



**BEFORE THE
COMPETITION COMMISSION OF PAKISTAN**

IN THE MATTER OF

**SECOND PHASE REVIEW
ACQUISITION OF THE GLOBAL VACCINES BUSIENSS
(EXCLUDING INFLUENZA VACCINES BUSINESS EXCEPT IN
CHINA) FROM
NOVARTIS A.G BY GLAXOSMITHKLINE PLC**

(F. NO: 675/MERGER/CCP/2014)

Date of hearing: 20-02-2015

Commission:

Ms. Vadiyya Khalil
Chairperson

Dr. Joseph Wilson
Member

Dr. Shahzad Ansar
Member

Mr. Mueen Batlay
Member

Mr. Ikram Ul Haque Qureshi
Member

Present on behalf of:
M/s. GlaxoSmithKline Plc.

Mr. Asim Nasim
Partner
M/s. Orr, Dignam & Co.,
Advocates



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Government of Pakistan

ORDER

1. GlaxoSmithKline Plc., ("GSK"), through its legal advisors, Orr, Dignam & Co., Advocates, submitted a pre-merger application pursuant to section 11 of the Competition Act, 2010 (hereinafter the "Act"), dated 19th September, 2014 seeking clearance from the Competition Commission of Pakistan (the "Commission") for the proposed acquisition by GSK of the global vaccines business (excluding influenza business except in China) from Novartis AG ("Novartis"), pursuant to a Share and Business Sale agreement dated 22nd April, 2014 (restated).

2. The transaction involves the acquisition of the vaccines business (excluding influenza vaccines business) of Novartis, one out of the two competitors of GSK that is engaged in the business of vaccines in Pakistan. GSK is a dominant player in the relevant product market of meningococcal ACWY vaccines (meningitis vaccines) and following the consummation of the envisaged transaction, GSK, would strengthen its dominant position in the relevant product market by acquiring the market share of Novartis, which raised competition concerns for the Commission.

3. Therefore, the Commission initiated the Phase II review of the transaction on 13 November, 2014, with the view to determine whether the merger situation is likely to substantially prevent or lessen competition in the relevant market.

A. UNDERTAKINGS

i. GlaxoSmithKline Plc.

4. GSK is incorporated as a public limited company under the laws of the United Kingdom and is a multinational pharmaceutical company. It is primarily engaged in the research, development, manufacturing and marketing of pharmaceuticals, consumer health, dermatological products and vaccines. GSK is a subsidiary of S.R. One International B.V., Netherlands, whereas its ultimate parent company is GlaxoSmithKline Plc, UK. GSK markets the following vaccines in Pakistan: i) Mencevax; ii) Synflorix; iii) Priorix-Tetra; iv) Havrix; v) Varil-Rix; vi) Typerix; vii) Infanrix Hexa; viii) Rotarix; x) Infanrix; xi) Cervarix; xii) Hiberix, and xiii) Priorix. GSK is present in Pakistan through its indirect subsidiary i.e., GlaxoSmithKline Pakistan Limited.



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ii. Novartis AG

5. Novartis, a Swiss company listed on the Swiss Stock Exchange. It is primarily engaged in the research, development, manufacturing and marketing of five broad areas of healthcare: pharmaceuticals, eye care pharmaceuticals, generics, consumer healthcare products (Over-the-Counter) and vaccines. Novartis markets the following vaccines in Pakistan: i) Menveo (Men ACWY); ii) Quinvaxem (DTPw-HepB-HIB); and iii) Rabipur (Rabies). Novartis is present in Pakistan through its indirect subsidiary i.e., Novartis Pharma (Pakistan) Limited, which is a subsidiary of Novartis Pharma AG.

B. RELEVANT MARKET

6. The only overlapping product between the merger parties is with respect to meningitis vaccines, which both the merger parties market in Pakistan. Only one product from each of the merger parties is substitutable with each other with respect to meningitis vaccines, Menveo of Novartis and Mencevax of GSK.

