CHAPTER
1

Medical Devices: A History

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Introduction

Medical devices have been integral to healthcare advancements, necessitating robust regulatory frameworks across the globe. Various regions like North America, Europe, Asia, South America, and Oceania have developed unique regulatory systems influenced by their distinct historical backgrounds and governmental structures. These systems ensure that medical devices are safe, effective, and high-quality, balancing innovation with public health safety. From the intricate federal laws in the US and Canada to the harmonized regulations in Europe, the evolving standards in China, the refining mechanisms in Brazil, and the stringent systems in Australia, each approach reflects a continuous effort to protect public health while fostering technological advancements.

North America

United States

To understand the governance of medical devices, it is important to have some knowledge of how medical device laws are enacted, the way medical device regulation is developed, and the historical context in which medical device laws have been established. A basic primer of the US federal government system, while out of the scope of this book, is useful in this context.[1]

The Department of Health and Human Services (HHS) is the government's principal agency for protecting the health of Americans and providing essential human services. HHS oversees the Food and Drug Administration (FDA), part of the Public Health Service (PHS), that is tasked with ensuring that food is safe; human and animal drugs, biological products, and medical devices are safe and effective; and electronic products that emit radiation are safe.[2]

The FDA is required by law to publish regulations in the Federal Register, the government's official publication for notifying the public of agencies' actions. Federal regulations are either required or authorized by statute. FDA uses a notice and comment rulemaking process to issue rules. This process opens proposed rules to public comment periods before finalization. The final rule will explain the regulatory requirements and the impact of the requirements on the industry or the public and respond to the comments on the proposed rule. The regulatory requirements, or codified portion of the final rule, are published in the Code of Federal Regulations (CFR).[3]

The CFR is the official print publication of the codified general and permanent rules published in the Federal Register by federal departments and agencies. In total, there are 50 titles in the CFR, with Title 21 corresponding to food and drugs. Typically, the CFR is cited by title, part, and section, if applicable, such as 21 CFR §812.3, which reads Title 21, Code of Federal Regulations, Part 812, Section 3. Regulations pertaining to medical devices are found in Chapter I, Subchapter H, Part 800-898 of the CFR.[4]

Federal agencies can also issue guidance. The FDA issues guidance documents to explain and publicize the agency's current thinking on a specific topic; however, guidance documents are not legally binding. FDA follows 21 CFR §10.115, good guidance practices, which are the FDA's policies and procedures for developing, issuing, and using guidance documents. All active, current FDA guidance documents can be found on the FDA's website.[5]

Food, Drug, and Medical Device Legislation

Prior to the 19th century, little regulation of food, drugs, or medical devices had been established. Regulation of food in the US dates from early colonial times. Federal controls over the drug supply began with the inspection of imported drugs in 1848, and the first federal biologics law, which addressed the provision of reliable smallpox vaccine to citizens, was passed in 1813. However, the major work of regulating drugs and medical devices occurred in the 20th century. Historically, the enactment of laws to regulate food, drugs, and medical devices has occurred in response to a terrible or catastrophic incident that spurred public outrage and demand for laws governing these products.

Pure Food and Drug Act of 1906 (The Wiley Act). Until the 20th century, states exercised the principal control over domestically produced and distributed foods and drugs, control that was markedly inconsistent from state to state. In 1883, Dr. Harvey Wiley started as the chief chemist at the Division of Chemistry (changed to Bureau of Chemistry after 1901) in the Department of Agriculture. Dr. Wiley was an early and outspoken activist for safe and unadulterated food. With Dr. Wiley's leadership, the government's handling of the adulteration and misbranding of food and drugs took a decidedly different course.[6] Dr. Wiley expanded the division's research in this area, exemplified by Foods and Food Adulterants, a 10-part study published from 1887 to 1902.[7] He

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demonstrated his concern about chemical preservatives as adulterants in the highly publicized Poison Squad experiments, in which 12 male volunteers consumed varying amounts of questionable food additives to determine their impact on health. His work did not lead to the enactment of protective legislation until 1906.

In 1904, author Upton Sinclair worked undercover in Chicago meatpacking plants. His experience was shared in his novel, The Jungle, which detailed the grave working conditions for meat packers and the unsanitary conditions under which meat was prepared and packaged for human consumption. Public awareness and support for food regulations assisted in the passage of the Pure Food and Drug Act of 1906.[8]

On 20 June 1906, President Theodore Roosevelt signed into law the Meat Inspection Act and the Pure Food and Drug Act, also known as the Wiley Act. The Pure Food and Drug Act prohibited misbranded and adulterated foods, drinks, and drugs from entering interstate commerce, and the presence and amount of eleven dangerous ingredients, including alcohol, heroin, and cocaine, had to be listed.[8] This Act was the predecessor of the Food and Drug Act of 1938. It was enforced by the Bureau of Chemistry in the Department of Agriculture.

Food, Drug, and Cosmetic Act of 1938. The Bureau of Chemistry was reorganized with the regulatory function going to the Food, Drug, and Insecticide Administration and was renamed the Food and Drug Administration in 1930.[9] Between 1906 and 1938, numerous spurious products were available for sale with little to no repercussions to the sellers or manufacturers from FDA. At the time, there was no requirement to submit information to FDA prior to marketing, and the government bore the burden of proof to show that a drug's labeling was false or misleading. Also, medical devices were not subject to the Pure Food and Drug Act.

From the 1700s, fraudulent medical devices were being sold with claims of curing all types of diseases. In 1917, nose straighteners, height-stretching machines, and heated rubber applicators advertised as a cure for prostate gland disorders flooded the US market.[10] Radiation added to the problem. The health hazards of radiation became known soon after the discovery of radium. Exaggerated health claims, brought to the attention of Congress in a 1926 report, continued for products containing radium.

Most FDA enforcement activity at the time concerned getting fraudulent devices like these off the market. While the agency continued to monitor products, it could only assist the Federal Trade Commission and the US Post Office, which were charged with overseeing devices and enforcing criminal penalties for mail fraud, respectively, FDA could take no action on its own.[10]

In 1933, a bill was introduced to overhaul the Pure Food and Drug Act, but these efforts were largely unsuccessful until disaster struck. In 1937, more than 100 people, including many children, died after taking a sulfonamide antibacterial preparation called Elixir Sulfanilamide. The product utilized diethylene glycol, a poison, as a solvent.[11] Public outcry to the disaster, including a personal plea to President Franklin Roosevelt from a grieving mother,[12] helped to drive passage of the Food, Drug, and Cosmetic Act (FDCA), which he signed into law on 25 June 1938.

This law included the following changes: medical devices were no longer defined as drugs; cosmetics and medical devices were regulated for the first time; manufacturers were required to provide scientific proof that new drugs were safe for their intended use before being placed on the market; and FDA was given authority to bring federal court injunctions, in addition to product seizures and criminal prosecutions, for violations of the FDCA.

