APPENDIX A

LEGAL PROVISIONS

1. Legal & Regulatory Regime of Indian Medical Device Sector:

1.1 The Drugs and Cosmetics Act, 1940, ("**DCA**"), together with Rules framed thereunder, viz. Drugs and Cosmetics Rules, 1945 ("**D&C Rules**") and the Medical Devices Rules, 2017 ("**MDR**") regulates the Indian medical device sector, by governing their authorization, import, manufacture, distribution and sale in India.

1.2 The MDR classifies medical devices into four classes as Class A (low risk), Class B (low-moderate risk), Class C (moderate-high risk) and Class D (high risk).

1.3 Each manufacturing location requires a separate license for each Notified Medical Device. The license for manufacturing a Class A or Class B device is issued by the State Licensing Authority whereas the licensing to manufacture a Class C or Class D device is issued by the Central Licensing Authority. Importing a Notified Medical Device into India requires additional legal formalities, including under the provisions of the Export and Import Policy of India.

1.4 The MDR regulates only certain categories of medical devices specifically notified for regulation by the Ministry of Health and Family Welfare. At the time of enactment of the MDR, only 15 categories of medical devices were regulated under those rules. 14 additional medical devices were notified and included within the regulatory framework in 2018 and 2019 with effect from different points of time in 2019, 2020 and 2021.

Recent Amendments:

1.5 On **11th February, 2020**, the Government of India gazetted two Notifications, whereby (a) vide S.O. 648(E), in pursuance of Section 3(b)(iv) of DCA, a new definition of medical devices was incorporated and (b) vide G.S.R. 102 (E), the Medical Devices (Amendment) Rules, 2020 were issued.

1.6 By virtue of the above S.O. 648(E) issued by the Ministry of Health and Family Welfare, which came into force on 1st April 2020, all medical devices were effectively brought within the scope of the MDR ("**Definition Notification**"). Rather than notifying each individual medical device, the Definition Notification includes an expansive and catch-all definition of medical devices.

1.7 The Definition Notification defines a medical device as follows.

"All devices, including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does **not** achieve its primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of —

(i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
(ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
(iii) investigation, replacement or modification or support of the anatomy or of a physiological process;
(iv) supporting or sustaining life;
(v) disinfection of medical devices; and
(vi) control of conception.

1.8 By virtue of the above G.S.R. 102 (E) issued by the Ministry of Health and Family Welfare, Medical Devices (Amendment) Rules, 2020 were published, stating inter alia that Chapter IIIA of MDR *(Registration of Certain Medical Devices)* shall be applicable to all devices notified under clause (b) of section 3 of the DCA except the medical devices and devices specified in the Annexure of Eighth Schedule of these Rules and further that those Medical devices shall be registered with the Central Licensing Authority through an identified online portal established by the Central Drugs Standard Control. Provided that registration under this Chapter shall be on voluntary basis for a period of eighteen months from the commencement of this Chapter, after which, it shall be mandatory.

1.9 Rule 90 of MDR provides that the medical devices specified in the Eighth Schedule shall be exempt from the provisions of these rules to the extent and subject to the conditions specified in that Schedule. The Eighth Schedule lists the following **devices:**

1. Disposable Hypodermic Syringes
2. Disposable Hypodermic Needles
3. Disposable Perfusion Sets
4. Substances used for in vitro diagnosis including Blood Grouping Sera
5. Cardiac Stents
6. Drug Eluting Stents
7. Catheters

