OTC JV its Indian business, Nigerian

- (c) Novartis will acquire part of the GSK oncology business portfolio. This transaction is assessed separately by the Commission in Case M.7275 – Novartis / GlaxoSmithKline Oncology Business.
- (7) The Vaccines and the OTC operations are notified together as GSK acquires control both of the Vaccines and of the Consumer Healthcare businesses and qualify for review as a single concentration under the Merger Regulation.
- (8) According to the Notifying Party, the Transaction is intended to accelerate GSK's strategy to generate sustainable sales growth and improve GSK's long term earnings as it will strengthen two of its core business: Vaccines and OTC products. According to the Notifying Party, the Transaction will enable GSK and the OTC JV to compete more effectively on the concerned markets.

Sole control of the OTC JV

- (9) GSK will acquire 63.5% of the OTC JV and Novartis will own a minority shareholding of 36.5%. GSK will be responsible for the day-to-day running and the overall direction, supervision, and management of the OTC JV. In addition, GSK will [...]. GSK will appoint 7 out of 11 members of the OTC JV's Board of Directors. Novartis will appoint the remaining 4. [...].⁵
- (10) As the Transaction does not create a joint venture in which the parties share equally the voting rights, joint control could only arise in this case out of (i) veto rights with respect to decisions that are essential for the strategic commercial behaviour of a joint venture; or (ii) commonality of shareholders' interests.
- (11) Veto rights that can be relevant for establishing control are those concerning budgets, appointment of management, business plans and investments, as well as other certain other rights such as the right to determine the OTC JV's pricing policy.
- (12) Novartis' approval is required in matters such as [...]. As such these matters are not decisive for the competitive strategy OTC JV. Moreover, Novartis [...]. These powers conferred on Novartis are intended to protect the value of its minority interest in the OTC JV and will not grant control.
- (13) Further, there is not a sufficiently high degree of mutual dependency among GSK and Novartis or any other factors that would lead to commonality of interests between GSK and Novartis in determining OTC JV's strategy, beyond the common interest inherent to any long-term commercial agreement.

Conclusion on the concentration

- (14) The Commission therefore concludes that the Transaction constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

businesses or pharmaceutical business. Novartis will not transfer to the OTC JV its animal health business, U.S. Nicotine Replacement Therapy business, pharmaceutical business, Alcon business or Sandoz generics business. A limited number of prescription products consolidated in Novartis' OTC business will be transferred. In this respect, the Parties submit that they have identified one overlap in relation to topical corticosteroid combinations in the UK, leading to no affected market.

⁵ [...].

III. EU DIMENSION

- (15) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million (GSK: EUR 30 578 million; Novartis' Consumer Health Business: EUR [2 000-3 000] million; Novartis' Vaccines Business excluding the Influenza business: EUR [500-1 000] million).⁶ Each of them has an EU-wide turnover in excess of EUR 250 million (GSK: EUR [5 000-10 000] million; Novartis' Consumer Health Business: EUR [500-1 000] million; Novartis' Vaccines Business excluding the Influenza business: EUR [0-500] million), but they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State.
- (16) The Transaction therefore has an EU dimension within the meaning of Article 1(2) of the Merger Regulation.

IV. VACCINES

- (17) Vaccines are biological medicinal products designed to improve immunity against one or several diseases. They stimulate the immune system by introducing weakened forms of the live organisms, its toxins or its surface proteins in the body. The immune system is then able to recognize the agent and destroy it more easily. Vaccines exist for both viral and bacterial diseases and can be based on activated or inactivated organisms as well as derived products. Following marketing authorisation, vaccines for specific diseases may be mandatory and included in national immunisation schedules.
- (18) The global Vaccines industry was valued at USD 26 billion in 2013.⁷
- (19) GSK has 30 different human vaccines against a large variety of bacterial and viral diseases such as hepatitis (A and B), diphtheria and tetanus, pertussis, measles, mumps, rubella, polio, typhoid, influenza and bacterial meningitis.
- (20) Novartis' portfolio contains 13 vaccines for treatment against a variety of bacterial and viral diseases such as bacterial meningitis, rabies, as well as legacy sales of polio vaccines and sales of antigen for diphtheria and tetanus.
- (21) The areas of horizontal overlap between the Parties' vaccines are:
- (a) Meningococcal vaccines;
 - (b) Diphtheria and tetanus vaccines;
 - (c) Typhoid and hepatitis A vaccines.
- (22) A vertical relationship also arises between the Parties regarding the bulk production of antigens used in vaccines manufacturing.

⁶ Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C95, 16.04.2008, p1).

⁷ GSK Circular to Shareholders, <http://www.gsk.com/media/560424/gsk-novartis-circular.pdf>.

IV.1. Relevant product markets

IV.1.1. Meningococcal vaccines

- (23) Bacterial meningitis is the main disease targeted by meningococcal vaccines and is an infection of the meninges (protective membranes) around the brain and spinal cord. Meningococcus (*Neisseria meningitidis*) is one of the three bacteria causing bacterial meningitis. There are at least 13 meningococcal serogroups, five of which cause the majority of cases of meningococcal disease: A, B, C, W, and Y. Vaccines are currently available against all five of these most common serogroups. While vaccination against one serogroup does not create cross-immunity against any other serogroup, there exist polyvalent vaccines that provide immunisation against more than one serogroup.
- (24) Meningococcal vaccines exist in two different forms: polysaccharide⁸ vaccines ("PS" vaccines) induce a less enduring immune response than conjugate vaccines ("CJ" vaccines), which attach the polysaccharide antigen to a protein carrier (such as diphtheria or tetanus toxoids).
- (25) The following types of meningococcal vaccines ("Men vaccines") are currently marketed in the EEA: MenC CJ, MenAC CJ, MenACWY PS, MenACWY CJ, MenB, and MenC-Hib⁹ CJ. The letters after 'Men' indicate which serogroup(s) the vaccine targets.
- (26) In the EEA, GSK markets MenACWY CJ, MenACWY PS and MenC-Hib vaccines, while Novartis markets MenACWY CJ, MenB and MenC CJ vaccines.

The Notifying Party's arguments

- (27) The Notifying Party submits that MenC, MenACWY, MenB and MenC-Hib vaccines each constitute separate product markets, whereas MenACWY PS and MenACWY CJ vaccines are part of the same market.
- (28) MenB vaccine provides protection for serogroup B while MenC, MenACWY and MenC-Hib cannot provide immunization against serogroup B. Therefore, the Notifying Party submits that MenB is a separate product market.
- (29) MenC-Hib is designed for a specific requirement in the UK and is not sold anywhere else in the EEA but for minor sales in Poland. It is used as a booster for protection against both Hib and MenC.¹⁰ The Notifying Party considers that monovalent MenC and Hib vaccines do not compete with MenC-Hib as boosters because of the desire to limit injections for infants and adolescents, and to some extent also for adults.
- (30) The Notifying Party considers MenACWY and MenC vaccines as two different markets for the following reasons. First, the two vaccines have different age recommendations since MenC is approved for use after 2 months of life and MenACWY after 1 to 2 years. Second, MenC and MenACWY vaccines are priced differently, which results from the fact that only the former is included in most of the EEA coun-

⁸ The polysaccharides are long chains of sugar molecules that compose the cell wall of meningococcal bacteria.

⁹ Hib stands for *Haemophilus influenzae* type B.

¹⁰ Minutes from a call with a customer dated 02 September 2014.