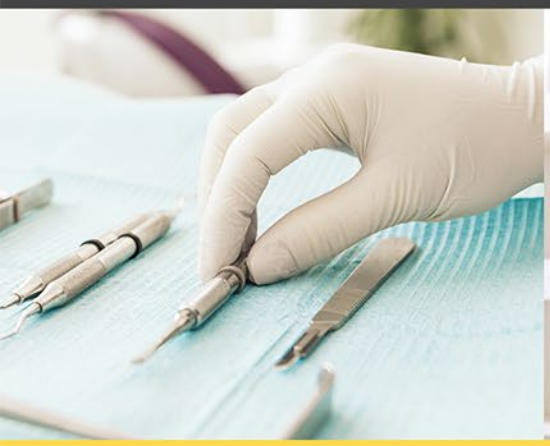
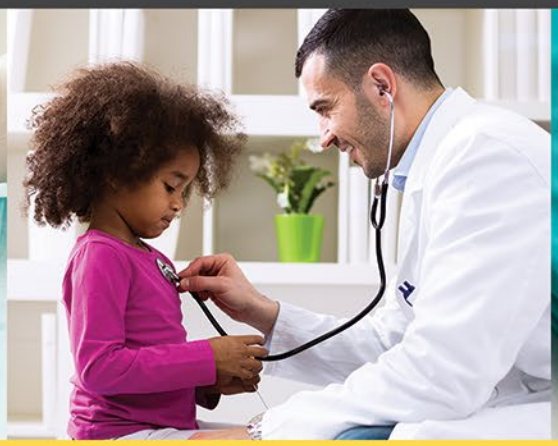
EU

Understanding Europe's New Medical Devices Regulation (MDR 2017/745)

Key changes contained in the proposed MDR and their impact on manufacturers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Europe: Getting Consensus from 28 Countries with 28 Opinions

The Medical Devices Regulation (EU) 2017/745

The European Single Market comprises 28 Member States of the European Union (including the United Kingdom), the European Economic Area (Iceland, Liechtenstein and Norway) and through bilateral treaties, Switzerland. Over 500 million consumers live there, and this is an aging population.

Free movement of goods is one of the cornerstones of the Single European Market. This implies that a product that is allowed on the market in one of the Member States is also allowed on the markets of other Member States. To enable this concept of free movement, the 2016 version of the "Blue Guide" on the implementation of EU products lists three conditions that must be met:

1. Essential requirements for the products involved must be defined;
2. Methods must be established to describe how product compliance with the requirements is addressed;
3. Mechanisms to supervise and control the actions of all Economic Operators and others involved in the manufacturing and distribution of the products must be created.

The predecessors of the Medical Devices Regulation (MDR) - the Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC and the Medical Devices Directive (MDD) 93/42/EEC - do just that: These Directives defined Essential Requirements, introduced harmonized standards helping to demonstrate conformity to the Essential Requirements. The Directives also defined conformity assessment procedures, and organized market surveillance functions by Competent Authorities (CAs) and Notified Bodies (NBs). These Directives, introduced in early 1992, have worked well and helped create the single market for medical devices in Europe.

However, the Directives had some inherent weaknesses, and changes in technology and medical science demanded additional legislation. These shortcomings challenged national Member States, and the interpretation of the Directives was not consistent across all national governments. Directive 2007/47/EC modified the MDD and AIMDD in an attempt to address these concerns, but this amendment did not achieve all goals. The scandal involving defective breast implants manufactured by Poly Implant Prosthesis (PIP) in France demonstrated additional structural weaknesses in the system.