8. Intra Ocular Lenses
9. I.V. Cannulae
10. Bone Cements
11. Heart Valves
12. Scalp Vein Set
13. Orthopedic Implants
14. Internal Prosthetic Replacements
15. Ablation Devices
16. Ligatures, Sutures and Staplers
17. Intra Uterine Devices (Cu-T)
18. Condoms
19. Tubal Rings
20. Surgical Dressings
21. Umbilical tapes
22. Blood/Blood Component Bags
*23. Organ Preservative Solution**
24. Nebulizer (effective from 1 Jan.2021)
25. Blood Pressure Monitoring Device(effective from 1 Jan.2021)
26. Glucometer (effective from 1 Jan.2021)
27. Digital Thermometer (effective from 1 Jan.2021)
28. All implantable medical devices Equipment (effective from 1, April,2021)
29. CT Scan Equipment (effective from 1, April,2021)
30. MRI Equipment (effective from 1, April,2021)
31. Defibrillators (effective from 1, April,2021)
32. PET Equipment(effective from 1, April,2021)
33. X-Ray Machine (effective from 1, April,2021)
34. Dialysis Machine (effective from 1, April,2021)
35. Bone marrow cell separator (effective from 1, April,2021)
36. Disinfectants and insecticide specified in Medical Devices Rules, 2017
37. Ultrasound equipment (effective from 1, November, 2020)

1.10 The Medical Devices (Amendment) Rules, 2020, also amended the Eighth Schedule. The amended Eighth Schedule provides that such exemption shall cease after a period of *thirty months* for low risk - Class A devices and low moderate risk - Class B devices and after a period of *forty-two months* for moderate high risk – Class C devices and high risk – Class D devices, respectively from the date of the notification.

1.11 The cumulative effect of these two notifications is that **all medical devices** will be brought under the fold of quality and safety regulation from the effective date of both these notifications – 1st **April, 2020**.

1.12 To allow manufacturers/importers of newly notified medical devices sufficient time to ensure compliance with the MDR, the Health Ministry introduced a **temporary exemption** from compliance requirements under the MDR. The exemption commenced on 11th February, 2020, and extends for a period of 30 months for Class A and Class B devices and 42 months for Class C and Class D devices ("**Exemption Notification**"). The exemption is conditional on manufacturers/importers registering their devices on the Online System for Medical Devices established by the CDSCO for this purpose.

Pricing

1.13 The Drugs (Prices Control) Order, 2013 ("**DPCO**") regulates the prices of all drugs and notified medical devices in India. Under the DPCO, prices of notified medical devices are regulated in two categories:

i. Medical devices specified in the National List of Essential Medicines/First Schedule to the DPCO (**"Scheduled Formulations**"); and
ii. Other notified medical devices ("**Non-scheduled Formulations**").

1.14 The ceiling prices of Scheduled Formulations is fixed by the NPPA. The prices of Non-scheduled Formulations are controlled indirectly.

1.15 As all medical devices in India are regulated from 1st April, 2020, they are consequently subject to price control since then. The Exemption Period under the MDR does not apply to price control as the prices of medical devices are controlled under a different regulation than the MDR.

Regulatory Authorities governing medical devices

1.16 The following regulatory authorities have jurisdiction over medical devices in India:

i. The Central Drugs Standard Control Organisation ("**CDSCO**") headed by the Drugs Controller General of India ("**DCGI**") under the Ministry of Health and Family Welfare

The CDSCO regulates import, manufacture, marketing and clinical trials of drugs, biologics and medical devices for the entire territory of India. Apart from co-ordination with state licensing authorities, the DCGI is responsible for handling matters of: (a). import of all Classes of medical devices; (b). manufacture of Classes C and D devices; (c). clinical investigation and approval of investigational medical devices; and (d). clinical performance evaluation and approval of new in vitro diagnostic devices.

ii. State drug licensing authorities (**'SLAs"**).

SLAs (who are the state-level Food and Drug Administration), independently regulates manufacture and sale of drugs, biologics and medical devices within the territory of that State. SLAs are responsible for handling matters of: (a). manufacture (for sale or distribution) of classes A and B devices; (b). licensing for sale, stocking, exhibition or offer for sale or distribution of medical devices of all classes

In certain cases, there is an overlap of function between DCGI and SLAs. In such cases, SLAs operate under the direction of DCGI.

iii. Gazetted officers authorised by the State Governments to enforce drug advertising regulations.

iv. National Pharmaceutical Pricing Authority ("**NPPA**") under the Department of Pharmaceuticals ("**DoP**").