Medical Device Amendments of 1976. From 1938, when the FDCA was enacted, until the early 1960s, medical devices were subject only to policing by the FDA. The agency could bring charges in court if a medical device were found to be filthy, defective, unsafe, adulterated, misbranded, or mislabeled. There were no premarket testing, review, or approval requirements.[10]

In 1962, President John F. Kennedy proposed changes to how medical devices entered the market. Congressional hearings were held, with proposals to regulate medical devices comparably to but separately from how drugs were regulated. In response to the thalidomide tragedy, the Kefauver-Harris Amendment (Drug Amendments of 1962)[9] was passed, but a companion bill that would require premarket approval of new medical devices, which is similar to the system used for drugs, was not.[10]

In 1970, at the behest of President Richard Nixon, the Cooper Committee, led by Dr. Theodore Cooper, director of the National Heart and Lung Institute, was formed to provide recommendations on future medical device legislation. The Cooper Committee calculated that 10,000 injuries were attributable to "therapeutic devices," and more than 700 of the injuries were fatal.[13] The Cooper Committee sent recommendations to Congress, which were still being debated in 1972 and 1973 when reports of pacemaker failures were reported. However, no legislation was put forward for medical devices until 1975, when hearings commenced on problems reported with the Dalkon Shield intrauterine device (IUD). There were thousands of reported injuries tied to the Dalkon Shield IUD.[10] Finally, on 28 May 1976, President Gerald Ford signed the Medical Device Amendments of 1976 into law. The Medical Device Amendments[14] introduced some of the most significant concepts and practices for medical device regulation that are still being used today, including:

- Risk-based classifications for medical devices (three classes);
- Regulatory pathways for new medical devices: Premarket Approval (PMA) and premarket notification (510(k));
- Regulatory pathway for new investigational medical devices (Investigational Device Exemption (IDE));
- Established good manufacturing practices (GMPs);
- Registration of establishments and listing of devices with FDA;
- Reporting adverse events involving medical devices; and
- Authorized FDA to ban devices.[15]

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Safe Medical Devices Act (SMDA) of 1990. The SMDA introduced the Humanitarian Use Device (HUD)/ Humanitarian Device Exemption (HDE) programs to encourage the development of devices to treat rare diseases. HUDs are defined as devices for use to treat or diagnose diseases or conditions affecting fewer than 4,000 patients in the US annually. The law also authorized FDA to require device manufacturers to perform postmarket surveillance on permanently implanted devices if permanent harm or death could result from failure of the device. User facilities such as hospitals and nursing homes were required to report adverse events as part of an improved postmarket surveillance initiative for medical devices. The SMDA defined substantial equivalence as one of the cornerstone requirements of premarket notifications (510(k)s).[15]

Food and Drug Administration Modernization Act (FDAMA) of 1997. FDAMA introduced the concept of "least burdensome" to the review of medical devices. FDA was directed to take this approach to medical device premarket evaluation in a manner that eliminates unnecessary burdens that may delay the marketing of beneficial new products while maintaining the statutory requirements for clearance and approval. Least burdensome is defined as the minimum amount of information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time.[16] FDAMA also required FDA to issue regulations allowing clinical study sponsors to modify any investigational device or study protocol by submitting a "notice of change" five days after instituting such a change, where the change(s) did not affect study design or patient safety significantly. Expedited review policies for certain medical devices, amended and clarified humanitarian device provisions, and recognition of other national or international standards were among the other provisions covered in FDAMA. FDAMA established a process and requirements so that FDA may order device tracking.[17]

FDAMA ushered in the start of the de novo process for medical devices. With the enactment of the Medical Devices Amendment of 1976, FDA classified all medical devices into three classification categories: Class I, Class II, and Class III. Any new devices that could not be classified as Class I or Class II were automatically classified as Class III. FDAMA introduced the de novo classification process, otherwise known as the evaluation of Automatic Class III designation. This was a four-step process:

- Sponsor or manufacturer submits a 510(k)
- FDA issues a 510(k) decision of Non-Substantial Equivalent (due to no predicate device)
- Sponsor or manufacturer submits a de novo request
- FDA decides to classify the device into Class I or Class II with a new classification and regulation[18]

Medical Device User Fee and Modernization Act of 2002 (MDUFMA). MDUFMA allows FDA to charge industry a fee for select medical device product reviews. FDA uses these funds to hire staff and develop better systems to support effective and timely product reviews, enact needed regulatory reforms, and ensure that reprocessed devices are as safe and effective as the original devices. Additionally, MDUFMA established the Office of Combination Products and enacted the small business determination program to allow reduced premarket approval fees for qualifying small businesses. MDUFMA has been reauthorized four additional times, with each reauthorization known as the Medical Device User Fee Amendment (MDUFA). The current and fifth iteration is MDUFMA V.[19]

Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). FDASIA was enacted on 9 July 2012.[20] FDASIA shepherded a new regulatory premarket pathway for medical devices called the direct de novo pathway. Previously, FDA had a de novo program for low-to-moderate risk devices to be classified into Class I or Class II instead of being automatically classified into Class III; however, a 510(k) had to be submitted for this determination to be made. The direct de novo pathway, instead of being a four-step process, became a streamlined two-step process. The two steps are: the sponsor or manufacturer submits the de novo request directly to FDA, and FDA decides whether to classify the device from Class III to Class I or Class II. If the FDA grants the direct de novo, they will publish an order announcing the new classification and controls and generate a decision summary. The directed de novo becomes a device that can be used as a predicate device for similar future devices.[18] Other changes for medical devices included reauthorization of MDUFMA, least burdensome provisions were expanded, FDA was permitted to work with foreign governments to harmonize regulatory requirements and the standards for disapproval of the IDE were changed.

21st Century Cures Act (CCA). The CCA, the most significant legislation enacted since FDASIA, was signed into law in December 2016. Significant provisions for medical devices include:

- Expedited review program for breakthrough devices was codified into law;
- Expanded the least burdensome principles for some premarket review;
- Streamlined the process for exempting devices from 510(k) requirements;
- Increased the population estimate required for HUD designation to not more than 8,000 patients per year from the previous 4,000 patients;
- Permitted the use of central institutional review board oversight for IDE and HDEs;
- Required FDA to revise the regulation of combination products;
- Codified a process for submitting requests for recognition/ nonrecognition of a standard; and
- Clarified how digital health products can be regulated by defining the categories of medical software that can and cannot be regulated as medical devices.[15]

Food and Drug Omnibus Reform Act of 2022 (FDORA). Significant new or clarified medical device regulations from FDORA are:[15]

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- Enhanced oversight of device establishments, including new authority to conduct remote regulatory audits and to inspect facilities that conduct research on devices;
- Gave FDA express authority to approve or clear devices with a predetermined change control plan (PCCP) ;
- Required cybersecurity information be provided in premarket submissions for cyber devices, and that sponsors of these devices must ensure their cybersecurity ;
- Clarified that the FDA can ban devices for one or more intended uses and that banned devices are not legally marketed devices;
- Required clinical trial sponsors to submit a diversity action plan with enrollment goals and plans to meet these goals beginning 180 days after the FDA issues final guidance on the subject;
- Permitted certification for devices manufactured in a foreign device establishment and shipped to another country, provided the same device is also marketed in the US and other criteria are met; and
- A new registration fee waiver for small businesses experiencing financial hardship beginning in FY 2025.

Other Medical Device Legislation

The laws listed above ushered in the most significant changes to medical device regulations; however, other laws affected medical devices and should be mentioned. **Table 1-1**[15] lists some of these other laws and the specific changes to medical device regulations.

Center for Devices and Radiological Health

When the Food, Drug, and Insecticide Administration was shortened to FDA in 1930 by an agricultural appropriations bill, radiological health was still not part of the FDA.[9] It was not until 1948, when the Radiological Health Unit was formed under PHS, that FDA had remit for radiological products.[13]

The Center for Devices and Radiological Health (CDRH) was constituted in 1984. The mission of CDRH is to protect and promote public health. CDRH accomplishes its mission by assuring that medical devices are safe, effective, and high-quality. Additionally, they ensure that radiation-emitting devices are safe. Another part of CDRH's mission is to facilitate innovation by providing predictable, consistent, transparent, and efficient regulatory pathways to industry and furthering regulatory science.[21]

Canada

Canada is a representative parliamentary democracy and a constitutional monarchy, where the Canadian people elect representatives to the legislature, and all governmental acts are carried out in the name of the monarch. As a federal state, Canada's powers are distributed among the federal government, the provinces, and the territories. To ensure effective governance, the federal government is organized into three branches—like the US—comprising the Executive, Legislative, and Judicial branches. A basic primer of the Canadian federal government system, while out of the scope of this book, is useful in this context.[22]

The Development of Medical Regulations

Before the 20th century, Canada's regulation of medical devices was noticeably underdeveloped. The medical landscape was different from today, with less technological integration and more reliance on traditional methods and instruments. Historically, regulation was more reactive than proactive, resulting in inconsistent and often vague rules that broadly focused on public health and safety without delving into the complexities and specifics of medical technologies and their development. This reactive approach to regulation was not uncommon, generally prioritizing immediate responses over systematic planning or foresight. Historically, many advancements in regulation stemmed from the need to address specific, critical issues that exposed patients to safety risks.

