

# FORM IV

**Disclaimer:**  
Under Section 29(2) of the Competition Act, the Hon'ble Competition Commission of India requires the parties to the combination to publish details of the combination for bringing it to the knowledge or information of the public and persons affected or likely to be affected by such combination. The contents given herein do not represent in any manner the views of the Commission and do not prejudice the view that the Commission may take of the proposed combination.

## The Competition Commission of India (Procedure in regard to the transaction of business relating to combinations) Regulations, 2011

### Publication of details of combination under Section 29(2) of the Competition Act, 2002 (as amended) ("Competition Act")

I. The Competition Commission of India ("Commission") is investigating the combination between Sun Pharmaceutical Industries Limited ("Sun") having its registered office at SPARC, Tandajia, Vadodra - 390 020, Gujarat, India and Ranbaxy Laboratories Limited having its registered office at Plot No. 90, Sector 32, Gurgaon, Haryana – 122001 ("Ranbaxy"). Sun and Ranbaxy are together the "Parties". Parties have agreed that Ranbaxy will merge into Sun. The resulting merged enterprise is referred to as the "Combined Entity". As a result of the Proposed Transaction, Sun would be indirectly acquiring Ranbaxy's shareholding of 46.79% in Zenotech Laboratories Limited ("Zenotech") and has announced an open offer for 28.1% shares of Zenotech through the Public Announcement dated 11 April 2014 to be commenced after completion of the Sun-Ranbaxy merger.

II. The details of the combination are:

#### Rationale, objectives, strategy and the likely impact of the Combination

- Objective:** To create a global pharmaceutical company with expanded geographical and therapeutic presence.
- Rationale:** To enhance value to customers, shareholders and other stakeholders of Sun and Ranbaxy. The proposed merger would create the 5th largest global specialty generics company. The Combined Entity would thereby be able to compete in the global speciality generics market on an equal footing.
- Strategy & Impact:** Combined Entity will have a diverse, highly complementary portfolio of specialty generic products targeting a spectrum of chronic and acute treatments across diverse geographies including India, USA and other international markets.
- The Combined Entity would benefit from operational and commercial synergies through enhanced revenue opportunities, expanded geographic reach, efficient procurement and focused R&D efforts.
- The proposed merger would create an opportunity for the shareholders of both Sun and Ranbaxy to participate in value creation in the Combined Entity.

#### The nature of the Combination

- The Proposed Transaction contemplates the merger of Ranbaxy into Sun pursuant to the Scheme of Arrangement ("Scheme") which has been approved by their respective Board of Directors under the Sections 391-394 and other applicable provisions of the Companies Act, 1956 (as amended).
- The amalgamation/merger will need approval by majority in number representing 75% (percent) in value at the shareholders' meetings of each of Sun and Ranbaxy.
- As per the Scheme, it is proposed that the shareholders of Ranbaxy ("Ranbaxy Shareholders") would receive 0.8 shares of Sun for each share of Ranbaxy that they own.
- Post the Proposed Transaction, the Ranbaxy Shareholders, are expected to own approximately 14% of the Combined Entity on a pro forma basis with Daiichi holding 8.9% of the Combined Entity and the promoter group of Sun is expected to own approximately 54.7% of the Combined Entity.

#### Area of activities of the parties to the combination

- Sun** is an international, integrated, specialty pharmaceutical company. Sun alongwith its subsidiaries has a total of 26 manufacturing facilities worldwide including 18 finished dosage manufacturing facilities (6 each in India and US, and 1 each in Canada, Brazil, Mexico, Hungary, Israel and Bangladesh) and 8 Active Pharmaceutical Ingredients ("API") manufacturing facilities (5 in India and 1 each in Israel, US and Hungary).
- Sun's key therapy areas in India are CNS, Cardiology, Orthopaedics, Ophthalmology, Gastroenterology, Nephrology, with increasing focus on complex, difficult to manufacture generic products & chronic therapies.
- Ranbaxy** is an integrated, research based, international pharmaceutical company producing a wide range of quality, affordable generic medicines, trusted by healthcare professionals and patients worldwide. Ranbaxy's focus on R&D has resulted in several approvals in developed and emerging markets, many of which incorporate proprietary Novel Drug Delivery Systems and technologies developed at its own labs.
- Ranbaxy's key therapies in India include Anti-infectives, Cardiovascular, Pain management, Respiratory, Dermatology, Orthopaedics, Nutritional and Urology. Biotech and Vaccines are two new segments that Ranbaxy has begun investing in.
- Ranbaxy's continued focus on Research & Development (R&D) has resulted in several regulatory approvals in both developed and emerging markets. It has multiple R&D centres in Gurgaon, Haryana, India with facilities for generic and innovative research.

