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HOW DOES THE NEW MEDICAL DEVICE REGULATION OF 2017 EFFECT THE DEVICE MANUFACTURERS AND THE MARKET?

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INTRODUCTION

Medical Devices is among the most expeditious growing networks in the world. India is the 4th most astronomically immense market in Asia preceded by China South Korea and Japan and is among the top 10 ecumenical markets in the world.

Under the Directive (93/42/EEC), Medical Devices is defined as "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means."[1]

The Medical Devices varies from an immensely colossal range starting from simple testers to involute diagnostic contrivances utilized in the medical field. The desideratum for regulating the "placing in the market", or for the purport of "making available these products" or appendages for such contrivances in the market for human use incremented with the developments in the field of medical industry. Although the term is relatively broad, we should not perplex ourselves of Medical Contrivances with other products used to remedy

[1] "COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 Concerning ..." (*europa*June 14, 1993) <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF> accessed 30 October 2019.

diseases. Drugs and other Pharmaceutical formulas used to remedy diseases does not fall under the category of Medical Devices. Medical Devices are essentially those apparatus or contrivances which are utilized in diagnostics and such processes unlike for remedying the ailment/disease. The European Union has Directives which regulate the certification, approval and release in the market of such Medical Devices. This paper discusses the old and new regulations with respect to the Directives and gives an analysis of why the new Directives were implemented and what changes would the medical industry and the Medical Devices producers would have to face with the coming into force of such Directives.

EUROPEAN UNION

Under the European Union, there is no single body that governs the aspects relating to marketing and certification of the Medical Devices. The body regulating such devices are three harmonised Directives namely-

1. Medical Devices Directive 93/42/EEC
2. Active Implantable Medical Devices Directive 90/385/EEC (AIMDD)
3. In Vitro Diagnostic (IVD) Directive 98/79/EC (IVDMDD)

The major task of these directives is to outline the essential requirements, free movement, laying down of standards, safety and performance requirements of the Medical Devices before being released in the market. With reference to aspects such as the source of the energy of the device, the duration of contact, the combination of the device (the active principles), the invasiveness of the device etc. the Directives have classified the Medical Devices into 4 broad categories. These are classes I, IIa, IIb, and III.[2]

The following are a few examples of devices that come under the said categories.

"Class I - Sterile plasters, Blood Pressure Monitors and Hospital Beds, bed pans, Thermometers, weighing scales etc.

Class IIa – Powered wheelchairs, Hearing aids, X ray diagnostic equipment, Ultrasonic diagnostic equipment etc.

Class IIb – ventilators, surgical lasers, Blood bags, Infusion pumps etc.

Class III – Vascular & Neurological implants, silicon gel-filled breast implants, PTCA balloons, Implanted cerebella stimulators, Drug Eluting Coronary Stents etc."[3]

The COUNCIL DIRECTIVE 93/42/EEC under Article 2 states that all member states shall undergo certain fulfilment of requirements before releasing any Medical Devices in the markets for use. Thus, it has to obtain a CE mark upon which the manufacturers are authorised to release such Devices for public use. To receive the CE certification on the Medical Device, the manufacturers are required to comply with the safety requirements of the

[2] "COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 Concerning ..." (*europa*June 14, 1993) <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF> accessed 30 October 2019.

[3] "REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF ..." (*europa*) Article 1, Article 2, Article 22, Article 23, Article 51, Article 52, Annex VIII, IX, X, XVI <http://academy.gmp-compliance.org/guidemgr/files/EU_2017_746_IVDR.PDF> accessed October 30, 2019.

EU Directives which is an obligatory requisite to be complied with afore putting the Device into the market except for Devices which are either Custom Made, for health protection under urgent circumstances, clinical investigations, devices for humanitarian use or for In-House use.

New Regulations-

On 5th April 2017, the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL was adopted for medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.[4] And the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL was adopted for in vitro diagnostic medical devices and repealing Directive 98/79/EC[5] and Commission Decision 2010/227/EU.[6]

The new Medical Devices Regulations will come into force after a transition period of 3 years as stated in the Directive which reads as "The necessary common specifications shall be adopted by 26 May 2020. They shall apply as from six months after the date of their entry into force or from 26 May 2020, whichever is the latest."[7] This essentially means that those Countries who have a single market base in the Europe would witness a significant change in their business routine.