Table 1-1. Other Medical Device Legislation[16]

Year	Legislation	Significant New or Revised Regulations
2007	Food and Drug Administration Amendments Act (FDAAA)	Required all registration and listing be performed electronically. Required the establishment of a unique identification (UDI) system for medical devices. Device labels must bear the UDI.
2017	Food and Drug Administration Reauthorization Act (FDARA)	Authorized risk-based inspection scheduling for device establishments. Decoupled accessory classification from classification of the parent device.
2020	Coronavirus Aid, Relief, and Economic Security Act (CARES)	The Food and Drug Administration (FDA) may issue certification for devices manufactured in a foreign device establishment and shipped to another country. Required manufacturers of certain devices to notify FDA of an interruption or permanent discontinuation in manufacturing during or in advance of a public health emergency.
2022	FDA User Fee Reauthorization Act of 2022 (FDAUFRA)	Reauthorized MDUFA V. Funded a new Total Product Life Cycle (TPLC) Advisory Program pilot
2022	Preparing for and Responding to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act)	Steeper penalties on counterfeit devices. Directed FDA to create a list of device types subject to mandatory notifications. FDA may rely on third parties to review request for emergency use authorizations for in vitro diagnostic devices

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However, as medical technology advanced, the necessity for a formal regulatory system became apparent.

Health Canada

Health Canada was established in 1993, evolving from the Department of National Health and Welfare, which itself was set up in 1944. This transition marked the latest in a series of transformations dating back to 1919, reflecting the ongoing development of Canada's public health infrastructure.[23]

Health Canada is the regulatory agency responsible for maintaining and modernizing the Canadian healthcare system and promoting public health. Its duties include regulating medical devices, drugs, foods, environmental and pesticide safety, sanitation, and industrial conditions. It is also responsible for disseminating information for disease prevention, promoting healthy lifestyles, conducting research, and overseeing public health surveillance and response to disease outbreaks.

The Food and Drugs Act and Medical Devices

The Food and Drugs Act was initially enacted in 1920. The initial scope was primarily focused on pharmaceuticals, based on the more evident risks associated with drug consumption. Yet, as medical technology evolved, the government became increasingly aware that devices used in medical treatment also posed significant risks if not adequately regulated.[24]

In 1975, the evolution of the Food and Drugs Act into a comprehensive regulatory framework for medical devices demonstrated a further shift towards a more proactive approach to public health. The government realized that the growing complexity of medical technologies and their potential risks required regulatory measures not just for immediate safety but also to ensure long-term reliability and effectiveness. Still, it was not until 1998 that the regulation of medical devices took a more defined shape with the enactment of the Medical Device Regulations.

Medical Devices Regulations (SOR/98-282)

The Medical Device Regulations were established on 16 May 1998 and officially took effect on 1 January 2003. They are the principal regulations that govern the sale, advertisement, manufacturing, and importation of medical devices in Canada. These regulations, including regulatory review where necessary, ensure that all medical devices undergo appropriate scrutiny before they can be made available in the Canadian market. Under the Medical Device Regulations, medical devices are classified into four classes based on the risk associated with their use, from Class I (lowest risk) to Class IV (highest risk). Based on their level of risk, devices must either apply for a medical device establishment license (MDEL) or a medical device license (MDL). Devices under Class II through IV must apply for an MDL, while Class I devices are overseen through the MDEL process.[25]

In 2003, the Canadian Medical Devices Conformity Assessment System (CMDCAS) was established to ensure that certain medical devices are designed and manufactured under a quality management system (QMS) registered and compliant with Canadian regulations.[26] In recent decades, Canada has participated in international efforts to harmonize regulations, such as through the International Medical Device Regulators Forum (IMDRF). In January 2019, Canada replaced CMDCAS with the Medical Device Single Audit Program (MDSAP), joining Australia, Brazil, Japan, and the US. MDSAP streamlines the QMS auditing process for medical device manufacturers by enabling a single audit to fulfill the regulatory requirements of those jurisdictions that are a part of the program.[27]

Europe

European Union

The regulation of European medical products was not introduced until the advent of the European Economic Union (EEU) in 1957.[28] The basic concept was to create a single European market where people, products, and services could move freely across national borders, eliminating barriers to trade between member countries. To remove legal barriers, a new legislative technique and strategy was implemented by the Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards, known as the New Approach Directives.[29] In 1992, the EEU was renamed the European Union (EU), reflecting that it was no longer a purely economic union but also a political one. The number of EU Member States has grown from 6 in 1957 to 28 in 2017. In addition, EU laws are also applicable in Norway, Iceland, and Liechtenstein (as members of the European Economic Area).

Regulating and harmonizing laws for every product was impractical. Old national laws that specified individual product regulations were replaced by the New Approach Directives, which regulated utilizing product families. Conformity to the New Approach Directives allowed for the CE mark (an acronym for the French "Conformite Europeenne") to be affixed to products, denoting that a product had met EU health, safety, and environmental requirements. The CE mark is not a quality indicator nor a certification mark for consumers but is meant to be more of a "passport" for products. It was a visible sign for EU authorities that the product manufacturer claimed to comply with the essential health and safety requirements of all directives that applied to the product.

The New Approach Directives set out a "modular" approach for the criteria and guidelines for conformity assessment procedures. The conformity assessment modules were divided into sections related to the products' design phase and their production/post-production phases. A key component of the new conformity assessment process was the use of harmonized standards that had to be published in the Official Journal of the European Union.[30] Harmonized standards allowed for a presumption of conformity to the legal requirements in particular directive. Often, these international standards, produced by the Organization for International Standards (ISO), European standards (European Norms "EN"), European Committee for Standardization (CEN), or the European Committee for Electrotechnical Standardization (CENELEC), would be accompanied by an annex which described its relationship to a particular New Approach Directive(s). A manufacturer using a harmonized standard in the design and/or production/

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post-production of a product was presumed to be in conformity with the essential requirements of the law.

In June 2016, citizens of the United Kingdom (UK) voted by referendum to terminate the UK's EU membership. After the "Brexit" procedure was completed, as of 1 January 2021, the UK is no longer part of the EU single market. The UK Medicines and Healthcare product Regulatory Agency MHRA[31] is developing its own regulatory system for medical devices.

EU Legislation

While the EU does not have a central agency for medical devices as it does for pharmaceuticals with the European Medicines Agency (EMA), medical devices are overseen by the European Commission (EC) Directorate-General for Health and Food Safety (DG SANTE).[32] Under the EU New Approach Directives and recent regulations, Member States officially designate third parties called notified bodies to perform work on behalf of Member States. A Member State informs the EC and the other Member States that the notified body fulfills the relevant requirements and has been designated for conformity assessment according to a directive or regulation. Notified bodies and specific medicinal product code designations are listed on the New Approach Notified and Designated Organisations (NANDO) Information System.[33] Notified bodies are charged with assessing a manufacturer's compliance with the applicable EU legislation in order for a manufacturer to affix the CE mark on its product's label – unless the manufacturer is allowed to self-certify depending upon device classification.

The Treaty of Rome is the foundation of EU legislation; it is the primary legislation.[28] Directives and regulations are secondary legislation. A directive obligates Member States to implement its provisions into national laws. A regulation is directly applicable in all Member States and obligates Member States to remove any conflicting provisions from their national legislation. Other forms of secondary legislation are decisions (binding on Member States or legal entities, e.g., legal persons or companies), opinions, and recommendations.