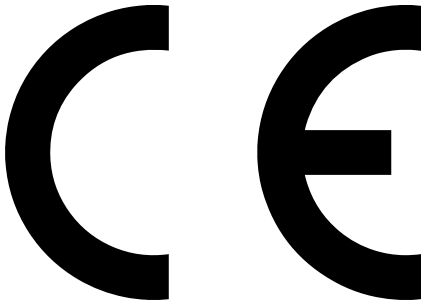
In September 2012 the European Commission published proposals for the MDR and the In-Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR). In April 2014 the European Parliament came up with a total of 347 amendments for the proposed MDR and 254 amendments for the proposed IVDR. The European Council responded in September 2015 to the proposals adapted by Parliament. The differences between these versions were of such magnitude that the European Commission decided to facilitate negotiations between European Parliament and Council, the so-called "Trilogues." The Trilogues resulted in a compromise text in June 2016. By the autumn of 2016, these texts had been translated into all European languages and (legal) errors and inconsistencies were corrected.

The Regulations were formally published in the Official Journal of the European Union in May 2017, heralding in the official transitional period to full implementation in May 2020.

Main Themes of the Regulation

Compared to the MDD, the MDR promotes a shift from the pre-approval stage (i.e., the path to CE Marking) to a life-cycle approach. This approach is similar to the life-cycle view advocated by the US Food and Drug Administration and advanced by many international standards.

The life-cycle approach is illustrated by the incorporation of European guidance (MEDDEVs) into the Regulation: Guidance on Authorized Representation, Clinical Evaluation, Vigilance, and Post-Market Clinical Follow-Up has been integrated into the MDR. As the MEDDEVs are not legally binding, this change reduces the flexibility in interpretation by industry as well as the authorities and NBs. At this moment, it is not foreseen that MEDDEVs for the MDR will be created, and the MEDDEVs generated to accompany the AIMDD and MDD will lose their validity for devices placed on the market under the MDR.



According to the current document, NBs would be placed under a strict regimen of supervision, although it remains unclear whether intended sanctions against an NB that violates MDR requirements could be implemented against the will of a Member State, should the need occur. The qualification requirements for auditing and reviewing NB staff are steeply increased.

Greater emphasis will be placed on clinical data and clinical evaluations. Equivalence, currently used to justify references to studies done with other devices, will be more rigorously interpreted, making this a far more challenging way to demonstrate clinical safety or performance for medical devices.

For implantable Class III devices, clinical investigations will be expected since NBs will generally no longer accept the equivalence approach, although some exceptions can be made. Clinical investigation requirements will not be applicable for devices that have been lawfully placed on the European market in accordance with the AIMDD and MDD where they demonstrate conformance based on sufficient clinical data and applicable Common Specifications (CS) or are of a specific family specified (see Article 61(6)). NBs will require a high level of quality with regard to investigations and clinical evidence in general.

The MDR attempts to make the time frames for review by various parties for different activities more transparent. In general, the Regulations provide greater details and codify information from guidance and standards. Finally, the MDR concentrates the harmonization efforts between European Member States by means of a new regulatory body called the Medical Device Coordination Group (MDCG). The objective of the MDCG is to foster cooperation between the Member States while at the same time increasing the Commission's power to act as needed in acute cases. The MDCG may establish sub-groups consisting of various stakeholders. This may closely resemble the current Medical Device Experts Group (MDEG) structure.

The following concepts are introduced in the MDR or described in more detail:

1. The introduction of a special procedure for NBs for certain high-risk devices, see Article 54. The introduction of manufacturers' liability, see Article 10(16).
2. Substances that are carcinogenic or that have other potential high-risk effects on the human body can only be used together with a strictly defined justification (Annex I, Section 10.4).
3. The introduction of strict rules for clinical investigations and alignment to the Clinical Trials Regulation, see Chapter VI, Articles 62-82.
4. Reprocessing of single-use devices is only allowed under specific conditions – permission by the member state is one of them – provided in Article 17.
5. The rules for designation of NBs have tightened. These are provided in Chapter IV, Annex VII and Annexes IX to XII. Procedures for vigilance and post-market surveillance are described in more detail, and the fact that they have to be used for ongoing conformity assessment of the device are given in detail. See Chapter VII.