Relevant product market:

7. Meningococcal ACWY Vaccines: is a vaccine used against Neisseria meningitidis, a bacterium that causes meningitis, meningococemia, septicemia, and rarely carditis, septic arthritis, or pneumonia.

8. Till the year 2013, Novartis and GSK were the only suppliers of meningococcal vaccines, where the relevant market was duopolistic.

9. As of now, there are currently three vaccines available in Pakistan, with the current entry of Sanofi Pasteur in September, 2014, to prevent meningococcal disease, all quadrivalent in nature, targeting Serogroups A, C, W-135 and Y:

| Company | Product | Type of Polysaccharide | Age Indication |
|----------------|----------|--------------------------|-----------------------------|
| GSK | Mencevax | Plain Polysaccharide | Above 2 years upto 55 years |
| Novartis | Menveo | Conjugate Polysaccharide | 2 months to 55 years |
| Sanofi Pasteur | Menactra | Conjugate Polysaccharide | 9 months to 55 years |

10. Polysaccharide vaccines are less immunogenic in infants and toddlers (< 2 years of age) and do not elicit "immune memory", i.e., protection lasts for at most around

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two to three years) and can cause hypo-responsiveness to repeated doses. In comparison, conjugate vaccines are typically well tolerated and induce a more enduring immune response. However, polysaccharide vaccines have been priced much lower than the conjugate vaccines and are more often used, given that they are cost effective especially for travellers requiring shorter term protection.

Relevant geographic market:

11. The relevant geographic market is mainly national in scope with GSK and Novartis distributing their meningococcal vaccines either directly or indirectly through distributors who would market and sell the products through various areas in Pakistan.

C. TRANSACTION

12. GSK intends to acquire the vaccines business (excluding Influenza vaccines business except in China) from Novartis. The consideration to be paid under the Share Purchase Agreement is USD¹ [REDACTED] (PKR [REDACTED]).

D. COMPETITION ASSESSMENT

13. Section 11, sub-section 1 of the Act lays down the substantive test for reviewing a merger, that is, whether a merger "substantially lessens competition by creating or strengthening a dominant position in the relevant market". Section 2(e) of the Act defines a dominant position as:

"dominant position" of one undertaking or several undertakings in a relevant market shall be deemed to exist if such undertaking or undertakings have the ability to behave to an appreciable extent independently of competitors, customers and suppliers and the position of an undertaking shall be presumed to be dominant if its share of the relevant market exceeds forty percent"

14. The number of competitors and their relevant market shares in the provision of meningococcal (ACWY) vaccines based on sales (volume and value) for the year 2013 is given in the table below:



As per the USD currency exchange rate on 28.10.14, 1 USD/PKR 102.99.

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| Ser.No. | Company | Product (mono-dose/ injection) | Volume (units) | Market Share (%) | Sales (PKR '000) | Market Share (%) |
|---------|--------------|--------------------------------|----------------|------------------|------------------|------------------|
| 1 | GSK | Mencevax | | | | |
| 2 | Novartis | Menveo | | | | |
| | Total | | | 100 | | 100 |

15. As can be seen from the above table, there were only two players in the market for meningococcal (ACWY) vaccines in the year 2013: GSK is the largest player in the market for meningococcal (ACWY) vaccines by having a market share of %, which is much above the market power threshold of 40% under Section 2(e) of the Act, making it a dominant player, while Novartis has a minimal market share of % which is much below the market power threshold of 40%. The merger parties' combined market shares is high, i.e., %. The recent entrant in the latter part of the year of 2014, Sanofi Pasteur, began selling and marketing its meningococcal vaccine, Menactra, in Pakistan. However, the market concentration data is over a short span of time i.e., less than six months, and the values would not provide a true picture of concentration levels of the market. However, we have taken into account the fact that there is a new entrant in the relevant market and that the market for meningococcal vaccines is no longer a duopolistic market.

16. Another reason for not taking into account the market concentration in the year 2014 is the fact that GSK supplies a large quantity of its meningococcal vaccine, Mencevax, to the Ministry of Religious Affairs, which did not issue the relevant tender in 2014. This was because the Government of Turkey donated a substantial amount of the meningococcal vaccines to the Government of Pakistan in 2014.