#### The market(s) (including its structure and state of competition) in which the combination will have or is likely to have an impact

- Both the Parties are engaged in the manufacture, sale and distribution of pharmaceutical products within India and globally. The Proposed Transaction involves the Indian pharmaceutical sector as well as Global Pharmaceutical sector. The combined market share of the Parties is approx. 9.2%<sup>9</sup> of the Indian pharmaceutical sector with Ranbaxy having a market share of 3.87% and Sun having a market share of 5.35%.
- Relevant Market:** Given that the various products of each of Sun and Ranbaxy are available all over India, the relevant geographic market for the Proposed Transaction is the market comprising the territory of India. Even though both Sun and Ranbaxy are engaged in the export of their products and maintain a significant presence in global markets, the relevant market for the assessment of the Commission would be the territory of India.
- The **relevant product market**, at its broadest, is the pharmaceutical sector in India. Narrower product market definitions would involve defining the products of the Parties to the Combination in context of the generally accepted classification of pharmaceutical products into first, Therapeutic Areas (or Categories); second, a level lower i.e., the Therapeutic Groups and, at its narrowest, the Molecules Level. For this purpose, the Parties to the Combination have referred to the classification of drugs by the All India Organization for Chemists and Druggists ("AIOCD"). The AIOCD follows the European Pharmaceutical Marketing Research Association ("EPHMA") Anatomical classification guidelines.
- The Parties have a combined presence in: (i) 18 Therapeutic Areas; (ii) 127 Therapeutic Groups; and (iii) 246 Molecules.
- Particularly at a molecules level, the following factors are relevant in context of the overlap between the products of the Parties:
  - Sun has a focus on chronic treatment whereas Ranbaxy's traditional focus has been acute treatments.
  - Both companies have a pan-India presence but Ranbaxy's presence in the rural and smaller cities does not overlap with Sun's wider reach in metros and tier-1 towns.
  - Some of the overlapping products such as ATORVASTATIN and LOSARTAN fall under the NLEM List (defined later) and are subject to price control by agencies of the government.
  - In many products, the incremental market share of the Combined Entity would be less than 5% such as QUETIAPINE, LEVETIRACETAM, and OXCARBAZEPINE.
  - In many of the products, other competitors would continue to retain their market leadership even post the merger such as LOSARTAN, PIOGLITAZONE, ESOMEPRAZOLE and SERTRALINE.
  - Many of the overlapping products are combination drugs. In these cases, it is possible for practitioners to prescribe and for patients to consume the single molecule products or drugs in addition to other clinical substitute products for instance, out of the 37 molecules (explained below) there are 16 formulations<sup>2</sup> which are combination products (e.g., PIOGLITAZONE + GLIMEPIRIDE, LOSARTAN + HYDROCHLORTHIAZIDE). In any case, it is the doctor / medical practitioner who determines the appropriate drug and dosage to be prescribed for an ailment.
  - Many of the overlapping products relate to small size markets. Markets may be of a smaller size for various reasons including that the products address rare illness, or that the product is new, or that the product was unsuccessful. In almost all cases, there is ample availability of clinical substitutes, which may be preferred by medical practitioners over the products of the Parties.
- The Parties have shortlisted 37 Molecules out of 246 Molecules where the combined market share of both the Parties is greater than 15% and the individual market shares of each of Sun and Ranbaxy is greater than 5%. Within the 37 molecules there are 2 molecules which are under NLEM (explained later) which are ATORVASTATIN and LOSARTAN. The following table depicts the distribution of the 37 Molecules in terms of the combined market share of the Parties based on MAT Feb 2014:

TABLE<sup>3</sup>

SR. NO.	MOLECULE	POST TRANSACTION MARKET SHARE
1.	TAMSULOSIN + TOLTERODINE   G4C13	93.7
2.	ROSUVASTATIN + EZETIMIBE   C10G6	91.7
3.	TERLIPRESSIN   H4D7	69.4
4.	ALFUZOSIN + DUTASTERIDE   G4C12	44.2
5.	OLANZAPINE + FLUOXETINE   N5A6	68.2
6.	TROSPIUM   G4D8	53.7
7.	DARIFENACIN   G4D7	54.6
8.	BAMBUTEROL + MONTELUKAST   R3A41	28.1
9.	VENLAFAXINE   N6A19	43.6
10.	TOLTERODINE   G4D4	44.1
11.	ATENOLOL + LOSARTAN   C7G2	37.9
12.	PIOGLITAZONE + GLIMEPIRIDE   A10B51	27.1
13.	THIOPOLCHICOSIDE + DICLOFENAC   M1A92	25.3
14.	ZOLEDRONATE   M5A8	16.4
15.	LEVOSULPIRIDE + ESOMEPRAZOLE   A3F49	62.7
16.	IBANDRONATE   M5A5	66.3
17.	FLUVOXAMINE   N6A9	53.1
18.	MONTELUKAST   R3A46	22.7
19.	SERTRALINE   N6A16	26.3
20.	PIOGLITAZONE   A10B18	25.5
21.	LACTITOL   V6E4	35.0
22.	EDARAVONE   N7X5	33.3
23.	ATORVASTATIN + EZETIMIBE   C10G1	26.7
24.	LOSARTAN + AMLODIPINE   C8D6	15.5
25.	DOMPERIDONE + ESOMEPRAZOLE   A3F10	33.3
26.	OLMESARTAN + AMLODIPINE + HYDROCHLORTHIAZIDE   C9E22	41.0
27.	ESOMEPRAZOLE   A2C2	25.2
28.	LOSARTAN   C9D3	23.9
29.	LOSARTAN + HYDROCHLORTHIAZIDE   C9I7	17.6
30.	ETORICOXIB   M1A28	33.9
31.	DIVALPROEX   N3A4	28.1
32.	ROSUVASTATIN + FENOFIBRATES   C10F6	33.8
33.	VOGLIBOSE + METFORMIN   A10B43	24.4
34.	LEUPRORELIN   H1C6	85.8
35.	VOGLIBOSE   A10B22	32.0
36.	ROSUVASTATIN   C10A6	34.6
37.	ATORVASTATIN   C10A1	23.5

- Structure & State of Competition:** The pharmaceutical sector in India is a highly fragmented and competitive market where there are a large number of players producing differentiated products with limited entry barriers. The pharmaceutical sector has more than 20,000 registered units, of which the leading 250 pharmaceutical companies control 70% of the market. There are about 250 large units and about 8000 Small Scale Units, which form the core of the pharmaceutical industry in India (including 5 Central Public Sector Units)<sup>4</sup>.
- There are a large number of competitors and a high availability of clinically substitutable brands for a majority of the molecules in which Sun and Ranbaxy both have a brand presence. For instance, the combined market share of the Parties in ESOMEPRAZOLE is 25.2%. However, there are at least 28 other manufacturers of this molecule. Esomeprazole is clinically substitutable by OMEPRAZOLE, RABEPRAZOLE and PANTOPRAZOLE as they treat the same indication.
- A unique feature of the Indian pharmaceutical market is that there is a significant degree of regulation by the Government and its agencies on the prices of drugs.
- For almost all markets in which both the Parties are present, significant existing and potential competition exists. For instance, the Combined Entity would have a market share of 36.4% in PRASUGREL. The significant competitors in this molecule are Torrent, Lupin, Glenmark, Cipla, and Zydus. The market for PRASUGREL has witnessed a steady growth and is expected to continue to grow on account of the high incidence of heart disease in the Indian population.

#### Information with reference to sub-section (4) of Section 20 of the Competition Act, 2002 (as amended) (as per the view of the Parties)

- Actual and potential level of competition through imports in the market:**
  - The total import of pharmaceutical products including formulations, APIs, devices, etc. in India for 2013-14 was INR 937,169 lakhs<sup>5</sup>.
  - Raw materials such as APIs are imported into India in significant quantities. The import of formulations is limited.
- Extent of barriers to entry in the market:**
  - There are no significant barriers to entry in this market. In a majority of the cases, for any existing pharmaceutical company, a period of, approximately 4-6 months would be required to launch a brand in an existing molecule.
  - Further, (a) regulatory barriers are low, (b) for a majority of the products there is ample availability of API, and (c) the level of complexity is low for manufacturing majority of the products. Thus, although the Pharmaceutical sector is heavily regulated in terms of pricing, it is easy for any company to manufacture and market any pharmaceutical product (including the products being acquired by Sun) given the low entry barriers.
- Level of combination in the market:**
  - The Indian pharmaceutical market is not concentrated. The top 10 pharmaceutical companies in India along with their respective market shares<sup>6</sup> are set out below:

TABLE

CORPORATE	MARKET SHARE %
Abbott	6.43
Sun Pharma	5.35
Cipla	5.00
Zydus + Biochem	4.38
Ranbaxy	3.87
Glaxo	3.80
Mankind	3.59
Alkem	3.50
Lupin	3.35
Emcure	2.81

Per news reports, there have been 27 acquisitions in the pharmaceutical sector in the last few years including Abbott's acquisition of Piramal, Zydus's acquisition of Biochem, Mylan's acquisition of Agila<sup>7</sup>. This is indicative of the fact that the market is rapidly growing and is very competitive.

