



सत्यमेव जयते



Fair Competition
For Greater Good

COMPETITION COMMISSION OF INDIA

(Combination Registration No. C-2014/07/188)

12.12.2014

Notice u/s 6 (2) of the Competition Act, 2002 given by:

- **GlaxoSmithKline plc**
- **Novartis AG**

Order under Section 31(1) of the Competition Act, 2002

INTRODUCTION

1. On 03.07.2014, the Competition Commission of India (“**Commission**”) received a notice under sub-section (2) of Section 6 of the Competition Act, 2002 (“**Act**”) given by GlaxoSmithKline plc (“**GSK**”) and Novartis AG (“**Novartis**”) (hereinafter, GSK and Novartis are collectively referred to as the “**Parties**”, and each a “**Party**”). The notice has been filed pursuant to the (a) Implementation Agreement entered into between GSK and Novartis, (b) Share and Business Sale Agreement entered into between GSK and Novartis, (c) Contribution Agreement entered into between GSK, Novartis and Leo Constellation Limited, and (d) Sale and Purchase Agreement entered into between GSK and Novartis (all the agreements were executed on 22.04.2014 and restated on 29.05.2014).
2. In terms of Regulation 14 of the Competition Commission of India (Procedure in regard to the transaction of business relating to combinations) Regulations, 2011 (“**Combination Regulations**”), vide letter dated 09.07.2014, the Parties were required to remove certain defects and provide information/document(s) by 20.07.2014. However, the reply was filed by the Parties on 04.08.2014 after seeking extension of time.
3. In terms of sub-regulation (4) of Regulation 5 and sub-regulation (2) of Regulation 19 of the Combination Regulations, vide letter dated 12.08.2014,



the Parties were asked to furnish additional information/ document(s) by 01.09.2014. After seeking extension of time, the Parties filed the reply on 03.09.2014. In terms of sub-regulation (3) of Regulation 14 of the Combination Regulations, vide letter dated 09.09.2014, the Parties were required to provide certain clarification and submit complete information / documents, with respect to their response submitted on 03.09.2014, by 12.09.2014. However, the Parties filed their reply on 19.09.2014, after seeking extension of time. In continuation of their response submitted on 19.09.2014, the Parties submitted certain information on 23.09.2014. The Parties sought further extension of time till 30.09.2014 to provide certain additional information in furtherance to their submission on 23.09.2014. Further, in terms of sub-regulation (4) of Regulation 5 and sub-regulation (2) of Regulation 19 of the Combination Regulations, vide letter dated 26.09.2014, the Parties were asked to furnish additional information/ document(s) by 13.10.2014. After seeking extension of time, the Parties filed the reply on 20.10.2014. In terms of Regulation 14 of the Combination Regulations, vide letter dated 28.10.2014, the Parties were asked to remove certain defects and provide information/document(s) by 03.11.2014 which was submitted by the Parties on 03.11.2014. Further, in terms of sub-regulation (4) of Regulation 5 and sub-regulation (2) of Regulation 19 of the Combination Regulations, vide letter dated 05.11.2014, the Parties were asked to furnish additional information/ document(s) by 26.11.2014. After seeking extension of time, the Parties filed the reply on 10.12.2014.

PARTIES TO THE COMBINATION

4. GSK is a global healthcare company which is stated to be active in three primary areas, namely, pharmaceuticals, vaccines and consumer healthcare. As per the information provided in the notice, in India, GSK has been active through its various subsidiaries i.e. Biddle Sawyer Limited, GlaxoSmithKline Asia Pvt. Limited, GlaxoSmithKline Consumer Healthcare Limited, GlaxoSmithKline Pharmaceuticals Limited and Stiefel India Private Limited.



5. Novartis, another global company is the ultimate holding company of a multinational group of pharmaceutical companies that are stated to be active in six broad areas of healthcare namely, pharmaceuticals, eye care, generics, animal health, consumer health and vaccines. In India, Novartis is present in all the aforesaid areas of healthcare and operates through four entities namely, Novartis India Limited, Novartis Healthcare Private Limited, Sandoz Private Limited and Chiron-Behring Vaccine Private Limited.

PROPOSED COMBINATION

6. As per the information provided in the notice, the proposed combination relates to the following three inter-conditional and inter-dependent transactions:

6.1 Acquisition of the global human vaccines business of Novartis (excluding its influenza vaccines business) by GSK (“**Vaccines Transaction**”) pursuant to the Share and Business Sale Agreement and the Implementation Agreement;

6.2 Formation of a consumer healthcare joint venture (“**J.V.**”), in which GSK will own an equity interest of 63.5 per cent and Novartis, will own the remaining 36.5 per cent equity interest. As per the information given in the notice, GSK will contribute its global consumer health care business (excluding *inter alia* GSK’s consumer healthcare business in India) and Novartis will contribute its over-the-counter consumer healthcare business (excluding the products that are managed by and reported for financial purposes within Novartis’ Pharmaceutical Division, Alcon Division, and Sandoz Division), to the J.V. (“**Consumer Healthcare Transaction**”), pursuant to the Contribution Agreement and the Implementation Agreement; and