Organization of the Regulation

The MDR combines legislation for medical devices and active implantable medical devices into one document. The Regulation commences with an explanatory memorandum, and with Recitals that are explanatory in nature and not legally binding. One recital of particular interest, Recital (4), acknowledges the guidance of the Global Harmonization Task Force (GHTF) and its successor organization, International Medical Device Regulators Forum (IMDRF). The Recital emphasizes the importance of "global convergence of regulations" and unique device identification (UDI) as well as other areas that would benefit from global regulatory harmonization.

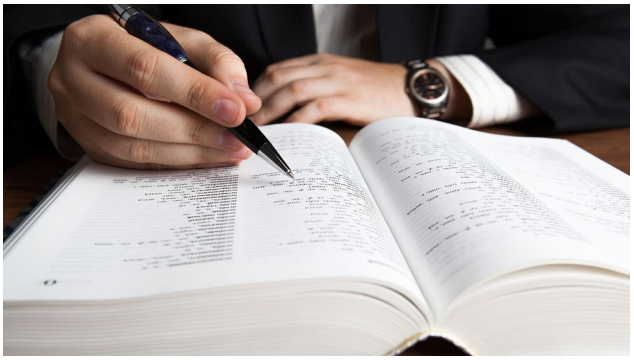
The official version of the Regulation consists of 92 pages, plus 83 pages of Annexes. The highest article number is 123. Recital 101 is the last Recital. The Regulation is further organized into ten Chapters that consist of Articles. The Chapters address important concepts and identify weaknesses. The Articles reference 17 Annexes.

Chapter I — Scope of the Legislation

Definitions and Scope of the Legislation

Article 1, about the scope of the MDR, brings products without an intended medical purpose that are listed in Annex XVI within its scope. The Article also states that medical devices, their accessories and the products listed in Annex XVI will be referred to as "devices." In the definition of accessories, no exception is made for products without a medical purpose that will be considered medical devices and therefore their accessories will also fall within the scope of the MDR.

Another significant extension of the MDR, compared to the MDD, can be found in the definition of a medical device: Devices for cleaning, disinfection or sterilization of devices will be considered medical devices. Previously, products used for cleaning, disinfection or sterilization were accessories to medical devices and hence not within the remit of the Directive[1]. This means their accessories will also fall within the scope of the MDR.



Products that fall within the scope of the MDR together with other Directives or Regulations are brought within the MDR, or, depending on their function and mode of action, placed within the other legislation. But the relevant safety and performance requirements for the device will remain applicable. This means, for example, that a product that is implanted to control fertility by slow release of hormones will be considered a medicinal product, but the implant itself will have to meet requirements applicable for medical devices, including the requirements for risk management, biocompatibility and user information. This requirement may be new to some pharmaceutical companies.

Article 2 contains a total of 71 definitions. This section is significantly expanded (the MDD only contained 14 definitions).

As stated above, the definition of medical devices is extended to include products for cleaning, disinfection and/or sterilization. The Article also covers in-vitro diagnostics (IVD) in order to align the MDR and the In Vitro Diagnostic Device Regulation (IVDR).

The definition of accessory is expanded to "assist" and not only "enable" [a device to be used]. Thus, the understanding of products that could be classified as accessories to medical devices is broadened. The term "label" is defined (Article 2(13)) as the physical label on the device or package. "Risk" is now defined as in the ISO EN 14971:2012 standard, which makes sense. The consequence is that risk can be limited by controlling the occurrence or severity of a harm. The term Common Technical Specifications (CTS) was introduced in the EU Commission draft. The EU Council draft deleted the word "Technical" and simply refers to CS. This term is borrowed from the In Vitro Diagnostic Devices Directive IVDD 98/79/EC and prescribes technical specifications as a way to augment standards. Many definitions currently found in the MEDDEVs have been added to the Regulation, such as those concerning clinical evaluation and vigilance.

There is no longer mentioning of "standalone software." Software may have a medical purpose, in which case it falls within the scope of the MDR. Annex VIII, Classification Rules now refers to "software that drives a device or influences the use of a device" versus software that is "independent of any other device."

