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*Fair Competition*
*For Greater Good*

**COMPETITION COMMISSION OF INDIA**

(Combination Registration No. C-2016/08/418)

**13th December 2016**

**Notice under Section 6 (2) of the Competition Act, 2002 given by Abbott Laboratories**

**CORAM:**

Mr. Devender Kumar Sikri
Chairperson

Mr. S.L. Bunker
Member

Mr. Sudhir Mital
Member

Mr. Augustine Peter
Member

Mr. U.C. Nahta
Member

Mr. G.P. Mittal
Member

**Legal Representative:** AZB & Partners and Shardul Amarchand Mangaldas & Co.

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

1. On 1st August 2016, the Competition Commission of India (hereinafter referred to as the "**Commission**") received a notice filed by Abbott Laboratories ("**Abbott**") under sub-section (2) of Section 6 of the Competition Act, 2002 ("**Act**"). The proposed combination has been filed pursuant to execution of an Agreement and Plan of Merger dated 27th April 2016[1] entered into between Abbott and St. Jude Medical, Inc. ("**SJM**"). (Hereinafter, Abbott and SJM are collectively referred to as "**Parties**".)

[1] The proposed combination was first notified on 27th May 2016 (Comb. Regn. No. C-2016/05/402). Since certain information was not available at the time of filing the notice, the Parties sought additional time until 27th July 2016, under Regulation 5(6) of the Competition Commission of India (Procedure in Regard to the Transaction of Business Relating to Combinations) Regulations, 2011 ('**Combination Regulations**') to furnish such information. Accordingly, the said notice being incomplete was invalidated. Parties were required to file the notice again with the requisite complete details.

2. The proposed combination has been structured as a reverse triangular merger and will be carried out by way of the following steps:

   **First Step:** Vault Merger Sub, Inc., a newly incorporated wholly-owned subsidiary of Abbott created for the purpose of the proposed combination, will merge into SJM, with SJM surviving as the First Surviving Corporation which will become a wholly-owned subsidiary of Abbott.

   **Second Step:** The First Surviving Corporation will merge into Vault Merger Sub, LLC - also a newly incorporated wholly-owned subsidiary of Abbott created for the purpose of the proposed combination, with Vault Merger Sub, LLC surviving as the Surviving Company. The Surviving Company will be renamed as St. Jude Medical, LLC and will be a wholly-owned subsidiary of Abbott.

3. In terms of Regulation 14 of the Combination Regulations, the Parties, vide Commission's letter dated 24th August, 2016, were required to furnish certain information relating *inter-alia*, to horizontal overlaps and vertical relationships between their products sold in India. The response to the same was provided on 16th September 2016 (**'Response-1'**). Thereafter, vide email dated 3rd October, 2016, the Parties submitted that they would file certain additional submissions forming part of the Response-1. Subsequently, Parties filed submissions relating to divestiture of the 'small hole' vascular closure devices ("**VCDs**") business of SJM on 21st October 2016, 28th November 2016, and 5th December, 2016.

4. Abbott, a company incorporated and listed in the USA, is engaged in research, development, manufacture and sale of a range of health care products on a global basis. It provides products and services, *inter-alia*, relating to paediatric and adult nutrition, medical devices comprising vascular and diabetes care, diagnostic systems and pharmaceutical products. Abbott is present in India through its four subsidiaries namely, Abbott India Limited, Abbott Healthcare Private Limited, Abbott Medical Optics Private Limited and Abbott Truecare Pharma Private Ltd. These subsidiaries are present in therapeutic areas relating to women's health, gastroenterology, neurology, thyroid, diabetes and urology, pain management, cardiology, dermatology, diabetes, neuropsychiatry, pain management, respiratory diseases, vascular, orthopaedics and refractive technologies for vision and eye care. Abbott also sells VCDs in India. The VCDs sold by Abbott in India are Perclose ProGlide and StarClose. While Perclose ProGlide, a suture based device, is

indicated to be meant for hole sizes up to 21F (1F = 1/3 mm), StarClose, a clip based device, is for small holes i.e. 5F to 8F.

5. SJM, a company incorporated and listed in the USA, is a global medical device company that researches, develops, manufactures, and sells cardiovascular medical devices. It provides products and services, *inter-alia*, relating to cardiac rhythm management, heart failure, cardiovascular products, vascular closure devices and atrial fibrillation. SJM is present in India through its subsidiary – St. Jude Medical India Private Limited. SJM offers three plug-based VCDs in its "Angio-Seal" product family: (i) STS Plus; (ii) VIP; and (iii) Evolution. While SJM has presence in VIP in India, it has zero sales of STS Plus and Evolution in India. These products are indicated to be meant for small hole sizes of 6F and 8F.

6. As stated in the notice, in India, the activities of the Parties overlap in the 'small hole' VCDs. VCDs are medical devices that are used to close holes created due to catheterisation in arteries during diagnostic as well as therapeutic procedures to treat vascular diseases. VCDs are available in the form of suture and clip-based devices and other devices that insert a plug or seal to close such holes. Further, different VCDs are indicated for the closure of different hole sizes in the range of 4F to 24F and may be specifically indicated for 'large holes' and 'small holes'[2]. Therefore, 'large hole' and 'small hole' VCDs differ from each other. Other methods of closure of holes include manual compression, surgical suturing and closure assist devices. Manual compression involves application of pressure by a healthcare professional, to the skin above the access site for several minutes until the hole begins to heal naturally. It has been submitted that apart from small hole VCDs, there is no overlap among the products of Parties in India. Further, Abbott does not have any such pipeline product which would be identical or substitutable with the pipeline products of SJM and vice versa. As per the information provided by the Parties, there exists no actual or potential vertical relationship between the activities of the Parties in India.