- 6.3 Acquisition of GSK's business relating to a portfolio of oncology products (excluding manufacturing) by Novartis ("**Oncology Transaction**") pursuant to the Sale and Purchase Agreement and the Implementation Agreement.
7. As stated above, the Parties have entered into three separate agreements relating to the Vaccines Transaction, the Consumer Healthcare Transaction and the Oncology Transaction together with an overarching Implementation Agreement. The Parties have submitted that whilst each of the abovementioned individual transaction is contractually inter-conditional on the other in as much as the proposed combination will be terminated if any of the other transactions are terminated, each transaction is distinct and complete in itself.
8. In this regard, it is also noted that on 22.05.2014, the Commission had received three separate notices under sub-section (2) of Section 6 of the Act, from Novartis and GSK. The Commission in its meeting held on 05.06.2014, decided that since the Parties envisage and admit the three steps/transactions as part of one wider transaction, the Parties be required to file one notice covering all the three transactions as provided under sub-regulation (4) of Regulation 9 of the Combination Regulations. It was also noted by the Commission in the said meeting that in terms of sub-regulation (5) of Regulation 9 of the Combination Regulations, the requirement of filing notice needs to be determined with respect to the substance of the transaction. Therefore, the Commission considered these three transactions as related transactions comprising one composite combination in view of the provisions of the Act and the Combination Regulations. Accordingly, the Parties were directed, vide letter dated 06.06.2014, to file a single notice for the proposed combination covering all the three above mentioned transactions. In view of the foregoing, a fresh notice dated 03.07.2014 under sub-section (2) of Section 6 of the Act was filed by GSK and Novartis pursuant to the said direction of the Commission.



9. The Commission considered the proposed combination in its meetings held on 25.09.2014, 27.10.2014, 05.11.2014 and 12.12.2014.

COMPETITION ASSESSMENT

A. Vaccines Transaction

10. As per the information provided in the notice, GSK offers vaccines for the immunisation against a number of infections, in India, including human papillomavirus, measles, mumps and rubella, human rotavirus (gastroenteritis), varicella (herpes), hepatitis, meningitis, DTP (diphtheria, tetanus and pertussis (whooping cough)), influenza and polio. It has been further stated that in 2013, Novartis was not active in the sale of vaccines for any of these infections and sold vaccines in India only for immunization against rabies. However, in March 2014, Novartis launched Quinvaxem (a pentavalent DTP vaccine) in India that is used to protect the infants against five infections i.e. diphtheria, tetanus, pertussis (whooping cough), hepatitis B and haemophilus influenza type B.
11. It is therefore, observed that both GSK and Novartis sell vaccines for DTP in India. However, Novartis sells a DTPw pentavalent vaccine (i.e. Quinvaxem) in India, which protects against the five infections, as mentioned above, whereas GSK sells a trivalent DTPa vaccine (i.e. Infanrix) and a booster vaccine (i.e. Boostrix) in India, which provides protection against the three infections i.e. diphtheria, tetanus and pertussis. In this regard, the Parties have submitted that the monovalent and multivalent vaccines belong to different product markets and therefore, the trivalent and pentavalent vaccines are not substitutable.
12. Further, it is observed that if the DTP vaccines of the Parties are considered to be in different relevant product markets, there is no overlap between the



products of the Parties in Vaccine Transaction. Even if the DTP vaccines of the Parties are considered to be substitutes, it is noted that in 2013, the market share of GSK was only [5-10] per cent in the market for the DTP vaccines, whereas Novartis launched its DTP vaccine in March 2014 only and presently has negligible sales. Further, there are other significant players present in this market like Bharat Serums, Sanofi Aventis, etc. Thus, it is observed that Vaccine Transaction is not likely to result in appreciable adverse effect on competition in India. Since the Vaccine Transaction does not raise competition concerns under any of the alternative product market definition as stated above; the exact market delineation may be left open in this case.

13. Further as per the information given by the Parties, there is a possibility of horizontal overlap between the existing and certain pipeline products of the Parties in the Vaccines Transaction. However, considering the negligible presence of the Party, already present in that market, and the presence of significant competitors, the Vaccines Transaction is not likely to result in appreciable adverse effect on competition in the market in India.
14. The primary competition concern due to any vertical integration post-merger is whether the proposed combination leads to input foreclosure (i.e., the merged entity raises downstream rivals' costs by restricting their access to an important input) or to customer foreclosure (i.e., the merged entity forecloses upstream rivals' access to their downstream customers). In relation to vertical relationship between the businesses of the Parties, it has been stated in the notice that there is a global supply relationship between the Parties pursuant to which Novartis currently supplies inputs (antigens) for manufacturing vaccines containing diphtheria and tetanus components. This supply relationship will be transferred from Novartis to GSK as part of the Vaccines Transaction and accordingly, post combination, GSK will be vertically integrated upstream. In this regard, the Parties have further submitted that Novartis has antigen supply relationships with other customers also, however, none of these other customers are active in the market for monovalent or



multivalent vaccine involving diphtheria, tetanus or pertussis antigens in India. Accordingly, it is observed that the vertical integration of GSK post combination is not likely to result in any vertical foreclosure in India.