The aim of the incipient Medical Directive Regulation is to address some innate impotencies in the old directives as well as the swift witnessed in the evolution of science and technology in the field of medical Devices. To do so, it introduces several key amendments, among them:

[4] "COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 Concerning ..." (*europa*June 14, 1993) <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF> accessed 30 October 2019.
[5] "Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in Vitro Diagnostic Medical Devices" (*Europa* October 27, 1998) <https://www.document-center.com/standards/show/98/79/EC> accessed October 30, 2019.
[6] "REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF ..." (*europa*) <http://academy.gmp-compliance.org/guidemgr/files/EU_2017_746_IVDR.PDF> accessed October 30, 2019.
[7] "Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices" (Europa) < https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN> accessed 29 October 2019, Article 1(2).

- The vigilance and market surveillance between the EU countries were furthered by improved coordination mechanisms.[8]
- It also provides for an EU database for existing Medical Devices and also provides for a Unique device identification system making is traceable by the authorities thus improving the transparency in the whole system.[9]
- The rule on clinical evidence was reinforced along with coordinated procedure for sanction of multi-centre clinical investigations.[10]
- more rigorous ex-ante control for high-risk contrivances via an incipient pre-market scrutiny mechanism with the involution of experts at EU level.
- Certain aesthetic devices having the same risk factors and posing same characteristics of a Medical Device shall be bought under the purview of this Regulation which, prior to the coming into force of this Regulation was not bound by the regulation of earlier Directives.
- The most market release surveillance of the Device has been strengthened.
- The designation and processes of the Notified Bodies (NB) shall be reinforced.
- The new Directive introduces a "implant card" provision for the records and all related information of implanted devices of a patient.[11]

Marketing Approval under the EU Regulations-

"Step 1 - Analyse which EU Medical Device Directive would be applicable to your device: 93/42/EEC -Medical Devices Directive (MDD) or 90/385/EEC - Active Implantable Medical Devices Directive (AIMDD) or In Vitro Diagnostic Devices Directive (98/79/EC).

[8] "Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices" (Europa) < https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN> accessed 29 October 2019, Articles 84, Article 85, Article 86, Article 87, Article 88, Article 93.
[9] "Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices" (Europa) < https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN> accessed 29 October 2019, Article 33.
[10] "Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices" (Europa) < https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN> accessed 29 October 2019, Article2, Article 55, Article 61, Annex XIV, Annex XV.
[11] "Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices" (Europa) < https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN> accessed 29 October 2019, Article 27, Article 87, Article 18, Article 19.

Step 2 – Analyse the classification of your device of the Medical Devices Directive (MDD): Class I (non-sterile, non-measuring), Class I (sterile, measuring), Class IIa, Class IIb or Class III/AIMD whichever is suitable among the classification. Active implantable medical devices are subject to the regulatory requirements as Class III devices.

Step 3 - For all devices except Class I (non-sterile, non-measuring), implement Quality Management System (QMS) in accordance with Annex II or V of the MDD. Companies apply the ISO 13485 standards to achieve the Quality Management System compliance. Quality Management System is generally not required for Class I (non-sterile, non-measuring). However, a Post- Market Surveillance (PMS) procedure is required, though not audited by a Notified Body (NB).

Step 4 – The next step it to prepare a Technical File which gives comprehensive information about the medical device for Class I, IIa, and IIb with demonstrating the compliance with Directive 93/42/EEC. A Clinical data would be required by all such devices. Further, a Digital Report is to be set forth for the Class III medical devices. Clinical studies are required for Class IIb and III implants, though existing clinical data may be acceptable. A European based Competent Authority must pre-approve the Clinical trials in Europe.