Chapter II — Commercializing on the Market

This chapter provides substantial definitions and responsibilities of the respective economic operators (EOs)[2]. This chapter delineates a demarcation between the responsibilities of the Authorized Representative (AR), the distributor and the importer. The current MEDDEV on ARs is essentially incorporated into the Regulation, which highlights the complementary but incompatible roles of the AR and the two other EOs (distributor and importer)[3]. There is an article that describes the process to change an AR. "Distance sales" are regulated in such a way that devices sold to European citizens through the Internet also have to comply with the Regulations. It is not clear how this will be controlled.

Chapter II also introduces the person responsible for regulatory compliance. This role should be filled by a highly educated and experienced person, and is intended to safeguard regulatory compliance within the manufacturer or AR where he or she works. Measures to ensure an injured patient can claim damage for defective products are also introduced in the EU Council draft.

Article 10(8) of Chapter II requires the manufacturer to supply CAs with all information necessary to demonstrate conformity, as well as to share that information with patients or their representatives claiming compensation. These requirements will obviously have an impact on manufacturers' technical documentation.

The AR is made jointly and severally liable for defective devices, together with the manufacturer. The importer also shares liability according to Product Liability Directive 85/374/EEC. Liability requirements may put further pressure on the willingness of manufacturers, ARs and importers to share information with CAs. The responsibilities of the importer and distributor are laid out, but there are no indications who would be liable in cases of non-compliance. It can be foreseen that the AR in such cases may not agree to be held fully liable.

Article 17 of Chapter II addresses reprocessing of single-use devices. Reprocessing may only take place where permitted by national law and under strict conditions. Full product liability is placed on the reprocessor, while the original manufacturer will no longer be mentioned on the label (though still continue to be on the IFU).

Note: The requirements for conformity assessment and the technical documentation that needs to be available will effectively eliminate the position of the Own Brand Label manufacturer. This will have a significant impact on many companies.

The MDR retains Article 3 of the MDD as Article 5 (2); medical devices must be compliant to relevant Annex I, General Safety and Performance requirements. Similarly, Article 5(1) of the MDD exists as Article 8 (1); compliance to EN harmonized standards published in the Official Journal of the European Union presumes compliance to Annex I. Furthermore, Article 18 requires that patients with implantable medical devices (there are exceptions) be provided implant cards. Distance sales and Internet services are addressed in Article 6. This article states that a device not placed on the market, but used for a diagnostic or therapeutic service to a person established in Europe, must also comply with the MDR. This also means that manufacturers of such devices must appoint ARs if they are not based in Europe.

Companies sterilizing procedure packs or systems have to either comply with the requirements in Annex IX (Quality system) or Annex XI (Product Verification), with NB involvement regarding sterility (Article 22(3)).

General Safety and Performance Requirements (Annex I)

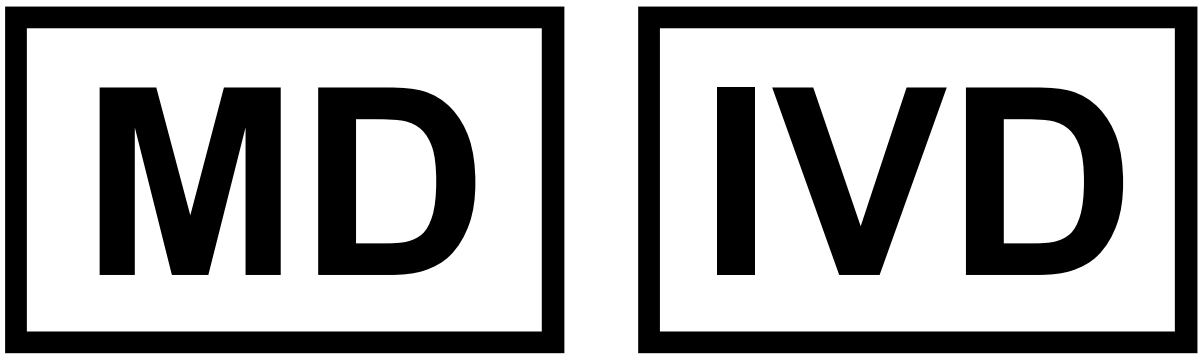
Annex 1 resembles the Essential Requirements of the current MDD. This annex is now called "General Safety and Performance Requirements (GSPR)." Chapter 1, Section 1 remains identical except for an important insertion: "taking into account the generally acknowledged state of the art." Of course, the use of current standards and published literature facilitates addressing this requirement. For non-medical products that are treated as medical devices and products for which there are no sufficient standards, the CS will also be used for this aim. Reduction of risk "as far as possible" is explained as reducing risk "without adversely affecting the risk benefit ratio." Also the manufacturer must use a risk management system (Section 1a). The number of "Essential Requirements" and the level of detail have increased. An initial count indicates that the new GSPR Checklist would have more than 220 items to review. Manufacturers using certificates issued under the current MDD should be aware that they must demonstrate state of the art under the new MDR. They should monitor competitors whose products, including devices, suddenly outdate their medical devices by introducing new technologies.

