



BEFORE THE
COMPETITION COMMISSION OF PAKISTAN

IN THE MATTER OF
ACQUISITION OF BUSINESS RELATING TO A PORTFOLIO OF
ONCOLOGY PRODUCTS (EXCLUDING MANUFACTURING) FROM
GLAXOSMITHKLINE BY NOVARTIS A.G

(File No. 667/Merger/CCP/2014)

ORDER

1. Novartis AG. ("Novartis"), through its legal advisors, Irfan & Irfan, Attorneys - At - Law, submitted a pre-merger application pursuant to section 11 of the Competition Act, 2010 (hereinafter the "Act"), dated 29 August 2014 seeking clearance from the Competition Commission of Pakistan (the "Commission") for the proposed acquisition by Novartis of the business relating to a portfolio of oncology products (excluding manufacturing) from GlaxoSmithKline Plc. ("GSK"), pursuant to a sale and purchase agreement signed on 22nd April, 2014 (restated and amended on 21 November, 2014).

2. GSK is a dominant player in the relevant product market and following the consummation of the envisaged transaction, Novartis, would create a dominant position in the relevant product market by acquiring the market share of GSK, which raised competition concerns for the Commission. Therefore, the Commission initiated the Phase II review of the transaction, with the view to determine whether the merger situation is likely to substantially prevent or lessen competition in the relevant market and to ascertain the probability that the merged entity in the post-merger market will behave competitively or cooperatively. The Commission granted its approval unconditionally documented below in this Order.

A. UNDERTAKINGS

i. Novartis AG

3. Novartis AG. ("Novartis"), a Swiss company listed on the Swiss Stock Exchange. The acquirer, Novartis, is primarily engaged in the research, development,

manufacturing and marketing of five broad areas of healthcare: pharmaceuticals, eye care pharmaceuticals, generics, and consumer healthcare products (Over-the-Counter) and vaccines. Novartis markets the following ten oncology products in Pakistan: i) Afinitor; ii) Aredia; iii) Desferal; iv) Exjade; v) Femara; vi) Glivec; vii) Sandostatin LAR; viii) Sandostatin SC; x) Tassigna; and xi) Zometa. Sandoz, the generic pharmaceutical division of Novartis, also markets the following generic oncology drugs in Pakistan: i) Anastrosole; ii) Docetaxel; iii) Gemcitabine; iv) Irinotecan; v) Leuprolide; vi) Ondansetron; and vi) Paclitaxel. Novartis is present in Pakistan through its indirect subsidiary i.e., Novartis Pharma (Pakistan) Limited, which is a subsidiary of Novartis Pharma AG.

ii. **GlaxoSmithKline Plc**

4. GSK was 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 five oncology products in Pakistan: i) Votrient; ii) Tykerb; iii) Revolade; iv) Hycamtin; and v) Zofran. GSK is present in Pakistan through its indirect subsidiary i.e., GlaxoSmithKline Pakistan Limited.

B. RELEVANT MARKET

3. Given that both the merger parties are engaged in selling and marketing oncology products in Pakistan, substitutability in the oncology pharmaceuticals is hard to cover since different oncology products target different types of cancer and are used in different lines of treatment and over different stages of cancer. The only overlapping product between the merger parties is with respect to Serotonin 5-HT₃ Antagonist, which both the merger parties market in Pakistan. Thus, out of the seventeen oncology products of Novartis and the five oncology products of GSK, only one product from each of the merger parties is substitutable with each other with respect to Serotonin 5-HT₃ Antagonist i.e., Ondansetron Sandoz of Novartis and Zofran of GSK. Both of these oncology products compete with each other in Pakistan.



Relevant product market:

4. Serotonin 5-hydroxytryptamine (5-HT₃) receptor antagonists are a group of drugs which are used to control nausea and vomiting. They get their name through their ability to block 5-hydroxytryptamine (also known as serotonin) from activating nerves that bring about the vomiting reflex. 5-HT₃, serotonin blockers, were originally discovered in the 1990s and are one of the newest types of anti-vomiting drugs on the market. The effectiveness of these drugs has revolutionized the management of nausea and vomiting, particularly in individuals undergoing chemotherapy or radiotherapy and in the treatment of nausea and vomiting after surgery.

5. They have little effect on vomiting caused by motion sickness and do not have any effect on dopamine receptors or muscarinic receptors. They are also on the World Health Organization's List of Essential Medicines.