- Degree of countervailing power in the market**
  - Given that there are a large number of competitors including large international and domestic companies are present in the market, the Proposed Combination will not result in any Appreciable Adverse Effect on Competition ("AAEC"). Please refer to the Para 29 above in this regard.
- Likelihood that the combination would enable the parties to significantly and sustainably increase prices or profit margins:**
  - The prices of pharmaceutical products are regulated by the Government of India and the National Pharmaceutical Pricing Authority ("NPPA") through the Drugs (Price Control) Order, 2013 ("DPCO"). The National List of Essential Medicines ("NLEM") (scheduled drugs) products are subject to the ceiling price prescribed by the NPPA in any case, severely limiting the freedom of companies to price its products.

- For non-scheduled drugs the NPPA prescribes a cap of 10% on increase in price relative to the MRP of previous 12 months. This means that the companies cannot in any case, increase the price of a product beyond 10% in a given financial year.

- Extent of effective competition likely to sustain in the market:**
  - There are many large international (e.g., Abbott, Pfizer, Glaxo Smith Kline, Sanofi) and domestic pharma companies (e.g., Cipla, Lupin, Alkem, Zydus, Dr Reddy's) that compete with the Parties in the market and will continue to exercise competitive constraints on the Combined Entity post the transaction. Please also refer to the market shares of the top 10 pharmaceutical companies in India provided in Para 29 above.
- Extent to which substitutes are available or are likely to be available in the market:**
  - Substitutability is an economic / antitrust concept which depends on various factors including end use, dosage form, strength, method of administration, etc. For most of the products marketed by the Parties there are other products, which are direct substitutes as well as products that are clinical substitutes and these may be preferred by medical practitioners as they may be more advanced or efficacious. For instance, (1) Lactitol and Lactulose treat the same indication, as do, (2) Esomeprazole, Omeprazole, Rabepazole and Pantoprazole, and (3) Olanzapine and Quetiapine.
  - For formulations that are combination drugs, the mono-drugs may also be prescribed separately. For instance, for ATORVASTATIN + EZETIMIBE, the constituent mono-molecules may be prescribed / consumed separately rather than the combination drug.
  - There are a sufficient number of brands of various pharma companies which provide enough competition to the Parties presently and which would continue to exercise competitive constraints on the Combined Entity post-merger.

#### H. Supply side substitutability

- It is submitted that a pharmaceutical company having the expertise and technical know-how to manufacture products which are categorized under a particular therapeutic super-group (as defined by the AIOCD) can easily switch or initiate production of any products in different sub-groups within the larger super-group, by procuring the relevant additional molecule/API which is required to manufacture such pharmaceutical products.
- Therefore, given the availability of clinical substitutes and the strong competition that domestic and international pharmaceutical companies exert, the Combined Entity is unlikely to possess significant market strength as a result of the Proposed Transaction, to be able to influence market forces or act independently. For instance, the Combined Entity's market share for TROSPIUM would be 53.7% but this molecule treats the same indication that is treated by another drug, Oxybutynin, which may also be prescribed by doctors and consumed by patients instead of Trospium. Further, Zydus and Cipla are two important competitors in the Trospium market.
- Similarly, the Combined Entity's market share for FLUVOXAMINE would be 53.1% but this molecule treats the same indication that is treated by another drug, CLOMIPRAMINE, which may also be prescribed by doctors and consumed by patients instead of FLUVOXAMINE. Further, Abbott and Cipla are two important competitors in the FLUVOXAMINE market.

#### I. Market share, in the relevant market, of the persons or enterprise in a combination, individually and as a combination:

- The combined market share of the Parties is approx. 9.2%<sup>8</sup> of the Indian pharmaceutical sector with Ranbaxy having a market share of 3.87% and Sun having a market share of 5.35%.

#### J. Likelihood that the combination would result in the removal of a vigorous and effective competitor or competitors in the market

- There are many large international and domestic companies present in the markets that would continue to provide effective competition to the Combined Entity. Ranbaxy has been facing regulatory and growth challenges in the last few years. The Proposed Combination is intended to create a strong company that will be able to compete effectively in the growing pharmaceutical market.