Chapter 2, Requirements regarding design and manufacture, has added the following Sections, albeit retaining many of the Essential Requirements from the MDD:

- Devices incorporating a medicinal product and devices composed of substances or combinations of substances intended to be absorbed or locally dispersed in the human body;
- Devices incorporating materials of biological origin;
- Construction of devices and interactions with their environment;
- Software in devices and software that are devices in and of themselves;
- Particular requirements for active implantable devices; and
- Risks concerning medical devices for lay persons.

Devices that contain more than 0.1% in weight of a carcinogenic, mutagenic, or toxic substance or substances having endocrine disrupting properties need to have a justification for their presence. Unauthorized access to active devices must be avoided.

Chapter 3, Requirements regarding the information supplied with the device covers labeling and instructions for use. Another addition by the Council (Section 23 .2 (q)) is that there should be an indication on the label that the product is a medical device, similar to the current identification of an IVD. This may lead to the introduction of a new 'MD' symbol.



Chapter III — UDI and Databases

The challenge[4] posed of how to keep track of devices placed on Europe's borderless yet fiercely sovereign market is addressed by a combination of mandatory inputs by NBs, EOs, and Member States into EUDAMED and other databases. Most of these databases will be publicly accessible, although some information will only be available to certain parties. The European Commission is responsible for these databases, but users will all be responsible for their own content. There will be an extensive amount of information collected and transmitted electronically, as well as a mandate to use UDI.

Class III medical device manufacturers must generate a summary of safety and clinical performance in language that can be understood by the intended patient (Article 32). The summary of safety and clinical performance will be assessed by the NB who uploads it into EUDAMED. There it will be publically accessible. It must be clear in EUDAMED who the EOs are, where they are based and their relation with each other in terms of who supplied what to whom. Distributors and importers must work together with the manufacturer or AR regarding traceability of devices. This will limit, if not eradicate, parallel imports into the EU. All these details will be registered.

Note: Mandatory Unique Device Identification (UDI) is introduced with the intention to facilitate the traceability of devices. Devices will be allocated a device identifier (DI) and production series or batches will be identified with a production identifier (PI). The basic device identifier must also be referenced in the Declaration of Conformity. Various databases for clinical investigations, product registration, and vigilance are introduced, under the aegis of the EU Commission. Member States will have to issue a Single Registration Number to each EUDAMED user. As this is the gateway into Eudamed, this is expected to be a complex and demanding process.

The Regulation attempts to professionalize the implementation of compliance by mandating a "Person Responsible for Regulatory Compliance" similar to the requirement placed upon manufacturers under the Medicinal Products Directive.

Note: EUDAMED will be part of a system of several databases, closely interacting with each other:

- Devices being placed on the market
- EOs
- Certificates
- Clinical investigations
- UDI database
- Summaries of safety and clinical performance of Class III and implantable devices
- Vigilance cases and post-market surveillance, including the results of data analysis
- NBs, including specific data related to the notification procedure, their functioning, subcontractors etc.
- Device nomenclature

Apart from the general public, EUDAMED will be accessible for EOs, NBs, CAs and Commission. These stakeholders will also upload their information directly into EUDAMED. They will each have different levels of access to information. For EUDAMED to properly function, access to international medical devices nomenclature will be provided free of charge. Although not specified in this Regulation, and Commission sources do not comment on this subject, it is expected that this will refer to GMDN terms.