Relevant geographic market:

6. The relevant geographic market is national in scope.

C. TRANSACTION

7. The transaction involves the acquisition of the business relating to a portfolio of oncology products (excluding manufacturing) from GSK by Novartis. The consideration to be paid under the Share and Purchase Agreement ("SPA") dated 22 April, 2014 (restated and amended on 21 November, 2014) is USD [REDACTED] (PKR [REDACTED]). Novartis will acquire the oncology business of GSK through a combination of share and asset sale.

D. COMPETITION ASSESSMENT

8. 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"



9. Novartis is a small player in the market for serotonin 5-HT₃ antagonist products, having a market share amounting to [redacted] while GSK is the [redacted] player, by having a market share of [redacted] which is [redacted] than the market power threshold of 40% under Section 2(e) of the Act, making it a dominant player. The merger parties' combined market shares is high [redacted]. Post-merger, GSK will not be the dominant player, rather, Novartis will be the dominant player by acquiring the market share of GSK. However, there are a large number of alternative serotonin 5-HT₃ antagonist (antiemetics and antinausants) products that are being marketed in Pakistan, thus, consumers will still have a choice after the completion of the proposed acquisition. The number of competitors and their relevant market shares in the provision of serotonin 5-HT₃ antagonist (antiemetics and antinausants) products for the year 2013 is given in the table below:

Ser.No.	Company	Product	Molecules	Sales PKR in 000'	Market Share (%)
1	Novartis	Ondansetron Sandoz	Ondansetron	[redacted]	[redacted]
2	GSK	Zofran	Ondansetron	[redacted]	[redacted]
3	Pharmedic	Onset	Ondansetron	[redacted]	[redacted]
4	CIPLA	Ranicip	Granisetron	[redacted]	[redacted]
5	Haji Medicine	Espasvit	Ondansetron	[redacted]	[redacted]
6	Roche	Kytril	Granisetron	[redacted]	[redacted]
7	Biopharma	Otron	Ondansetron	[redacted]	[redacted]
8	Graton Pharma	Gratron	Granisetron	[redacted]	[redacted]
9	Rotex Medica	Esposvite	Ondansetron	[redacted]	[redacted]
10	CCL	Graniset	Granisetron	[redacted]	[redacted]
10	Al-Habib	Onfran	Ondansetron	[redacted]	[redacted]
11	Amogen	Nilsetran	Tropisetron	[redacted]	[redacted]
12	Others			[redacted]	[redacted]
	Total				100

9. The Commission had two concerns with the transaction as originally notified, namely:

- that Novartis would create a dominant position in the developing and marketing of serotonin 5-HT₃ antagonist products;
- that it may reduce choice for consumers that may rely on the existing product of GSK, Zofran.

10. While taking the envisaged transaction to Phase II, we further assessed the relevant market by taking into account the factors laid down in Regulation 6 of the Competition (Merger Control) Regulations, 2007 which the Commission may consider when assessing substantial lessening of competition. In order to dispel the competition concerns stated above. We found the following observations:

- that it would have reduced from 11 to 10 major companies developing and distributing serotonin 5-HT₃ antagonist products (antiemetics and antinausants). These are a large number of players.

- history of collusion has not been found.
- total sales generated from Ondansetron Sandoz of Novartis, is PKR █████ million, which constitutes █████% of its total oncology products sales, which is negligible.
- the drugs in question, serotonin 5-HT₃ antagonist products (antiemetics and antinausants) are not products for the treatment of cancer. They are generic drugs that are low priced to treat nausea and vomiting following chemotherapy or radiotherapy. There is a low price difference between the products of Novartis (Ondansetron Sandoz) and GSK (Zofran). Thus, the possibility of the price of Zofran escalating seems unlikely. Also, hypothetically, in the case of a 10% increase in the price of Zofran, consumers and purchasers may switch to one of many alternative products that are available.

11. Novartis' interim supply agreement for Ondansetron shows that it does not plan to discontinue Ondansetron Sandoz and intends to market this product under the brand name of Zofran. Thus, consumers and suppliers will still have the choice of purchasing Zofran.

E. CONCLUSION

12. Considering the facts on record and the details provided by the merger parties and the information gathered by the Commission independently, the Commission is of the view that the proposed acquisition is not likely to have appreciable adverse effect on competition in Pakistan and therefore, the Commission hereby authorizes the acquisition under section 31(1)(d)(i) of the Act.



(MUEEN BATLAY)

Member

Islamabad, the 9th February, 2015