NPPA fixes prices of certain essential drugs, biologicals and medical devices for the entire territory of India. It monitors price movements of other drugs, biologicals and medical devices to ensure that the prices do not increase more than 10% year on year.

v. Controller of Legal Metrology (**"Controller"**)

Each State, through its Controller, regulates packaging and labelling of medical devices. The Controller does not have jurisdiction over drugs and biologicals.

2. Statutes governing Labelling requirements of Medical Devices (MDs)

2.1 The labelling of Notified Medical Devices is governed by the following statutes:

2.1.1 **Drugs & Cosmetics Rules, 1945 ("D&C Rules")** & The **Medical Devices Rules, 2017 ("MDR")** – A Notified Medical Device must be labelled according to specifications outlined in the MDR before it is sold or distributed in India. It is permissible for importers to print the mandatory declarations on a label and stick the label to the package. The MDR

prescribes the contents of the label to the package, such as name of the medical device, name of manufacturer and address of manufacturing premises, the details necessary for the user to identify the device and its use, etc.

2.1.2 **Legal Metrology Act ("LMA")** and the **Legal Metrology (Packaged Commodity) Rules, 2011** – The LMA and the Rules, notified under the Legal Metrology Act, 2009, regulates the packaging and labelling of pre-packed commodities in India. Since 1st January, 2018, Notified Medical Devices are required to bear additional declarations and particulars on retail package as prescribed under the Legal Metrology (Packaged Commodity) Rules, 2011.

2.1.3 **Drug (Prices Control) Order, 2013 –** It requires all manufacturers and importers of Notified Medical Devices to declare the MRP on the label.

3. Analysis of Provisions for Labelling of MDs

3.1 Under **D&C Rules & MDR**

3.1.1 Rule 32 of D&C Rules provides that no drug shall be imported unless it is packed and labelled in conformity with the rules in Parts IX and X and further conforms to the standards laid down in Part XII provided that in the case of drugs intended for veterinary use, the packing and labelling shall conform to the rules in Parts IX and X and Schedule F.

3.1.2 Rule 96 of D&C Rules provides the Manner of Labelling of any Drug.

3.1.3 Rule 109 of D&C Rules provides specifically for Labelling of Medical Devices:—The labelling of Medical devices shall confirm to the Indian Standards Specifications laid down from time to time by the Bureau of Indian Standards in addition to any other requirement prescribed under the said rules.

3.1.4 MDR are applicable to devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of DCA. MDR provides that before

a Notified Medical Device is sold or distributed in India, it must be labelled according to specifications outlined in the MDR.

3.1.5 Rule 44 of the MDR prescribes the contents of the label of medical devices, such as name of the medical device, the details necessary for the user to identify the device and its use, name of manufacturer and address of manufacturing premises where the device has been manufactured, statement as to the net contents (in terms of weight or measure), license number, date of manufacture, date of expiry (alternatively, its shelf life), applicable storing and handling conditions, warnings and precautions, the batch number, as well as the manufacturing license number under which it is manufactured (if manufactured in India).

3.1.6 Imported products must display the import license number, name and address of the importer, address of the actual manufacturing premises and the date of manufacture. Medical devices that are manufactured for export to other countries are exempted from certain labelling requirements and are instead required to adopt the requirements of the law to which the device is being exported.

3.1.7 The precise labelling requirements for medical devices under the MDR are contained in **Rule 44 of MDR** for devices intended to be marketed in India and **Rule 45** of MDR contains exemption from labelling requirements for export of medical devices.

3.1.8 Rule 46 of MDR states that with effect from 1st day of January, 2022, a medical device, approved for manufacture for sale or distribution or import, shall bear unique device identification, which shall contain device identifier and production identifier.