Within the legislative structure, there are also official EU guidance documents. Guidance documents interpreting the medical device and in vitro diagnostic directives are called MEDDEVs. Since 2017, with the introduction of the EU Medical Device Regulation (EU MDR) and EU In Vitro Diagnostic Regulation (EU IVDR), the Medical Device Coordination Group (MDCG) has issued interpretation and guidance documents. These non-binding consensus documents interpret and explain the legal texts and intend to help manufacturers and other stakeholders fulfill their regulatory obligations. However, it is not unusual for notified bodies to use these formal interpretation guidance documents as de facto requirements.

Historic Factors in the Development of Medical Product Regulations

Ethics is the foundation of healthcare regulations. Originally, the main objective of healthcare regulations was to protect individuals from unethical and unsafe human trials. The first European healthcare regulations concerned the ethical treatment of human subjects.

After World War II, the Allied Forces organized a series of military tribunals in Nuremberg, Germany, to prosecute prominent Nazi leaders who had participated in the Holocaust and other war crimes. These trials, known as the Nuremberg Trials, also included the Doctors' Trials, which prosecuted Nazi physicians for conducting medical experiments on prisoners in concentration camps. As a result of the Doctors' Trials, a set of research ethics principles for human medical experiments called the Nuremberg Code was drafted in 1947.[34] The Helsinki Declaration of 1964 further developed the Nuremberg Code and tied it to the Declaration of Geneva (1948), an internationally acknowledged statement of physicians' ethical responsibilities. Although the Helsinki Declaration is not a formal law, it has profoundly influenced national laws on clinical research worldwide, including in Europe.

After the Helsinki Declaration, laws were drafted to regulate which products could be placed on the market, and the claims manufacturers could make about them. Today, medical product regulations target not only ethical, safety, efficacy, and performance concerns but also economic issues, including increased availability of information, continuing technological and product innovations, market structure changes, and consumer protection.

Consequences of Unsafe Products

Safety incidents have been catalysts for medical product regulations. The Poly Implant Prothèse (PIP) breast implant case is notable in the European medical device regulatory realm.

In the PIP case, a French manufacturer used industrial-grade – not medical-grade – silicon oil breast implants, resulting in a higher prevalence and incidence of rupture than other silicone implants.[35] The scandal acted as a catalyst for medical device regulation reform, leading to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on 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 – also known as EU MDR[36] – and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU – also known as EU IVDR. [37]

Evolution of Current Regulations - Product Legislation in the EU

The fundamental purpose of creating the EU was to create a single European market. Harmonized product legislation is a prerequisite to achieving this single market concept, and harmonized product legislation implies harmonization of technical specifications. Medical device regulation in the EU is based on this New Approach product legislation.

The New Approach includes a fast legislative pathway with defined content and structure. Its legal basis is Article 95 of the EU Treaty, enabling EU institutions to adopt measures to promote the internal market's establishment and operations.

When Member States incorporate the New Approach requirements, they may include additional provisions to apply them more effectively. These harmonized directives limit public

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authority intervention and enable industry to meet its obligations in a manner suitable to the specific situation or device, without the need for a cumbersome regulatory approval process. The decreased regulatory burden for industry and public authorities has enabled approval processes to advance much more quickly.

An essential feature of the New Approach is distinguishing between the essential requirements for safety and performance and the technical requirements. The essential requirements are included in the legal texts (such as in Annex I of the medical devices directive [Council Directive 93/42/EEC of 14 June 1993]) concerning medical devices. Technical specifications and requirements are described in the standards. Standards can be drafted on an international (ISO), regional (EN), or national level. In principle, any company or individual interested in a particular standard is welcome to participate in the drafting process. In practice, most participants in standardization processes come from industry, but public authorities, academia, and patients' representatives are also involved.

After a standard has been drafted and approved by a recognized standardization body on the international, regional, or national level, it must be harmonized before it can be used in the context of the New Approach Directives. The harmonization process was described in Council Directive 83/189/EEC of 28 March 1983, which laid down a procedure for providing information on technical standards and regulations.[38] In addition, Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998[39] laid down a procedure for the provision of information in the field of technical standards and regulations and of rules in information society services and Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012.[40] Harmonization is achieved by approving a standard suitable to provide a "presumption of conformity." Presumption of conformity means that if a product fulfills a harmonized standard's requirements, the Member States presume the product to be in conformity with the essential requirements. The EC publishes updates to the list of harmonized standards in the Official Journal regularly.

A guide to the implementation of directives based on the New Approach from 2000, called the Blue Guide after its blue cover, gives a detailed description of how standards are to be utilized within the New Approach Directives.[41] The EU Commission published new versions of the Blue Guide in 2014, 2016, and 2022.[42]

Harmonized EU Medical Device Directives

EU regulations relating to medical device safety and performance were up to individual Member States until the 1990s, when they were finally harmonized within the EU, following the New Approach legislative principles.

The core legal framework consisted of the following three directives:

- Council Directive 90/385/ EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (AIMDD);[43]
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD); and[44]
- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (IVDD);[45]

European legislators in the mid-1980s wanted the regulation harmonization process to start with medical devices with the highest public health risks, e.g., pacemakers and other active implantable devices, followed by a series of other categorical medical device directives (e.g., orthopedic implants, medical imaging) until the whole spectrum of medical devices was covered. This plan was later abolished, as legislators realized such a stepwise harmonization process would take decades to complete. The decision to cover all medical devices by one general medical device directive was a major achievement, having regulated such a large and diverse group of products successfully in one directive. More than 100,000 different medical devices were on the market in Europe at that time, and these were regulated by 60 pages of legal text.

Because of their specific characteristics, only in vitro diagnostics (IVDs) were covered by a separate directive (IVDs are not applied to humans but to human specimens).

The AIMDD, MDD, and IVDD were introduced in line with the New Approach. The manufacturer could choose among the various conformity assessment procedure routes defined in these directives. The device's classification determined the routes from which a manufacturer could choose. The classification rules were based on the human body's vulnerability and considered potential risks associated with the device's technical design and manufacture. This classification system comprised 18 rules; in principle, each medical device risk class could be assigned by applying these rules. There are four risk classes for Medical Devices: Class I for low-risk, Class IIa and Class IIb for medium-risk, and Class III for high-risk devices. There was a special Annex (Annex VII) on risk classification. Medium- and high-risk class devices required a design and manufacturing inspection by a notified body.

The IVDD distinguished four groups based on the risk associated with using the respective products: List A, List B, Devices for Self-Testing, and Other IVD Products. All products in List A and List B require the participation of a notified body in all aspects of the conformity assessment procedure.

For medical devices falling within the scope of other EU regulations, e.g., the Low Voltage Directive and Electromagnetic Compatibility (EMC) Directive for electrical medical equipment and the EURATOM Directive for ionizing radiation-emitting medical imaging equipment, the relevant requirements of other applicable regulations had to be fulfilled before the manufacturer was allowed to include the CE mark on its product and place the product on the EU market.

Further Development of the EU Medical Device Regulatory System

The MDD was introduced in 1993, and its provisions had to be fully implemented in 1998. Stakeholders (Member States, EU institutions, industry, notified bodies, etc.) undertook major efforts to implement the new directives during the transition period, but, in general, stakeholders thought this harmonized regulatory system functioned effectively.