Chapter IV and Annex VII — Notified Bodies

By far the greatest change brought by the MDR is the metamorphosis of the role of NBs from an industry partner into a police-like extension of the CAs' market surveillance apparatus.

Although on legal grounds, the formal designation and assessment of NBs is left to Member States in practice, the power to notify, manage the scope and notification, and prescribe corrective measures is transferred from the CAs to "peer-reviews" by multi-national teams, "Joint Assessment Teams." NBs are monitored to ensure they are competent and ethical.

For Class III implantable devices as well as Class IIb devices intended to administer and/or remove a medicinal product[5], the NB will be obliged to send its clinical evaluation assessment report to the relevant expert panel (through the EU Commission) (Annex IX, Chapter II, Section 5.1). The expert panel may decide to issue an opinion on the application, in which case the panel will do so within 60 days. After that, or after the expert panel has declined providing an opinion, the NB can certify the device. These expert panels (Article 106) will be appointed by the Commission, as considered necessary in relevant fields of expertise or specific risks.

Costs related to these expert panels may be covered by fees paid to the Commission by the manufacturer. In setting the level of the fee, the size of the manufacturer will be taken into account.

Under the proposed conditions, the real challenge for the majority of NBs will be to gain and retain highly qualified staff with the education and experience mandated in Annex VII. Both Chapter IV and Annex VII abound with language describing the demise of NBs and how to monitor the competence of the remaining ones.

NBs are required to take out liability insurance to cover cases where they may be obliged to withdraw, restrict or suspend certificates (Annex VII, section 1.4). NBs will also have to make public a list of standard fees for their conformity assessment activities.

NBs will be accredited by the 'authority responsible for notified bodies' (which may be the national CA) in the Member State where they are based. This authority will do a review of such a request and pass their conclusions on to the Commission, which then transmits the decision to the MDCG. The MDCG will assign a joint assessment team consisting of at least three experts, who will review the application documentation. This joint assessment team, together with the national 'authority responsible for notified bodies', will perform an on-site assessment, including sites in other Member States or outside the Union. The process entails strict timelines, but there are no consequences for the 'authority responsible for notified bodies' or the MDCG if they do not meet these timelines.

Note: As Notified Bodies are required to have similarly competent staff for Technical File/Design Dossier reviews and audits, it is easy to foresee a shortage in the availability of qualified personnel. This may lead to significant delays and higher costs for manufacturers.

Classification remains essentially the same under the MDR, but it is recommended to do a thorough assessment of all devices and not to rely on current classification schemes. The definitions and basic principles have some minor changes.

There are 22 classification rules (Annex VIII). Rule 3 now places substances in contact with cells, tissues or organs before administering in the body into Class III. Rule 4 also applies to invasive devices that come into contact with injured mucous membranes. Rule 6 keeps the reusable surgical instruments in Class I, but at the same time these devices get a similar status as sterile or measuring devices, and NB involvement is required; a new classification, Class I r, applies to these devices as well.

Additional classification changes under the MDR include the following:

- The MDR considers surgical meshes Class III.
- A new rule is introduced – Rule 11 – for classification of software. Software can fall under any risk class.
- Rule 18 states that non-viable tissue of human or animal cells will be considered Class III.
- Rule 19 classifies nano-materials depending on their potential for internal exposure.
- Rule 20 places devices intended for inhalation of medicinal substances in risk Classes IIa or IIb.
- Rule 21 places devices composed of substances absorbed or dispersed in different classes based on their level of internal exposure.
- Rule 22 places active therapeutic devices with an integrated diagnostic function, which provides data on patient management in Class III (e.g., closed loop systems or automated external defibrillators).