7. While Abbott is active in India in 'large hole' VCD, SJM is only selling 'small hole' VCD which is not substitutable with 'large hole' VCD. Therefore, the Parties' activities overlap in 'small hole' VCDs. As per submissions of the Parties, the relevant product market includes small hole VCDs and manual compression. However, the Commission noted that

[2] Holes sizes up to and including 8F are considered to be small holes.

manual compression cannot be considered a substitute for VCDs considering that it is time consuming, labor-intensive and cheap. Further, different VCDs are indicated for the closure of specific hole sizes. Therefore, the Commission is of the view that small hole VCDs form a separate segment. The Commission has also examined the overlapping products for the individual hole sizes in the range of 5F - 8F. With regard to the relevant geographic market, the Commission observed that it is whole territory of India.

8. With regard to the presence of the Parties in the market for small hole VCDs, the Commission observed that in 2015, the combined market share of the Parties in the small hole VCDs as well as the individual hole sizes within small hole VCDs, was in the range of 90-100 percent. The other competitor i.e. Cardinal Health had a market share of only 0-5 percent. Therefore, the proposed combination enhances the merged entity's market power in the market for small hole VCDs in India. Further, the market for small hole VCDs in India is already highly concentrated. The Commission also observed that small hole VCDs are imported into India.

9. In order to address the concerns emanating from the proposed combination, vide their submission dated 21st October, 2016, under Regulation 19(2) of Combination Regulations, Parties have submitted a modification in the form of a plan of divestiture of the entire small-hole VCD segment of SJM on a worldwide basis ("**Modification proposed**") to Terumo Corporation, Japan ("**Terumo**").

10. The Commission, in its meeting held on 21st November, 2016, considered and assessed the proposed combination as well as the Modification proposed and decided to seek additional information from the Parties relating to the Modification proposed. The same was communicated to the Parties vide Commission's letter dated 24th November, 2016. Parties provided the required additional information relating to Modification proposed on 28th November, 2016 and 5th December, 2016. The details of the Modification proposed and Terumo, as submitted by the Parties are as under:

    i. Purchaser: Terumo is a global producer of medical products. Its cardiac and vascular business, which accounts for around 50 percent of its global revenues, sell a broad range of devices used in cardiac and vascular surgery and interventional procedures performed inside blood vessels. In India, Terumo has been present for the last 16 years through its subsidiaries Terumo India Private Limited ("**Terumo**

Limited ("**Terumo India**") and Terumo Penpol Pvt. Limited ("**Terumo Penpol**"). Terumo India, *inter-alia*, manufactures and supplies Terumo interventional systems, cardiovascular products and infusion systems. Terumo Penpol primarily manufactures blood bags in India for sales to Indian customers, including leading hospitals and also uses its Indian manufacturing facility as an export hub for making sales to various countries.

ii. There are no structural and financial linkages of Terumo with Parties and thus Parties and Terumo are independent entities.

iii. Products/Trademarks being sold: With regards to the overlapping business, the plan of divestiture includes sale of the products globally for SJM's Angio-Seal™ and Femoseal™ VCDs. Amongst these, only one product line, Angio-Seal, is being sold in India by SJM.

iv. Sale of technology, know-how and manufacturing facilities: The divestiture includes SJM's global VCD manufacturing capability, including SJM's production facility in Puerto Rico which accounts for most of SJM's global VCD sales, intellectual property rights, including patents, trademarks and know-how as well as employees.

v. The divestment business will include transitional services as agreed with Terumo including IT, Finance/accounting and other applicable support.

11. The Commission observed that Terumo is an independent company, neither controlled by Abbott nor SJM and has no common directors with either Abbott or SJM. Further, although Terumo does not produce or sell VCDs anywhere in the world (including in India), it is present in related businesses and has expertise in researching, developing, marketing and selling cardiovascular products. It has a well-developed cardiovascular marketing and sales team in India and established industry presence and reputation with current purchasers of SJM's VCD business. The Modification proposed would remove the overlap between Abbott and SJM in India, i.e. in small-hole VCDs, and addresses the Commission's concerns emanating from the proposed combination.

12. Considering the facts on record and the details provided in the notice 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 proposed combination along with the

Modification proposed, is not likely to have an appreciable adverse effect on competition in India. Therefore, Commission hereby approves the same under sub-section (1) of section 31 of the Act, subject to carrying out of the Modification proposed by the Parties.

13. The Parties are directed to inform the Commission as soon as the Modification proposed by them is carried out and the proposed combination is consummated. In case, there is any change in the terms and conditions of the Modification proposed or if the Modification proposed is not carried out, Parties are directed to intimate the Commission of such changes without any delay and the Commission may reconsider its order of approving the proposed combination.

14. This order shall stand revoked if, at any time, the information provided by the Parties is found to be incorrect.

15. The information provided by the Parties is confidential at this stage in terms of and subject to provisions of Section 57 of the Act.

16. The Secretary is directed to communicate to the Parties accordingly.