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The MDD (and, if applicable, the AIMDD and IVDD) were amended by:

- Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma,[46] which brought medical devices incorporating stable human blood derivatives within the MDD's scope;
- Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001 amending Council Directive 93/42/EEC concerning medical devices,[47] which clarified that stable human blood products as such (not incorporated in a device) are not in the MDD's scope;
- Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices, [48] which classified breast implants in risk Class III;
- Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee, and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices, [49] which up-classified hip, knee, and shoulder implants from risk Class IIb to risk Class III;
- Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements regarding the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilizing tissues of animal origin.[50] The aim was to improve protection against the overall risk of transmitting animal spongiform encephalopathies (TSE/BSE); and
- Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices, which allows instructions for use for some medical devices (e.g., for professional use) to be delivered in electronic format.[51]

All the above legal changes impacted specific, isolated sections of the MDD. The Commission was obligated to evaluate the MDD's overall functioning and effectiveness within five years of its coming into force and report to the Council. This evaluation exercise resulted in a proposal for an update to the AIMDD and MDD in 2005, leading to adoption of Directive 2007/47/EC of the European Parliament and Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of laws of Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices, and Directive 98/8/EC concerning placing biocidal products on the market.[52]

The AMDD and MDD revisions left the existing framework untouched; it was a technical revision. The main changes included bringing software explicitly into the definition of a medical device, adding obligatory checks of representative samples of Class IIa and Class IIb device design dossiers by notified bodies to the quality system conformity assessment module (MDD Annex II), and extending clinical evaluation obligations. These provisions came into force in March 2010.

In 2008, the EC initiated the next revision by issuing a public consultation. This revision's timing raised questions. Most respondents to the public consultation (in particular, Member States and industry) considered a 2008 revision premature since the previous revision by Directive 2007/47 was to take effect in March 2010. Eventually, the EC published its proposal for a new medical device regulation and a new in vitro diagnostic regulation in September 2012. The subsequent legislative procedure took more than four years. It resulted in EU MDR, which maintains the New Approach requirements, including the role of notified bodies in the certification of mid- and high-risk devices. However, these new regulations include several extended and/or new requirements, especially for clinical studies.

The requirements for notified bodies have also substantially expanded. In addition, the designation process is no longer executed by one individual national authority but by a team of authorities led by the EC. The designation process has taken much longer than anticipated by authorities and notified bodies.

To ensure a smooth transition from the MDD to the EU MDR, a so-called "soft transition" provision was included. Devices with a valid certificate under the MDD could remain on the EU market under certain conditions. First, Regulation 2020/561 of the European Parliament and of the Council of 23 April 2020[53] postponed the date of application of certain EU MDR provisions for one year until 26 May 2021, primarily due to the COVID-19 pandemic. Subsequent extensions in 2023 have revised the "soft transition" timeline for certain medical devices.

Additional Discussions on In Vitro Diagnostics

Because of their specific nature, in vitro diagnostics were regulated in a separate directive (IVDD). The IVDD came into force in 1998. Its provisions became applicable to new IVDs in 2000 and to IVDs already on the market in compliance with existing national legislation in 2003. IVDs are reagents, reagent products, calibrators, control materials, kits, instruments, apparatus, equipment, or systems used for the in vitro examination of human samples to make a medical diagnosis. Blood and tissue donations are also covered.

The IVDD followed the same format as the MDD but with some differences. The IVDD includes special provisions for self-testing devices (e.g., pregnancy tests) that require notified body involvement. Additionally, tests and reagents developed in health institutions' laboratories do not have to comply with IVDD provisions before being used to make a medical diagnosis if they are used only within the same health institution and are not placed on the market.

The most striking difference between IVDD and MDD is the risk classification system. Unlike the MDD, IVDD risk classification was not rule-based. IVDD Annex II included two lists of diseases and biomarkers: List A and List B. If an IVD was included in Annex II, a notified body's intervention is required. List A included reagents for determining blood groups, hepatitis, and HIV. List B included a variety of reagents for infectious and congenital diseases. Annex II's content was considered state-of-the-art healthcare in the early 1990s. Since it has not been updated

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since 1998, the Annex is outdated. Diagnostics for infectious diseases emerging since 1998 (e.g., SARS, avian flu, Ebola, MRSA, and COVID-19) were not included in Annex II, so no notified body involvement was legally required. This is now addressed in the new EU IVDR. The EU IVDR includes a major change in the risk classification system, evolving from a list-based system, as described above, to a rule-based system (Class A, B, C, and D). The involvement of a notified body is needed for all Class B, C and D devices, as well as sterile Class A IVDs. The different routes of assessment according to the class of the IVD are described in Article 48 and Annexes IX, X, and XI of the EU IVDR.

This new classification system is analogous to the system already used for medical devices. It also will result in a substantial increase in notified body involvement. For example, for IVDs on the market in the Netherlands, it was estimated that the percentage of IVDs with obligatory notified body involvement would rise from 7% under the IVDD to 84% under the EU IVDR.

While the EU IVDR officially was effective in May 2022, it too included a "soft transition" provision, allowing IVDs with a valid certificate under the IVDD to remain on the EU market under certain conditions through May 2024. In 2021, it became apparent that more time would be needed for a smooth transition from IVDD to EU IVDR. The transition periods for diagnostics to comply with the regulation were extended in 2022 amid pressure from industry and fears of a market collapse for diagnostics. Regulation (EU) 2022/112 of the European Parliament and the Council of 25 January 2022[54] introduced a staggered extension of the transition periods for EU IVDR. They deferred the application of conditions for in-house devices.

While the EU IVDR has been applicable since 26 May 2022, the amendment allowed for its progressive rollout regarding in vitro diagnostics covered by a certificate or a declaration of conformity issued under the previous IVD Directive 98/79/EC. The EU extended the transition periods to 26 May 2025 for high-risk IVDs, 26 May 2026 for moderate-risk IVDs, and 26 May 2027 for lower-risk IVDs.

Additional "Soft-Transition" Extensions for EU MDR and EU IVDR

On 15 March 2023, the European Union extended the transition periods again with Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023, amending the EU MDR and the EU IVDR.[55]

The EC said it wanted to give manufacturers more time, as a significant number of IVDs on the market have not yet taken the necessary steps to come into compliance. On 13 June 2024, the EC finalized Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024, amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices. Under the regulation, high-risk class D diagnostics must undergo a conformity assessment under EU IVDR by 31 December 2027, while Class C, or high individual and/or moderate public health risk devices, will have until 31 December 2028, and low-risk Class A sterile and Class B devices will have until 31 December 2029. The regulation also provides for a partial rollout of EUDAMED and requires manufacturers to report certain supply chain interruptions.[56]

Product Innovation

Recent developments in nanotechnology, 3D printing, wearables, diagnostics for new biomarkers, medical software applications, and artificial intelligence (AI) did not exist when the EU medical device regulatory system was designed. Technology evolves faster than legislation to regulate it can be drafted. As a result, adequate regulation may not exist for new and innovative technologies.

The EC, the Member States' national competent authorities, and the notified bodies all play a role in governing innovative medical devices and IVDs. However, for innovative devices or novel therapies, trying to obtain a central opinion in the EU for the necessary evidence and market pathway, with so many different and diverse governing bodies overseeing the market entry – often presents quite a challenge for innovative developers/manufacturers.

Innovative product developers may benefit from the lack of regulatory specificity. On the other hand, a lack of adequate regulation might lead to uncertainty about which rules apply and the conditions under which a product under development is allowed on the EU market. This might hamper or delay the market entry of innovative products for which a clear medical need exists.

Information Availability and Transparency

With the advent of social media and supported by the internet, information on medical products is available almost immediately to virtually everyone. This information overload can no longer be controlled by authorities or industry. For individuals without a medical education, it can be very challenging to distinguish between reliable, trustworthy, and accurate information from misinformation.

Maintaining public confidence in the healthcare system is crucial. In the late 1990s, EMA began publishing scientific information on medicinal products on the European market to answer growing societal demands for information and transparency. Because the scientific information published on medicinal products was difficult for the public to understand, EMA decided to introduce a public-friendly medicinal product summary for pharmaceuticals on the EU market.