The MDCG is expected to provide expedient judgments of difficult classification cases (Article 51). Conformity assessment has been simplified (routes to conformity assessment Annexes IX through XI), with many instances for mandatory Quality Management Systems. There is better correlation between risk and data requirements.

The technical documentation elements specified in Annex II are largely based upon the GHTF STED guidance. (The STED document can be found on the IMDRF[6] website.) Annex III describes the technical documentation on post-market surveillance. This consists of the post-market surveillance plan, the post-market performance follow-up plan and the periodic safety report . Annex IV describes the Declaration of Conformity (DoC).

Class I self-certified medical devices do not have a route to conformity assessment (Article 52(7)); manufacturer must set up a quality system (“in the most effective manner and in a manner that is proportionate to the risk class”Article 10(9)), compile the technical documentation according to Annexes II and III and sign the DoC.

Annex IX, Conformity Full Quality Assurance and Assessment of Technical Documentation

This is the equivalent of MDD, Annex II, Section 3.3 Audits, and Section 4, Examination of the design of the product.

Section 3.3 states that NB audits and assessments of quality management systems and post-market surveillance processes should occur at least yearly. Section 3.4 adds that the NB is to perform unannounced inspections of the manufacturer and the manufacturer's suppliers or subcontractors at least once every five years. The NB will be mandated to test samples from the production or manufacturing process. NBs are also encouraged to analyze samples from the market. Nevertheless, it is unclear who will pay for testing of these samples.

Chapter VI, Annexes XIV and XV — Clinical Evaluation and Investigation

As expected, the roles of clinical evaluation and clinical investigation become far more prominent under the MDR. Inclusion of MEDDEV 2.7/1 and parts of ISO 14155 into the MDR is to be applauded. Informed consent and the protection of incapacitated subjects get special attention.

Note: New and tighter criteria are introduced for demonstrating equivalence. As a result, more clinical data must be obtained from clinical investigations of the device. Implantable and Class III devices generally require clinical investigations, unless a rationale can be provided for why this should not be the case. Manufacturers of implantable and Class III devices may consult an expert panel on a voluntary basis prior to the clinical evaluation. A manufacturer may rely on clinical data of another device if the new device is a modification of the old device, if the NB has confirmed this is only a modification, and if the manufacturer has full access to the technical documentation of the other device.

To avoid having to perform clinical investigations on devices that are currently considered compliant and that have been used for years without major incidents, an exception is made for implantable and Class III devices currently placed on the market. These devices must comply with the current requirements for clinical data, and with possible future CS. Data concerning clinical investigations need to be entered into EUDAMED as well. The electronic system must also be used for PMCF studies. The design, execution, and requirements for documentation of a PMCF study have to meet many requirements applicable to clinical investigations.

Article 83

PMS is explicitly intended for gathering and analyzing information with the aim of deciding about preventive and corrective actions. This implies that the information must be collected and analyzed about incidents and adverse events, trend reporting, relevant literature, information from users and publicly available information about similar devices.

Also, the manufacturer's Periodic Safety Update Report and Fields Safety Corrective Actions are sources of information. The PMS system may result in preventive or corrective actions, changes in the Clinical Evaluation Report, changes in the Periodic Safety Update Report, reports for the NB and/or the CA and alterations in EUDAMED. The Summary of Safety and Clinical Performance, required for implantable and Class III devices and written in language for lay users, may also have to be updated as a result of PMS. Periodic reports of Class III and implantable devices must be uploaded to EUDAMED for review by the NB and then be available to the CAs.

Manufacturers are required to report a serious incident (or Field Safety Corrective Action (FSCA)) to the relevant CAs by using EUDAMED within 15 days, in case of death or unanticipated serious health deterioration the maximum is 10 days; in case of a serious public health threat this timeframe is limited to two days (Article 87).