3.2 Under **LMA and Rules** framed thereunder

3.2.1 LMA is an Act to establish and enforce standards of weights and measures, regulate trade and commerce in weights, measures and other goods, which are sold or distributed by weight, measure or number and for matters connected therewith or incidental thereto.

3.2.2 **Section 18 of LMA** contains provisions for **Declarations on pre-packaged commodities.** It mandates that - No person shall manufacture, pack, sell, import, distribute, deliver, offer, expose or possess for sale any pre-packaged commodity unless such package is in such standard quantities or number, and bears thereon, such declarations and particulars in such manner as may be prescribed. It also mandates that any advertisement mentioning of the retail sale price of a pre-packaged commodity should also contain a declaration as to the net quantity or number of the commodity contained in the package in such form and manner as may be prescribed.

3.2.3 The Legal Metrology (Packaged Commodity) Rules, 2011, ("**PCR**") notified under the Legal Metrology Act, 2009, regulates the packaging and labelling of pre-packed commodities in India. From January 1, 2018, Notified Medical Devices are required to bear additional declarations and particulars on the retail package as prescribed under the PCR. Like the MDR, it is permissible for importers to print the mandatory declarations on a label and sticker the label to the package. PCR applies to medical devices in addition to the MDR.

3.2.4 **Chapter II of** PCR contains provisions applicable to **PACKAGES** intended for **RETAIL SALE**. **Rules 3 to 23** fall under Chapter II.

3.2.5 Rule 3 states that the provisions of Chapter II shall not apply to-

(a) packages of commodities containing quantity of more than 25 kilogram or 25 litre;

(b) cement, fertilizer and agricultural farm produce sold in bags above 50 kilogram; and

(c) packaged commodities meant for industrial consumers or institutional consumers.

3.2.6 Rule 4 of PCR provides for Regulation for pre-packing and sale etc., of commodities in packaged form. It states that on and from the commencement of these rules, no person shall pre-pack or cause or permit to be pre-packed any commodity for sale, distribution or delivery unless the package in which the commodity is pre-packed bears thereon,

or on a label securely affixed thereto, such declarations as are required to be made under these rules.

3.2.7 Rule 6 of PCR provides for Declarations to be made on every package. It states that every package shall thereon or on label securely affixed thereto, a definite, plain and conspicuous declaration made in accordance with the provisions of this chapter as, to common or generic names of the commodity contained in the package and in case of packages with more than one product, the name and number or quantity of each product shall be mentioned on the package.

*Under **Rule 6,** the following **Declarations** are to be made on every package:*

(a) the name and address of the manufacturer, or where the manufacturer is not the packer, the name and address of the manufacturer and packer and for any imported package the name and address of the importer shall be mentioned on every package.

(b) The name of the country of origin or manufacture or assembly in case of imported products shall be mentioned on the package;

(c) The common or generic names of the commodity contained in the package and in case of packages with more than one product, the name and number or quantity of each product shall be mentioned on the package.

(d) The net quantity, in terms of the standard unit of weight or measure, of the commodity contained in the package or where the commodity is packed or sold by number, the number of the commodity contained in the package shall be mentioned.

(e) The month and year in which the commodity is manufactured or pre-packed or imported shall be mentioned in the package.

(f) If a package contains a commodity which may become unfit for human consumption after a period of time, the 'best before or use by the date, month and year' shall also be mentioned on the label:

(g) the retail sale price of the package shall clearly indicate that it is the maximum retail price inclusive of all taxes and the price in rupees and paise be rounded off to the nearest rupee or 50 paise;

(h) Where the sizes of the commodity contained in the package are relevant, the dimensions of the commodity contained in the package and if the dimensions of the different pieces are different, the dimensions of each such different piece shall be mentioned.