The next step on the transparency path came in 2001, with the publication of technical reports (summaries) of scientific committee meetings on EMA's website. Today, EMA agendas, meeting minutes, and highlights are published publicly.[57]

EU MDR and EU IVDR enhanced transparency related to medical devices, chiefly by creating a European database on medical devices (EUDAMED). Once the database is online, manufacturers will be required to draft a summary of safety and clinical performance (SSCP) for certain high-risk devices to be published on EUDAMED. SSCPs need to be clearly drafted to be understandable to the general public.[58]

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In addition, the EC publishes the agendas and minutes of the Medical Device Coordinating Group (MDCG) and its working groups.[59]

Economic Issues

Although public health protection is the primary driver of healthcare regulation, economic considerations also began to have an impact in the second half of the 20th century. With the establishment of the first health insurance systems, the growing availability and number of healthcare products increased costs for Member States. The transfer of healthcare costs from individuals to private or public insurance systems necessitated a product pricing policy, confirming that limited economic resources had to be spent prudently. This was aggravated by subsequent economic crises. The pressure to limit public expenditure led to stringent healthcare cost-cutting measures in several Member States.

Market access for medical products is controlled by EU regulations, but pricing and reimbursement are national responsibilities. This continues to be a sensitive area. Health technology assessment (HTA) has been the standard method in the pharmaceutical world for medical product reimbursement decisions for a long time. HTA is, in principle, done at the national level; however, some EU-level documents are in place to encourage and facilitate cooperation between national HTA organizations. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU entered into force on 1 January 2022.[60] This new regulation contributes to improving the availability of innovative health technologies for EU patients, such as medicines and certain medical devices.[61]

Falsification and Counterfeiting

The increasing economic value of medical products has made them attractive targets for falsification and counterfeiting, which represents a growing threat to public health. The risk of detection and prosecution is low compared to other criminal activities, and potential financial gains are high. Internet sales contribute to the problem. The World Health Organization (WHO) has found that over 50% of medicines purchased on internet sites that conceal their real addresses are counterfeit.[62]

Counterfeit medical devices are a problem, e.g., counterfeit condoms, glucose test strips, and insulin needles have been seized on the EU market.[63]

Regulators recognized the importance of fighting these criminal activities in the interest of public health. In 2011, the Council of Europe issued the Medicrime Convention.[64] This international convention makes any contribution to falsified medical products a criminal offense and provides a framework for national and international cooperation. Medicrime entered into force in 2016 in those jurisdictions that have signed it.[65]

The EU MDR and EU IVDR introduced the unique device identification (UDI) system, designed to prevent falsified devices, enhance postmarket safety-related activities, reduce medical errors, and improve purchasing, waste disposal, and stock-management policies.[36,37]

United Kingdom (UK)

The UK is a constitutional monarchy and parliamentary democracy, where citizens elect representatives to the legislature, and all governmental actions are performed in the name of the monarch. As a unitary state with devolved governments, the UK's central government retains sovereignty but shares powers with the devolved administrations of Scotland, Wales, and Northern Ireland. To ensure effective governance, the UK government is structured into three branches—executive, legislative, and judicial. A basic primer of the UK government system, while out of the scope of this book, is useful in this context.[66]

The UK and the EU

Initially hesitant to join the earlier forms of European integration, the UK applied to join the European Economic Community (EEC) in the 1960s but faced vetoes from France. The UK successfully joined the EEC on 1 January 1973. This marked the beginning of the UK's formal economic relationship with Europe, which deepened politically when the Maastricht Treaty transformed the EEC into the European Union (EU) in 1993. While the UK participated in the EU, it maintained certain opt-outs, reflecting its unique constitutional context and historically complex relationship with broader European integration. This relationship ended with the Brexit vote of 2016, leading to the UK's official departure from the EU in January 2020. This decision has impacted its trade of medical devices with the EU.[67]

The Development of Medical Regulations

The formal regulation of medical devices in the UK began significantly later than that of medicines, with regulatory frameworks only established in the mid-1990s. However, the beginning of medical device control in the UK dates to World War II, when the Ministry of Supply created a medical equipment section to encourage domestic production of previously imported items. After the war, the expertise and insight gained from the Ministry of Supply's efforts were transferred to the Ministry of Health's Technical Services Group, tasked with inspecting and testing medical equipment.[68]

The complexity and availability of medical devices kept growing, and by the 1960s, recruitment of product specialists to advise hospitals and develop standards and purchasing specifications was necessary. In 1969, the UK Department of Health established a defect and adverse incident reporting system and created the Scientific and Technical Board (STB), which, along with a voluntary quality assurance system, enhanced the safety and quality of medical equipment by managing a medical device evaluation program whose legacy continues today under the Medical Devices Agency (MDA). These systems then evolved into the Manufacturer's Registration Scheme (MRS), registering 580 manufacturing sites globally before being replaced by the Medical Device Directive 93/42 in 1998.

The Medical Devices Agency

In the 1980s, the STB was integrated into the National Health Service (NHS) Procurement Directorate and later split into the NHS Supplies Authority and the Medical Devices Directorate, becoming

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an Executive Agency of the Department of Health known as the MDA in September 1994.

European Directives and the Medical Devices Regulations 2002

Before MDD and IVDD, EU Member States, including the UK, had varying standards and procedures for medical devices. This lack of uniformity created barriers to trade within the European single market and potentially compromised patient safety.

Through the Department of Health, the UK government drafted the Medical Devices Regulations 2002 to incorporate the provisions of the EU Directives into UK law. This was necessary to ensure that UK manufacturers could compete on an equal footing in the EU market and that UK patients benefited from the same level of health protection as those in other EU countries. The regulations were subject to scrutiny by both houses of the UK Parliament.

Ultimately, the regulations set up the risk-based categorization system that separates the medical devices into four classes based on risk and specifies conformity assessment procedures for each class. For example, Class I devices are considered low-risk and include items like bandages, handheld surgical instruments, and reusable surgical retractors. Manufacturers of these devices can self-certify their conformity. However, they must register with the Medicines and Healthcare products Regulatory Agency (MHRA) and ensure a proper quality assurance system is in place. Class III devices represent the highest risk category within the UK's medical device classification system, which mirrors the stringent regulatory frameworks established by the EU. Devices classified under Class III include those that are implanted into the human body and are intended to sustain life or prevent a health condition from worsening, and all Active Implantable Medical Devices are subject to the highest controls and require manufacturers to undergo a thorough conformity assessment that involves a notified body. This process would include a detailed examination of the technical documentation and design dossier to ensure compliance with safety and performance standards. Additionally, these devices typically require clinical data and ongoing postmarket surveillance to monitor their performance after they have been introduced to the market.

Brexit and Changes to Medical Device Regulation

Following Brexit, the UK is no longer a part of the EU. To address the need for medical device regulation, Great Britain has introduced the UK Conformity Assessed (UKCA) marking, replacing the CE mark for devices placed on the market in England, Wales, and Scotland. The Medical Devices Regulations 2002 (UK MDR 2002) are the current regulatory framework. As such, the UK continues to follow the former European Directives: Directive 90/385/EEC on active implantable medical devices, Directive 93/42/EEC on medical devices, and Directive 98/79/EC on in vitro diagnostic medical devices. Depending on the device type and the directives they comply with, Great Britain continues to recognize CE-marked devices until certain dates ranging from 2028 to 2030.[69]

Unlike Great Britain, Northern Ireland remains under the EU regulations and follows EU MDR and EU IVDR. Devices in Northern Ireland require CE marking, which must be performed by an EU-recognized notified body. If a device is assessed by a UK notified body, it will also bear the UKNI marking. The UKCA marking will not be recognized in Northern Ireland.

Notified Bodies

Notified bodies in the UK are now known as approved bodies. They are no longer able to provide CE marking for devices to be sold in the EU. Instead, they can perform conformity assessments to provide the UKCA marking.[70]

Asia

China

This section delves into the development journey of modern medical device regulation in China, maintaining its unique Chinese characteristics while drawing on international advanced experiences. It covers the origins, the creation of regulations, international exchanges and cooperation, and the publication and implementation of the newly revised Regulations on Supervision and Management of Medical Devices (referred to as "the Regulations" in the rest of this chapter).[71] Furthermore, it looks forward to the future development directions of medical device regulation in China.

