





## COMPETITION COMMISSION OF INDIA

(Combination Registration No. C-2016/07/413)



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purchase of BI's global consumer healthcare business<sup>1</sup> ("**BI CHC**") by Sanofi ("**CHC Agreement**") and (b) Agreement for sale and purchase of Sanofi's global animal health business ("**Merial**")<sup>2</sup> by BI ("**AH Agreement**"). The proposed combination is part of the global business swap transaction between the Parties, subject to approvals in other competition jurisdictions around the world. It is stated in the notice that the aforementioned two transactions are interconnected and contingent upon the execution of each other.

2. *Vide* letter dated 28.07.2016, issued under the provisions of Regulation 14 of the Competition Commission of India (Procedure in regard to the transaction of business relating to Combinations), Regulations, 2011 ("**Combination Regulations**"), the Parties were required to remove certain defects in the Notice and, *inter alia*, to identify the overlaps, if any, at the 'molecule level' in the consumer health care segment and animal health segment. The Parties submitted their partial response on 12.08.2016 and complete response on 05.09.2016, after seeking extension of time.
3. Sanofi, having its registered office in Paris, is a public company and is listed on Euronext and the New York Stock Exchange. Globally, it is engaged in research, development, manufacture and sale of healthcare products, such as (i) pharmaceuticals, (ii) human vaccines, and (iii) animal health. In India, it is present in human vaccines, primary health care and consumer health care/over the counter ("**OTC**") products, and therapeutic & nutrition products for production and companion animals in the animal health segment, through its subsidiaries.
4. BI, registered in Germany, is stated to be engaged in the development, production, distribution and marketing of pharmaceuticals, particularly (i) prescription products; (ii) consumer health care products; (iii) biopharmaceuticals; and (iv) animal health products. In India, BI is active through its wholly owned subsidiary Boehringer Ingelheim India Private Limited ("**BI India**"). Presently, BI India operates in the areas of prescription medicine, consumer health care, animal health and clinical operations.

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<sup>1</sup> Excluding BI's consumer healthcare business in mainland China.

<sup>2</sup>It is stated in the notice that Sanofi's animal health business is globally operated through a separate chain of companies' i.e. Merial, in certain countries including in India.



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5. On the basis of submissions and subsequent responses of the Parties, it is noted that both Sanofi and BI India are broadly engaged in consumer healthcare segment and animal health segment in India. The Commission also noted that these segments in India are characterised by the presence of a number of players. Given the limited presence of the Parties in both the segments in India, the Commission observed that the proposed transaction is not likely to raise significant competition concern and accordingly decided that the exact delineation of the relevant market be left open.
  
6. With regard to the horizontal overlaps in the consumer health care business, the Commission noted that there are two overlaps, at ATC-3 classification level- a) A3A-Antispasmodics and Anticholinergics, and b) A3D-Antispasmodic/Analgesic combinations. However, it has been submitted that Sanofi has discontinued both of them since 2013. Based on the decisional practice in the past, the Commission also examined the overlaps at ATC-4 classification level and noted that there is one overlapping product – paracetamol. Based on the internal estimates of the parties and data collected from third party agency, the combined market share of the Parties in A3A, A3D and paracetamol product markets are about 15.36 percent, 2.47 percent and 3.971 percent respectively, in India. The Commission noted that at ATC-3 and ATC-4 level, the combined market share of the Parties in the consumer health care may not raise significant concern in markets in India. Further, the Commission observes that the consumer health care segment is characterised by the presence of many players like Martin Harris, Zydus, Wockhardt, IPCA Labs, Glaxo SmithKline, Alkem and Micorlabs competing with the Parties in the consumer healthcare market.
  
7. In relation to the horizontal overlaps in the animal health business, the Parties submitted that EC has consistently segmented animal health products in three main categories namely, i) Biologicals (vaccines), ii) Pharmaceuticals and iii) Feed supplements. EC also takes into account (i) active substance/chemical family; (ii) route of administration; and (iii) animal size to define the antimicrobial product markets. In the *Eli Lilly/Novartis* case, the Commission while analysing the market for antimicrobials, considered i) target species; ii) the intended therapeutic effect; and iii) the mode of



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administration of drugs for defining the relevant markets in the animal health sector. As per the submissions of the Parties, the overlaps exist in the category of 'pharmaceuticals' and 'feed supplements' in India. Within the broader market of pharmaceuticals in India, the Parties' activities overlap only in the sub-segment 'antimicrobials'. Based on these factors, and the EC's previous decisional practice, in the antimicrobials market, the parties have identified overlaps in two narrower product markets: i) Mastitis inflammatory in lactating cows and ii) Enrofloxacin. Further within the feed supplements market in India, the overlap exists in two sub categories namely, i) Oral Liquid Calcium and ii) Mineral Vitamin Powder. On the basis of internal estimates of the Parties and data provided by third party agency, it has been submitted that the combined market share of the Parties in the market for mastitis inflammatory in lactating cows, enrofloxacin, oral liquid calcium and mineral vitamin powder are 2.3 percent, 2.24 percent, 3.9 percent and 12.21 percent respectively.

8. Further, the parties have submitted that apart from the products manufactured by them, cognizance may also be taken of products manufactured by Zoetis India Limited ("Zoetis"). As submitted, one of the Indian entities of Sanofi, namely Sanofi-Synthelabo (I) Private Limited ("SSIPL"), has entered into a distribution agreement with Zoetis. Pursuant to this distribution agreement, Merial (through SSIPL) would purchase certain animal health products from Zoetis (in the narrower product markets of (a) Mastitis intra-mammary in lactating cows (Pharmaceuticals); and (b) Oral Liquid Calcium (Feed Supplements)) for distribution and marketing of these products under Zoetis' brand names. Zoetis distribution agreement is considered for the purpose of assessing market share of the Parties result in the combined market share in Mastitis inflammatory in lactating cows and mineral vitamin powder of 5.99 percent and 10.07 percent respectively. As per the data provided by the Parties, the Commission observed that there are various entities like Zydus, Vetoquinol, Intas, Virbac, Merck etc. in the animal health segment supplying competing products, who would continue to pose competitive constraints on the Parties.
9. The Commission also examined the overlaps in the pipeline products of the Parties in consumer healthcare segment and noted that such products of the Parties do not raise / significant potential overlaps in the consumer health care segment. As per the



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submissions of the Parties, there is no horizontal overlap in the pipeline products in the animal health segment.

10. Considering facts on record, details provided in the notice given under sub-section (2) of Section 6 of the Act and assessment of the proposed combination on the basis of factors stated in sub-section (4) of Section 20 of the Act, the Commission is of the opinion that the proposed combination is not likely to have an appreciable adverse effect on competition in India and therefore, the Commission hereby approves the same under sub-section (1) of Section 31 of the Act.
11. This order shall stand revoked if, at any time, the information provided by the Parties is found to be incorrect.
12. The information provided by the Parties is confidential at this stage, in terms of and subject to the provisions of Section 57 of the Act.
13. The Secretary is directed to communicate to the Parties accordingly.