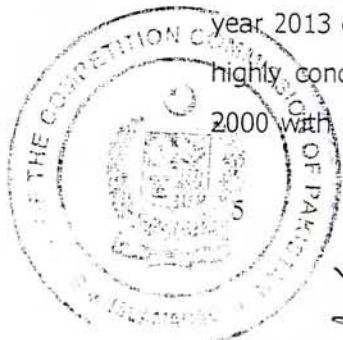
17. The Commission identified the following concerns with the transaction as originally notified, namely:

- i. Based on the market concentration data of 2013, the envisaged transaction will result in only two players in the market for meningococcal vaccines in Pakistan. Until now, GSK is still a dominant player, which will further strengthen its dominant position in the relevant market, based on sales in 2013, and consequently it would have increased market power.
- ii. The Herfindahl Hirshman Index (HHI) calculation based on sales (value) for the year 2013 of was above 2000, which meant that the relevant market is highly concentrated. The post-merger HHI was The HHI was above 2000 with delta of , which meant that the relevant market will be highly

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Government of Pakistan
Islamabad



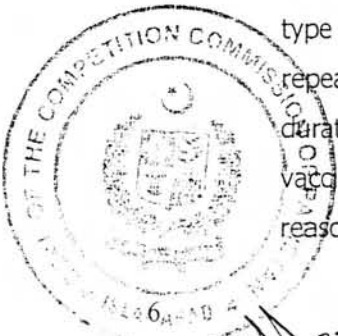
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concentrated. As per the Merger Guidelines, the Commission is likely to find horizontal competition concerns in a market with a post-merger HHI of above 2000 and a delta above 250.

- iii. After consummation of the proposed acquisition, GSK will own and control Mencevax, the polysaccharide vaccine, which is a meningococcal vaccine, also suitable for short-term travelers and also priced low, and Menveo, the conjugate vaccine priced higher and used for long term effects for ages under 55 years. GSK may be able to escalate the price of Mencevax given that Menveo is priced highly, which would harm the end users, that is the hospitals, clinics and pharmacies.

18. While taking the envisaged transaction to Phase II on 13 November, 2014, we further assessed the relevant market by taking into account the factors laid down in Regulation 6 of the Competition (Merger Control) Regulations, 2007 (hereinafter the "CMCR") which the Commission may consider when assessing substantial lessening of competition. As part of the competition assessment of the envisaged transaction, the Commission undertook its own research regarding the relevant market and approached several hospitals to provide the Commission with information on the market for Meningococcal (ACWY) vaccines in Pakistan. In response, Aga Khan Hospital and Medical College Foundation vide letter dated 10 February, 2015, submitted the following:

- i) Menactra (Sanofi Pasteur) and Menveo (Novartis) are conjugate vaccines while Mencevax (GSK) is a polysaccharide vaccine.
- ii) As per CDC, Menactra and Menveo are preferred vaccines for people aged 55 years or younger, while, Mencevax has been approved by the FDA for use in children 2 years and older.
- iii) The duration of immunity mediated by polysaccharide vaccine is 3 years or less in children aged under 5 because it does not generate memory T cells. Boosters are not recommended with this type of vaccine due to its inability to overcome this problem by repeated immunization. Conjugate vaccines result in enhanced duration of protection, increased immunity with booster vaccinations and effective herd immunity. Given the above reasons, polysaccharide vaccines are suitable for travellers



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requiring short-term protection and for older children who do not require repeated doses, and not suitable for national health prevention programs.

- iv) Given the fact that polysaccharide vaccine is suitable for travellers and is cost effective, being priced much lower than its alternatives, it is acquired for pilgrimage travellers.