Early Beginnings

Tracing back to the late 1980s, the pharmaceutical industry management department at the time was the State Pharmaceutical Administration of China. Authorized by the State Council, the State Pharmaceutical Administration was responsible for the unified management of the production and market circulation of pharmaceuticals and medical devices. However, due to the diversity of the professional fields involved in medical devices and the relatively backward production level of medical devices in China at that time, a unified industry had not yet formed. The production and market management of medical devices in China were carried out by different industrial management departments.

In the late 1980s, preparations were made to establish a department to specifically implement a unified management program for medical devices. From 1988 to 1996, the State Pharmaceutical Administration sent medical device management delegations to developed countries and regions such as the US, Europe, Canada, Australia, and Japan multiple times yearly. These delegations conducted investigations to understand the history, system, models, technical means, and specific laws and regulations of medical device regulation in these countries and regions.[72]

Evolution of Regulatory Framework

In 1990, the State Pharmaceutical Administration reported its plan for medical device legislation to the State Council. It began drafting China's administrative regulations for medical device supervision and management based on the organization and summary of regulatory systems, regulations, and experiences of developed countries.

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In 1992, the medical device regulation project was included in the State Council's legislative plan.

In 1993, the State Pharmaceutical Administration submitted the first draft to the State Council.

In 1994, the State Pharmaceutical Administration established the Department of Medical Device Administrative Supervision. By then, China had preliminarily completed the preparatory work for implementing unified management of medical devices.

After the initial draft was submitted to the State Council, the council's Legislative Affairs Office deliberated whether the management measures and the proposed management system outlined were suitable for China's national conditions and practically feasible, as there were no precedents to follow. It was deemed inappropriate to issue State Council regulations at that time. Instead, it was considered more appropriate to first issue them in the form of departmental regulations by the State Pharmaceutical Administration.

In 1996, the State Pharmaceutical Administration issued the Interim Provisions for Clinical Trials of Medical Device Products and the Administrative Measures for the Registration of Medical Device Products (the Measures).

The Measures stipulated that starting 1 January 1997, "any medical device product entering the Chinese market must be registered with the Chinese government's medical device administrative supervision and management department by the product manufacturer or their authorized representative."

In 1998, with the continuous deepening of reform and opening up, the State Council carried out government institutional reforms. It abolished the State Pharmaceutical Administration, which was responsible for industry management, and established the State Drug Administration (SDA), focusing on market supervision, thereby creating a modern drug (including medical devices) supervision and management system. At the same time, the Legislative Affairs Office of the State Council restarted the work on formulating medical device regulations.

After the establishment of the SDA, while continuing to implement the medical device registration system based on the Measures, the SDA redrafted the regulatory articles, taking into account the effects, experiences, and issues identified following the implementation of the Measures. By retaining the basic framework of the original registration system and improving aspects such as postmarket supervision, it resubmitted the draft to the Legislative Affairs Office of the State Council.

In January 2000, the State Council issued the Regulations, which officially came into effect on 1 April 2000. This was the first set of medical device supervision and management regulations issued at the State Council level in China.[71]

This marked a new phase in the legalization of medical device supervision and management in China, signifying the progress of China's medical device market towards standardization and order. With the Regulations as the superior law, SDA revised and improved the Measures, reissued the Provisions for the Registration of Medical Devices, and formulated and issued departmental regulations such as the Provisions for the Supervision and Management of Medical Device Manufacturing Enterprises and the Provisions for the Supervision and Management of Medical Device Distribution Enterprises.

On 18 March 2021, the State Council of China announced newly revised Regulations, marking another significant milestone in the history of medical device regulation in China.

The newly revised Regulations introduced features to encourage innovation and development. They specify that the state will formulate industrial planning and policies for medical devices, prioritize medical device innovation as a key development focus, give priority to the review and approval of innovative medical devices, support the clinical promotion and use of innovative medical devices, and promote the high-quality development of the medical device industry.

The revised Regulations also address risk management across the entire product lifecycle, in a fashion similar to the essential principles outlined by IMDRF.

On 8 September 2023, the Standing Committee of the 14th National People's Congress included the Medical Device Management Law in its legislative planning projects. The National Medical Products Administration has established a leadership team, working groups, and expert advisory groups to begin drafting the relevant legal texts.[73]

Latin America (LATAM) and the Caribbean

Brazil

Brazil operates under a federal republic system, blending features of both a federal state and a republic. In this framework, Brazil functions as a federation of states with a republican governance structure. The central government, headquartered in Brasília, holds authority over the entire nation, while individual states retain autonomy to govern their internal affairs. This division of power between the central government and states aims to maintain a balance, fostering both national unity and regional diversity. To ensure effective governance, the Brazilian government is structured into three branches—mirroring the classic separation of powers—comprising the executive, legislative, and judicial branches. A basic primer of Brazil's federal government system, while out of the scope of this book, is useful in this context.[74]

The Development of Medical Device Regulation. Brazil's National Institute of Metrology, Quality, and Technology (INMETRO) This organization plays a role in ensuring the safety, quality, and competitiveness of products in the Brazilian market. Established in 1973, INMETRO oversees standardization, metrology, and certification processes across various industries, including healthcare. Specifically related to medical devices, INMETRO accredits testing laboratories, establishes technical standards, and conducts conformity assessments to verify compliance with regulatory requirements. By ensuring that medical devices meet rigorous quality and safety standards, INMETRO promotes consumer safety, facilitates market access, and enhances Brazil's position in the global medical device industry.[75]

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Agência Nacional de Vigilância Sanitária (ANVISA)

The Brazilian Health Regulatory Agency, commonly known as ANVISA (Agência Nacional de Vigilância Sanitária), was established in 1999 and operates under the Ministry of Health.[76] ANVISA is characterized by its administrative independence, financial autonomy, and stable leadership. Its primary objective is to safeguard public health by conducting surveillance over products, services, processes, ingredients, and technologies that may pose health risks. The agency's mission is to protect and promote public health, intervening in risks associated with regulated products while coordinating with other governmental entities. Additionally, ANVISA oversees health control at ports, airports, and borders, and engages in international relations concerning health surveillance. ANVISA's global engagement extends to its membership in the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), where it collaborates with other regulatory bodies to ensure global health standards.

Resolution RDC 185/2001

This resolution established the classification criteria for medical devices in Brazil, categorizing them into Classes I, II, III, and IV based on their risk level. It also established procedures for the registration of medical products and administrative penalties, including suspension and cancellation of registrations.[77]

Resolution RDC 16/2013

This resolution established good manufacturing practices for medical devices and in vitro diagnostics, including records and documentation controls, design controls, process and production controls, and storage, handling, distribution, and labeling.[78]

Resolution RDC 36/2015

This resolution established regulations for in vitro diagnostic products, including the classification of risks, registration and control systems, and labeling for instructions for use.[79]

Resolution RDC 751/2022

ANVISA updated Regulation No. 185/2001 to include risk classification, notification, and registration procedures, and labeling guidelines for medical devices and accessories. Significant changes include expanded definitions, aligning with EU MDR, and a revised classification system from Classes I to IV, each corresponding to a specific risk level. Lower-risk devices follow simplified pathways, while Class III and IV devices undergo registration and are valid for 10 years. All devices require a Medical Device Technical Dossier, with a new Documentary Repository for document storage. Notification and registration tasks are managed by the Brazil Registration Holder (BRH). Existing manufacturers should conduct a gap assessment against the new regulation, especially regarding classification changes, with adjustments required by 29 February 2024, for up-classified devices.[80]

Oceania

Australia

Australia is a constitutional monarchy and parliamentary democracy, where citizens elect representatives to the legislature, and all governmental actions are performed in the name of the monarch. The Australian Constitution establishes the Federal Government by establishing three branches: Parliament, the Executive Government, and the Judiciary. A basic primer of the Australian government system, while out of the scope of this book, is useful in this context.[81]

The Development of Medical Device Regulations. During the period leading up to 1938, the market for medicine in Australia was largely unregulated, leading to the proliferation of medicines with questionable therapeutic claims. In response, some state governments began to take steps to regulate these claims, while the Commonwealth increased controls on imported biological products. The National Health and Medical Research Council (NHMRC) also began pushing for national standards for labeling and emphasized the importance of independent laboratory testing.[81]

From 1939 to 1988, the Australian government took additional action by enacting legislation to regulate medicine standards. However, this was primarily focused on pharmaceuticals, with the establishment of the National Biological Standards Laboratory, which was tasked with independently testing medicines on the Australian market and regulating their manufacture. This era marked the beginning of a more systematic approach to regulating therapeutic goods.

