HISTORY OF MEDICAL DEVICE REGULATIONS

A **medical device** is any device intended to be used for medical purposes. Significant potential for hazards are inherent when using a device for medical purposes and thus medical devices must be proved safe and effective with reasonable assurance before regulating governments allow marketing of the device in their country. As a general rule, as the associated risk of the device increases the amount of testing required to establish safety and efficacy also increases. Further, as associated risk increases the potential benefit to the patient must also increase.

Study of archaeology and Roman medical literature also indicate that many types of medical devices were in widespread use during the time of ancient Rome. In the United States, it was not until the Federal Food, Drug, and Cosmetic Act (FD&C Act) in 1938 that medical devices were regulated at all. It was not until later in 1976 that the Medical Device Amendments to the FD&C Act established medical device regulation and oversight as we know it today in the United States. Medical device regulation in Europe as we know it today came into effect in 1993 by what is collectively known as the Medical Device Directive (MDD).[5] On May 26, 2017, the Medical Device Regulation (MDR) replaced the MDD.[6]

Medical devices vary in both their intended use and indications for use. Examples range from simple, low-risk devices such as tongue depressors, medical thermometers, disposable gloves, and bedpans to complex, high-risk devices that are implanted and sustain life. Examples of high-risk devices include artificial hearts, pacemakers, joint replacements, and CT scans. The design of medical devices constitutes a major segment of the field of biomedical engineering.

The global medical device market was estimated to be between $220 and US$250 billion in 2013.The United States controls ≈40% of the global market followed by Europe (25%), Japan (15%), and the rest of the world (20%). Although collectively Europe has a larger share, Japan has the second largest country market share. The largest market shares in Europe (in order of market share size) belong to Germany, Italy, France, and the United Kingdom. The rest of the world comprises regions like (in no particular order) Australia, Canada, China, India, and Iran.

Definition

Medical devices were used for surgery in ancient Rome.

A global definition for medical device is difficult to establish because there are numerous regulatory bodies worldwide overseeing the marketing of medical devices. Although these bodies often collaborate and discuss the definition in general, there are subtle differences in wording that prevent a global harmonization of the definition of a medical device, thus the appropriate definition of a medical device depends on the region. Often a portion of the definition of a medical device is intended to differentiate between medical devices and drugs, as the regulatory requirements of the two are different. Definitions also often recognize In vitro diagnostics as a subclass of medical devices and establish accessories as medical devices.

Definitions by region

United States (Food and Drug Administration)

Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act defines a device as an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, *or*
- Intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term 'device' does not include software functions excluded pursuant to section 520(o)."

European Union

According to Article 1 of Council Directive 93/42/EEC, 'medical device' means 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;"

EU Legal framework

Based on the *New Approach*, rules that relate to safety and performance of medical devices were harmonised in the EU in the 1990s. The *New Approach*, defined in a European Council Resolution of May 1985, represents an innovative way of technical harmonisation. It aims to remove technical barriers to trade and dispel the consequent uncertainty for economic operators, to facilitate free movement of goods inside the EU.

The previous core legal framework consisted of three directives:

- Directive 90/385/EEC regarding active implantable medical devices
- Directive 93/42/EEC regarding medical devices

- Directive 98/79/EC regarding *in vitro* diagnostic medical devices (Until 2022, the In Vitro Diagnosis Regulation (IVDR) will replace the EU's current Directive on In-Vitro Diagnostic (98/79/EC)).

They aim at ensuring a high level of protection of human health and safety and the good functioning of the Single Market. These three main directives have been supplemented over time by several modifying and implementing directives, including the last technical revision brought about by Directive 2007/47 EC.

The government of each Member State must appoint a *competent authority* responsible for medical devices. The competent authority (CA) is a body with authority to act on behalf of the member state to ensure that member state government transposes requirements of medical device directives into national law and applies them. The CA reports to the minister of health in the member state. The CA in one Member State has no jurisdiction in any other member state, but exchanges information and tries to reach common positions.

In the UK, for example, the Medicines and Healthcare products Regulatory Agency (MHRA) acted as a CA. In Italy it is the Ministero Salute (Ministry of Health) Medical devices must not be mistaken with medicinal products. In the EU, all medical devices must be identified with the CE mark. The conformity of a medium or high risk medical device with relevant regulations is also assessed by an external entity, the Notified Body, before it can be placed on the market.

In September 2012, the European Commission proposed new legislation aimed at enhancing safety, traceability, and transparency. The regulation was adopted in 2017.

The current core legal framework consists of two regulations, replacing the previous three directives:

- The Medical Devices Regulation (MDR (EU) 2017/745)
- The In Vitro Diagnostic medical devices regulation (IVDR (EU) 2017/746)

The two regulations are supplemented by several guidances developed by the Medical Devices Coordination Group (MDCG).

Japan

Article 2, Paragraph 4, of the Pharmaceutical Affairs Law (PAL) defines medical devices as "instruments and apparatus intended for use in diagnosis, cure or prevention of diseases in humans or other animals; intended to affect the structure or functions of the body of man or other animals."

Rest of the world

Canada

Bags of medical supplies and defibrillators at the York Region EMS Logistics Headquarters in Ontario, Canada

The term medical device, as defined in the Food and Drugs Act, is "any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in: the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in a human being; the

restoration, correction or modification of a body function or the body structure of a human being; the diagnosis of pregnancy in a human being; or the care of a human being during pregnancy and at and after the birth of a child, including the care of the child. It also includes a contraceptive device but does not include a drug." The term covers a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition. Health Canada reviews medical devices to assess their safety, effectiveness, and quality before authorizing their sale in Canada. According to the Act, medical device does not include any device that is intended for use in relation to animals.

India

India has introduced National Medical Device Policy 2023. However, certain medical devices are notified as DRUGS under the Drugs & Cosmetics Act. Section 3 (b) (iv) relating to definition of "drugs" holds that "Devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals" are also drugs. As of April 2022, 14 classes of devices are classified as drugs.