19. Given the above facts and information, the Commission identified the following competition concerns:

- i. There is only one area of competitive overlap in Pakistan, which involves the supply by GSK and Novartis of Meningococcal (ACWY) vaccines (relevant market). The relevant market will be reduced from two players to one based on the market information obtained till the year 2013; from three players to two based on the market information obtained till the year 2014. Either way, the proposed acquisition raises competition concerns in this market. GSK and Novartis are particularly close competitors in the supply of Meningococcal (ACWY) vaccines with Sanofi Pasteur being the only other company supplying these vaccines in Pakistan;
- ii. Following the proposed acquisition, Novartis' Meningococcal (ACWY) vaccines would cease to compete independently of GSK and thereby remove or lessen competition of GSK with its two significant competitors, i.e. Novartis and Sanofi Pasteur;
- iii. The acquisition would weaken competitive constraints on the remaining suppliers/distributors, which may offer them with an increased incentive or ability to raise prices and/or offer lower levels of service; and
- iv. The Commission realizes that new entry or expansion in relation to Meningococcal (ACWY) vaccine products requires substantial investment in research and development, given that it took many years before a new entrant like Sanofi Pasteur could enter the relevant market in Pakistan.
- v. Given the views of the medical community, and the effectiveness of each vaccination program which differs in terms of age usage and duration of protection, it is important to have all meningococcal (ACWY) vaccinations available in the market.



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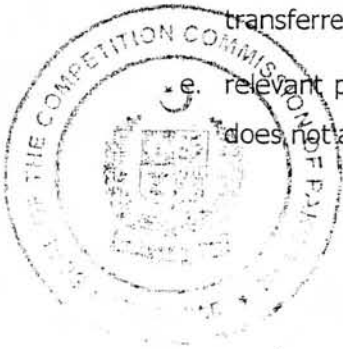
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E. REMEDIES/CONDITIONS

20. The legal counsel of parties, having understood the concerns of the Commission, proposed and committed to implement the following commitments given by the parties on 09 February, 2015, to alleviate competition concerns:

- i) As committed to the European Commission on 21 January, 2015, GSK commits the same to the Commission and undertakes to divest its global MenACWY vaccines business, with a view to removing any possible concerns relating to MenACWY overlaps, including in Pakistan.
- ii) GSK will divest its worldwide MenACWY business to a suitable purchaser, who will be an independent third-party vaccines supplier with the capability to maintain and continue to develop the divestment business as a viable and active competitive force. GSK will enter into an agreement with a third-party purchaser within a period of 6 months from the receipt of the EU clearance decision; failing which an independent divestiture trustee, who will be appointed by the European Commission, will have the mandate to sell the Divestment Business at no minimum price within another 6 months.
- iii) The divestment business will include the following elements:
 - a. GSK's MenACWY vaccines business, including IP rights and secret products know-how, and marketing authorizations;
 - b. A transitional supply of GSK's MenACWY vaccines (or parts thereof) that will be manufactured by GSK according to the Purchaser's requirements for the duration of the proposed technology transfer to the Purchaser;
 - c. GSK's Gembloux site in Belgium, which can be redeveloped into a bulk antigen production, tetanus toxoid production and/or MenACWY conjugation as well as quality control and R&D site if required by the purchaser;
 - d. ongoing tender contracts (to the extent that they can legally be transferred) or the economic benefit from these contracts; and
 - e. relevant personnel will be transferred to the extent that the purchaser does not already have the necessary personnel and expertise.



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21. In addition to the above commitments, we are of the considered opinion that the purchaser with respect to divestment must have an established presence in distribution channels used in the vaccine business in Pakistan.

22. The Commission, hereby, allows the proposed transaction subject to the commitments made in paragraph 20 and the condition laid out in paragraph 21 above.

23. Without prejudice to Section 11(14), or any other provision under Act or the CMCR thereunder, the Commission reserves the right to assess the effects of the transaction on the relevant market after one year from the date of the closing of the transaction under Section 11(13) of the Act.

24. The applicant is directed to file an update report with the Registrar of the Commission every three months until the divestment is complete.


25. Ordered accordingly.


(Ms. Vadiyya Khalil) (Dr. Joseph Wilson) (Mr. Mueen Batlay) (Dr. Shahzad Ansar) (Mr. Ikram Ul Haque Qureshi)
Chairperson Member Member Member Member



Islamabad, 20th of February 2015

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