(i) such other matter as are specified in these rules:

3.2.8 Chapter III of PCR contains provisions applicable to Wholesale Packages. Rule 24 thereunder states that every wholesale package shall bear thereon a legible, definite, plain and conspicuous declaration as to:

(a) The name and address of the manufacturer or importer or where the manufacturer or importer is not the packer, of the packer;

(b) the identity of the commodity contained in the package; and

(c) the total number of retail package contained in such wholesale package or the net quantity in terms of standard units of weights, measures or number of the commodity contained in wholesale package;

3.2.9 **Chapter IV** of PCR contains provisions pertaining to **Export and Import of Packaged Commodities.** Rule 25 thereunder contains provisions for restrictions on sale of export packages in India.

3.2.10 **Chapter V** of PCR contains provisions pertaining to Exemptions. Clause (c) of Rule 26 exempted packages if it contains **scheduled formulations** and **non-scheduled formulations** covered under the Drugs (Price Control) Order,1995 made under Section 3 of the Essential Commodities Act, 1955. However, by virtue of **G.S.R. 629(E) dated 23rd June, 2017**, issued by the Ministry of Consumer Affairs, Food and Public Distribution (Department of Consumer Affairs)**, Rule 26 was amended w.e.f. 01.01.2018 by inserting the following proviso:-**

***"Provided that no exemption shall be applicable to medical devices declared as drugs"*.**

3.2.11 The impact of this amendment is that medical devices came under the purview of PCR on and from 01.01.2018.

4. Penalties under LMA and PCR

4.1 Section 16 of LMA provides for **Forfeiture** of infringing package**.** It states that every package made in contravention of section 18, used in the course of, or in relation to, any trade and commerce and seized under section 15, shall be liable to be forfeited to the State Government.

4.2 **Section 36** of LMA provides for **Penalty for selling, etc., of non-standard packages.** It states that whoever manufactures, packs, imports, sells, distributes, delivers or otherwise transfers, offers, exposes or possesses for sale, or causes to be sold, distributed, delivered or otherwise transferred, offered, exposed for sale any pre-packaged commodity which does not conform to the declarations on the package as provided in this Act, shall be punished with fine which may extend to twenty-five thousand rupees, for the second offence, with fine which may extend to fifty thousand rupees and for the subsequent offence, with fine which shall not be less than fifty thousand rupees but which may extend to one lakh rupees or with imprisonment for a term which may extend to one year or with both. It further provides for a penalty in the event of error in net quantity, which penalty shall be punishment with fine of not less than ten thousand rupees but which may extend to fifty thousand rupees and for the second and subsequent offence, with fine which may extend to one lakh rupees or with imprisonment for a term which may extend to one year or with both.

4.3 **Section 48** of LMA provides for **Compounding of offences.** It inter alia states that any offence punishable under section 25, sections 27 to 39, sections 45 to 47 of the LMA, or any rule made under sub-section (3) of section 52 may, either before or after the institution of the prosecution, be compounded, on payment for credit to the Government of such sum as may be prescribed.

4.4 **Section 49** of LMA provides inter alia that where the offence is committed by a company, it is only those persons who are specified in Clauses (a)(i) and (a)(ii) who would be deemed to be guilty of the offence or, in other words, they would be vicariously liable to be punished. However, even for such persons a succor is provided under the proviso to sub-section (1) to establish and prove that the offence alleged to have been committed by the company was without his/her knowledge and he/she had exercised all due diligence to prevent the commission of such offence. In fact, sub-section (2) of Section 49 enables the company to nominate a person to be in-charge of, and responsible to, the company for the conduct of the business of the company and in the event of such nomination having been made, it would be such person only who can be arraigned as an accused. In other words, those persons who are not even remotely connected to the conduct of the business of the company and not being responsible for the conducting of day-to-day business of the company or persons who are not in-charge of the company cannot be implicated as an

accused, merely because they are either the officer of the company or the director of the company, as the case may be.

4.5 **Rule 32** of PCR contains provisions of **Fine for contravention of rules -** Whoever contravenes any provisions of these rules, for which no punishment is provided, shall be punished with fine of five thousand rupees. **Rule 32A** specifies the sum of compounding of offences committed under the Act in the Table thereunder.

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