The Therapeutic Goods Act 1989 and the Therapeutic Goods Administration

From 1989 to 2007, the regulatory framework was integrated and refined further. In 1989, the Therapeutic Goods Act was established.[82] It is a comprehensive framework for the control of the quality, safety, efficacy, and marketing of therapeutic goods, including both drugs and medical devices, used or sold across Australia. The Therapeutic Goods Administration (TGA) was then established to uphold and administer the Therapeutic Goods Act 1989 and was instrumental in creating a national system for the regulation of therapeutic goods, which continued to grow into an internationally harmonized regulatory system.[83]

The TGA's key functions include evaluating medical devices before they enter the Australian market, monitoring them once they are in use, and conducting audits and inspections to ensure compliance with manufacturing and operational standards.
To maintain global best practices, the TGA collaborates with several international regulatory bodies. This cooperation helps align Australia's regulations with international norms, facilitates the smooth import and export of medical devices, and ensures global standards are met.

The Therapeutic Goods (Medical Devices) Regulations

The Therapeutic Goods (Medical Devices) Regulations 2002 in Australia established the risk-based classification system and the Australian Register of Therapeutic Goods (Register) that exists today.[84] The risk-based classification system categorizes medical

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devices into Classes I, IIa, IIb, III, and AIMD (Active Implantable Medical Devices) based on their associated risk levels, with Class I devices posing the lowest risk and Class III the highest. This classification system influences the rigor of the conformity assessment process each device must undergo before receiving TGA approval. Conformity assessment is a process that evaluates whether a device meets the necessary regulatory requirements for safety and efficacy. Additionally, upon this regulation, all medical devices began to be placed on the Register before they could be marketed in Australia. This Register provides a transparent record of all approved devices, ensuring that only those meeting strict standards are available to the Australian public.[85]

The Therapeutic Goods Regulations were then amended in 2010, improving the understanding and expectations of the postmarket surveillance and recalls of health products, ensuring that any safety issues could be quickly identified and addressed.[86] Definitions of health products within the regulations were clarified and expanded, providing all stakeholders, including manufacturers and regulators, with a clear understanding of compliance requirements. This included several clarifications for medical device classification and the conformity assessment process, and a re-classification scheme for certain medical devices, aligning them more accurately with their risk levels and ensuring that higher-risk devices underwent more rigorous evaluation and monitoring. Administrative processes related to the registration and listing of medical devices on the Australian Register of Therapeutic Goods (ARTG) were also streamlined, and the TGA was granted the ability to conduct more effective inspections, impose penalties for non-compliance, and, if necessary, remove non-compliant devices from the market.

The most recent update to the Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023 was approved by the Executive Council on 23 November 2023 and registered on 27 November 2023. Key amendments include extending transitional timeframes for medical device reforms to align with similar initiatives in the EU. These reforms also involve the reclassification of certain medical devices, such as those in direct contact with critical body systems, and regulations pertaining to personalized medical devices. Additionally, the amendments enhance the safety of medical devices used in clinical trials by clarifying the authority of personnel to oversee trial sites and ensure compliance with good clinical practice.[87]

International Medical Device Regulators Forum (IMDRF) and Medical Device Single Audit Program (MDSAP)

In recent decades, Australia has participated in international efforts to harmonize regulations, such as through the IMDRF. In 2018, Australia joined Canada, Brazil, Japan, and the United States. MDSAP streamlines the QMS auditing process for medical device manufacturers by enabling a single audit to fulfill the regulatory requirements of those jurisdictions that are a part of the program.[88]

Conclusion

The regulation of medical devices is a dynamic field shaped by historical events, technological innovations, and regional governance. Different parts of the world have constructed unique regulatory frameworks that address their specific challenges and opportunities, ensuring the safety, effectiveness, and quality of medical devices. Understanding these diverse approaches provides insight into the continuous effort required to balance public health protection with fostering innovation. As the medical device industry evolves, ongoing international cooperation, harmonization, and adaptation of regulatory practices will be crucial in meeting global healthcare needs.

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CHAPTER 2

Overview of Medical Device Policy and Regulation

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Introduction

The ability to grasp diverse regulatory landscapes across regions is essential in our current era of medical advancements that are pivotal to improving global health. This chapter offers an extensive overview of medical device policy and regulation within major global territories: North America, Europe, Asia, Oceania, and Latin America. Each region has crafted unique frameworks that govern the introduction and utilization of medical devices, reflecting their distinct healthcare challenges and regulatory focuses. By delving into these varied environments, this chapter provides insights into how different regions navigate the complexities of medical device regulation, ensuring the safety, efficacy, and accessibility of medical technologies.

North America

This section reviews the regulations and policies that currently define the medical device regulatory paradigm in the United States (US) and Canada. The US Food and Drug Administration (FDA), often known as the "gold standard" setter for regulatory processes, has a well-documented history of medical device regulation interspersed with landmark legislative milestones. The US and Canada are close working partners on major harmonization initiatives, especially in emerging technologies.

United States

Legislative Background

FDA's legal authority to regulate medical devices is the Federal Food Drug and Cosmetic Act (hereinafter FDCA).[1] The statute defines FDA's level of control over products. The statutory authority is then fulfilled by the regulatory agency through developing, publishing, and implementing regulations. Proposed regulations are first published in the Federal Register (FR), and the final regulations are codified in the Code of Federal Regulations (CFR) and published in the FR. Title 21 CFR Part 800-1299 contains regulations pertaining to medical devices and radiation-emitting products. The scope of the regulations is very broad and covers general controls such as quality system; labelling; establishment registration; special device controls, such as premarket submission regulatory requirements; and postmarket surveillance.

The Medical Device Amendments of 1976 (MDA) serves as a landmark legislative amendment in the history of the medical device regulation.[2] The MDA of 1976 significantly expanded FDA's statutory authority over the regulation of medical devices. From that point on, Congress has enacted further amendments to expand FDA's authority to conduct premarket clearance and approval prior to commercialization. Some prominent examples of expanded authority are the collection of user fees for device submissions. For more details on the history of medical device regulation, refer to Chapter 1.

The FDCA[3] defines a medical device as follows: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, (2) 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 (3) 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.

Medical Device Classification

In the US, medical devices are classified in one of the three regulatory classes based on the level of control required to ensure their safety and effectiveness. All devices are subject to general controls regardless of classification. Class I devices have the lowest risk and are subject to general controls. Medical devices with the highest level of risk are assigned to Class III and require the most stringent regulatory review. Moderate-risk devices, which make up most of the devices on the US market, are Class II, which are subject to special controls in addition to general controls. Refer to Chapter 5 on device classification for further details.

Compliance with General Control Requirements

General controls are regulatory requirements authorized by the FDCA to apply to all classes of medical devices, unless exempted by regulations. General controls include the following FDCA provisions listed in **Table 2-1**.

In addition to general controls, Class II devices are subject to special control requirements. These special controls include performance standards, postmarket surveillance, patient registries,

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