#### K. Nature and extent of vertical integration in the market:

- Manufacturing and sale of API is not the primary business of either of the Parties. The revenue derived by the Parties from the sale of APIs is very limited compared to their respective total revenues. Sun's revenue from the sale of API constitutes 5% of its total revenues<sup>9</sup>. For Ranbaxy, the revenue from sale of APIs is approx. 6.37% of its total revenues<sup>10</sup>.
- A manufacturer of formulation can procure the API from any API supplier. APIs are bulk drugs and are not branded products. There are a myriad number of suppliers both within India and outside India which supply APIs to Indian formulation manufacturers. The merger between Sun and Ranbaxy would not foreclose the upstream market for APIs or the downstream market for formulations.
- The APIs for which there is vertical relationship between the parties contribute marginally to the Parties' revenue leaving little or no incentive for parties to foreclose the market. Also, other API suppliers would be able to substitute the products sold by the Parties.

#### L. Nature and extent of innovation, and relative advantage, by way of the contribution to the economic development and benefits of the combination:

- The Proposed Combination should synergize innovation and R&D activities of the Parties and contribute to efficient production of new drugs and / or upgradation of existing forms of drugs. Some other benefits of the Proposed Combination are as follows:
  - The Proposed Combination is intended to help build a strong company in order to compete effectively in a competitive market.
  - Ranbaxy has faced regulatory and growth challenges in recent times. Combined with the SUN brand of quality assurance and compliance, the merger is intended to create an effective international pharmaceutical company that caters to global and domestic markets.
  - Ranbaxy's strong presence in the management of acute conditions in patients and Sun's association with chronic illness, will result in an expansion of the product portfolio of the Combined Entity.

#### Expected timeframe for completion of various stages of the Combination.

- The completion of the Proposed Combination remains subject to the approval of judicial and regulatory agencies including the Hon'ble High Courts of Gujarat and Punjab & Haryana, the approval of the Hon'ble Commission and the approval of the antitrust regulators in the other jurisdictions. Till date, No Objection Certificates (NOCs) have been obtained from the stock exchanges (National Stock Exchange (NSE) and Bombay Stock Exchange Limited (BSE)) in India, and unconditional approvals have been received from anti-trust authorities in all applicable markets excluding India and the US. The Parties expect that the merger of Ranbaxy into Sun would be effective by end of calendar year 2014 subject to receipt of the pending approvals for the Proposed Combination.

- In order to determine whether the combination has or is likely to have an appreciable adverse effect on competition in the relevant market in India, the Commission invites comments/objections/suggestions in writing, from any person(s) adversely affected or likely to be affected by the combination, as provided under sub-section (3) of section 29 of the Act, to be addressed to the Secretary, Competition Commission of India, the Hindustan Times House, 7th Floor, 18-20, Kasturba Gandhi Marg, New Delhi-110001, **within fifteen working days** from the date of this publication.

#### IV. The comments/objections/suggestions shall state:

- name, address and contact details of the person(s) writing to the Commission, and
- with supporting documents, how such a person(s) is adversely affected or is likely to be affected by the combination, keeping in view the relevant provisions of the Act/ factors provided under sub-section (4) of Section 20 of the Act.

The Commission is not likely to consider unsubstantiated objections.

<sup>1</sup>Source: AIOCD – AWACS dataset for MAT Feb 2014.  
<sup>2</sup>Formulations and molecules are used interchangeably in the pharmaceutical industry.  
<sup>3</sup>Classification and market shares is based on AIOCD- AWACS database MAT Feb 2014.  
<sup>4</sup>Source: <http://www ASSOCHAM.org/australia-chapter/pharmaceuticals.php>  
<sup>5</sup>Source: Department of Commerce, Export Import Data Bank, please see: <http://commerce.nic.in/eidb/icomq.asp>  
<sup>6</sup>Based on AIOCD- AWACS database for MAT Feb 2014.  
<sup>7</sup>Source:<http://profit.ndtv.com/news/industries/article-2013-few-bitter-pills-booster-injections-for-pharma-sector-376156>  
<sup>8</sup>Source: AIOCD – AWACS dataset for MAT Feb 2014.  
<sup>9</sup>For the Financial Year 2013-2014. Source: Investor Presentation, August 2014.  
<sup>10</sup>For the Calendar Year 2013. Source: Internal Data.