Step 5 – An Authorized Representative located in Europe (EC Rep) is to be appointed if the company does not have a location in Europe. The qualification for the EC Rep is that he should be able to sufficiently handle the regulatory issues. The Companies are then required to place the name of the EC Rep along with the address either on the device label or on the outer packaging or on the Instructions of Use manual.

Step 6 - For all devices except Class I (non-sterile, non-measuring), your QMS and Technical File or Design Dossier must be audited by a Notified Body, a third party accredited by the European authorities to examine the products and the Producing Companies.

Step 7 - For all devices except Class I (non-sterile, non-measuring), you will be issued a European CE Marking Certificate for your device and an ISO 13485 certificate for your capacity after the examination is successfully done by the Notified Body. ISO 13485 certification must be renewed every year. Further, a 3-year life is given to every CE Marking certificate is typically granted.

Step 8 – A Declaration of Conformity is then to be prepared, which is to be a legally binding document which clearly state that the applicable Directive is complied with is to be prepared by the manufacturer of the Medical Devices.[12]

Step 9 – Every Medical Device falling under the Class I shall be registered where the Manufacturer's EC Rep is based with the Competent Authority. Devices falling under Classes IIa, IIb, and III are also required additional registrations in some of the European Union states before it is released in the market.

Step 10 – Under this provision, the annual Notified Body reports are not required for the Class I Medical Devices which included non-sterile and non-measuring devices. Although, a Clinical Evaluation Report update along with the Post-Market Surveillance activities is mandatory."[13]

The Directive 2017/745 introduces minor changes in the process of obtaining the CE mark for approval of Medical Devices. It requires a Person Responsible for Regulatory Compliance to be appointed before the determination of classification criteria. Further, for Class I Devices, a QMS is required to be done through a Notified Body intervention[14]. With the New Legislation in picture, all the devices including the Legacy Products would require a clinical data in place. The provisions regarding renewal and validity of the CE marking certificate remains the same as the 93/42/EEC, 98/79/EC and 90/385/EEC. Also, a Unique Device Identifier (UDI)[15] system is introduced which shall also be registered and be put up on the label and the regulatory documents.

[12] "COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 Concerning ..." (*europa*June 14, 1993) Annexure IV <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF> accessed 30 October 2019.

[13] Elizabeth Pugh "Europe Medical Devices Regulation (MDR) CE Marking Regulatory Process" (*Emergo*September 23, 2019) <https://www.emergobyul.com/resources/europe-medical-devices-regulation-mdr-ce-marking-regulatory-process> accessed October 31, 2019.

[14] "REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF ..." (*europa*) Article2, Article 55, Article 61, Annex XIV, Annex XV <http://academy.gmp-compliance.org/guidemgr/files/EU_2017_746_IVDR.PDF> accessed October 30, 2019.

[15] "Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices" (Europa) < https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN> accessed 29 October 2019, Article 27, Article 87, Article 18, Article 19.

CONCLUSION

The two new Regulations, i.e. Regulation (EU) 2017/745 of the European Parliament and of the Council, and the Regulation (EU) 2017/746 of the European Parliament and of the Council are designated to modify the safety and quality features of the Medical Devices in the European Union Market. It tries to improve the standard of quality check, reinforce the designation of Notified Bodies, provides for rigid Pre-Market Scrutiny, and takes special regards to high risk devices. The new regulations also cater to better Post-Market Surveillance and Clinical evidences. It is also to be taken into consideration that the New modification is in the form of a Regulation and not Directives. As compared to Directives, Regulations are on a better footing as far as implementation is concerned since Regulations are directly applicable to the market and producers unlike in Directives which has to be transposed into the National Laws of the Member States for it to be implemented. It also reduces the risk of disparity while interpreting the provisions across all Signatory States.

With the new Regulation in place, the manufacturers of the Medical Devices are expected to work closely with the Notifying Body as per the provisions applicable depending upon the classification of Devices, for the consistency while interpreting the Regulations. It is also quite prominent that the Medical Devices Manufacturers might face huge burdens due to the implementation of provisions such as the UDI, additional clinical evidences, changes in the quality system and technical files etc. However, expecting a pro-active approach towards the new Regulations for its proper implementation, such changes should be prioritised.