B. Consumer Healthcare Transaction

15. As already stated, under the Consumer Healthcare Transaction, the Parties will establish a J.V. in which GSK will have 63.5 per cent, and Novartis will have 36.5 per cent equity shareholding respectively. However, in relation to India, in accordance with the Contribution Agreement, the business of GlaxoSmithKline Consumer Healthcare Limited (i.e. an Indian subsidiary of GSK) will not be contributed to the J.V. and it is only the consumer healthcare / over the counter (OTC) business of Novartis operating in India, through Novartis India Limited, that is proposed to be transferred to the J.V. Additionally, the research and development facility of Novartis in Hyderabad in India is also proposed to be transferred to the J.V.

16. In this regard, it is noted that the Consumer Healthcare Transaction broadly includes (a) OTC products and (b) other healthcare products. As per the information given in the notice, the Parties have overlapping products in six product segments, identified on the basis of their therapeutic indication i.e. calcium, top anti-rheumatics & analgesics, systemic nasal preparations, cold preparations, expectorants, antitussives and antihistamines systemic. In none of these segments, the combined market share of GSK and the business of Novartis being transferred to the J.V. is more than 10 per cent. If the market is defined at formulation level, it is noted that the Parties have overlapping products in four market segments wherein the combined market share of the Parties is less than 25 per cent. Moreover, the incremental market share in these four formulations is [0-5] per cent except in one formulation where the incremental market share is [5-10] per cent.



17. As per the information given by the Parties, there is a possibility of horizontal overlap between existing products and certain pipeline products of the Parties in the Consumer Healthcare Transaction. However, considering the negligible presence of the Parties and presence of significant competitors in the product market, the Consumer Healthcare Transaction is not likely to result in any appreciable adverse effect on competition in the market in India.

C. Oncology Transaction

18. As already stated, the Oncology Transaction relates to the acquisition by Novartis of GSK's business relating to the portfolio of oncology products, excluding manufacturing. Pursuant to the Oncology Transaction, Novartis will acquire eleven existing oncology products and two pipeline products of GSK. As per the information given in the notice, out of these eleven products being acquired by Novartis, only four products are currently being sold in India by GSK i.e. the formulations containing (a) Lapatinib sold under the brand name Tykerb, (b) Eltrombopag sold under the brand name Revolade, (c) Pazopanib sold under the brand name Votrient and (d) Topotecan sold under the brand name Hycamtin.
19. It is noted from the information given in the notice that Novartis does not sell formulations containing any of the above said four molecules in India. Accordingly, if the formulations based on the same APIs are considered to constitute a separate relevant product market, there is no overlap between the existing oncology products of Novartis and the oncology products being acquired by Novartis from GSK in India. However, the oncology pharmaceutical products may also be differentiated on the basis of the type/stage of cancer, line of treatment and mechanism of action. The Parties have submitted that there is no overlap between the oncology products of Novartis and the oncology products of GSK being sold to Novartis in India on the basis of these factors.



20. In this regard, the Commission also sought the expert opinion from the leading hospitals in India i.e. (a) All India Institutes of Medical Sciences, New Delhi, (b) Tata Memorial Hospital, Mumbai, (c) Rajiv Gandhi Cancer Institute and Research Centre, New Delhi and (d) Christian Medical College and Hospital, Vellore, in relation to the oncology products of GSK and Novartis, under Section 36 of the Act read with sub-regulation (3) of Regulation 19 and Regulation 34 of the Combination Regulations. These institutions have confirmed the submission of the Parties that oncology products can be differentiated on the basis of the type/stage of cancer, line of treatment and mechanism of action. They have also confirmed that the oncology products of the Parties cannot be used interchangeably during the course of treatment of the patients in India. Thus, it is observed that Oncology Transaction is not likely to result in appreciable adverse effect on competition in India. Since, the Oncology Transaction does not raise competition concerns under any of the alternative product market definition as stated above; the exact market delineation may be left open in this case.

21. As per information given in the notice, there are certain pipeline oncology products of the Parties which are part of the Oncology Transaction. However, these products are based on different molecules which can also be differentiated on the basis of the type/stage of cancer targeted, line of treatment and mechanism of action. Accordingly, it is observed that there are no overlaps between the pipeline oncology products of the Parties.

CONCLUSION

22. Considering the facts on record and the details provided in the notice given under sub-section (2) of Section 6 of the Act and the assessment of the combination after considering the relevant factors mentioned in sub-section (4) of Section 20 of the Act, the Commission is of the opinion that the



COMPETITION COMMISSION OF INDIA



proposed combination is not likely to have appreciable adverse effect on competition in India and therefore, the Commission hereby approves the proposed combination under sub-section (1) of Section 31 of the Act.

23. This approval is without prejudice to any other legal/statutory obligation as applicable.
24. This order shall stand revoked if, at any time, the information provided by the Parties is found to be incorrect.
25. The Secretary is directed to communicate to the Parties accordingly.