In case of non-serious events the manufacturer must report this to the relevant CAs with a rationale for why this should be considered a non-serious event. The CA may disagree, after which the event should be treated in accordance with the recommendation by the CA. The EU database will be used to share these vigilance reports to the following (Article 92): Member State where the incident occurred, Member State(s) where the FSCA is undertaken, for FSCAs the Member State where the manufacturer (or their AR) is based, and for all vigilance reports to the NB. It is expected that FSCAs and Field Safety Notices (FSNs) will be made publicly available, and this will likely also apply to reports on serious incidents. It is anticipated that other authorities or international organizations will also have access to this database.

The draft FSN needs to be submitted for review "except in case of urgency (Article 89(8))." In practice, our experience has been that currently all manufacturers treat the release of the FSN as urgent and have not shared the draft for review.

Confidentiality

Article 109 ensures confidentiality of certain information, but patients seeking compensation will likely get access to detailed information about the device (see Article 10(14). For non-European manufacturers, their ARs will have to supply this information. Also, Article 1(16) ensures freedom of information for the press as dealt with in any Member State individually. It is currently not clear how this potential conflict of interest (and possible misuse!) may be resolved. Confidentiality of information provided to any database as part of this Regulation is respected as far as this concerns personal data or commercially confidential information, unless disclosure is in the public interest. This disclaimer appears to be in slight conflict with the intention to safeguard confidentiality in order to promote effective implementation of this Regulation, as the results of inspections, investigations and/or audits may be considered to be of public interest.

Article 103-106

The intended use for the MDCG seems intended to replace the proliferating Member State-only bodies (CMC, COEN, MSOG), structures that are trying to coordinate the CAs[7]. Apart from the fact that it has proven impossible to find even a 75% consensus in all but a few MDEG meetings, the difficulty to find truly "independent" experts (as witnessed by the FDA in its expert panels!) and the lack of sanctions for exceeding the review periods do not bode well. In any case an appeal procedure is sorely missing. The MDCG may be assisted by expert panels and expert laboratories. These experts have to be independent from NBs or manufacturers when providing their scientific opinion. Expert panels must take into account relevant information from stakeholders.

Standards

The role of standards seems to be maintained. (Articles 8(1) and 9(2) state that if there are standards and CS, and the manufacturer is compliant, the manufacturer is presumed to be compliant to the relevant aspects of the Regulation.) But after 27 October 2016, when the European Court of Justice ruled that harmonized standards are part of European Law[8], the European Commission has been reluctant to issue new harmonized standards. The European standardization organizations are not European bodies, and therefore they do not work under the European Commission. This is an issue that remains unsolved. The MDCG will play an important role in developing CS and scientific guidelines. However, it should be noted that this will introduce a system where the MDCG is empowered with significant responsibilities[9].

Transitional Provisions

The Regulation entered into force on 26 May 2017. It applies from 26 May 2020. Certificates issued under the current system may remain valid until they expire. However, NBs may issue certificates to the MDD or AIMDD up until the date of application; these certificates are valid for five years to allow for a smoother transition period (Article 120), though at the latest become void four years after application of the MDR (25 May 2024). Devices legally placed on the market compliant to the MDD or AIMDD and prior to the date of application can be sold until five years after that date. NBs accredited before the date of application can start issuing certificates under the MDR.

Closing Remarks

Member States have the possibility to levy fees to cover costs associated with this Regulation. The fees must be transparent and based on cost recovery. Also, the Commission will be funding costs associated with the joint assessment activities, while at the same time developing a structure to recover these costs.

In conclusion, Article 113 defines the need for penalties, but not against whom. Neither does it define the penalty for Member States if they transgress their powers or violate their obligations. This would be a good addition because several steps in placing devices on the market depend on actions done by CAs. If they do not have the resources to perform these processes, the manufacturer may suffer damage. Or worse, patients may not receive the treatment they need.

It is evident that this Regulation is vastly more "legal" in nature than its predecessor, which took more of a "good will" approach in many ways. This will have consequences for staffing at CAs, NBs, and the EOs, manufacturers included.

Although the proposed Regulation may have many similarities with the MDD, the devil is in the details. The Regulation will change the European regulatory environment as more stringent clinical data requirements, extended data management, more complex conformity assessment procedures (particularly for high-risk medical devices), and product liability and penalties will be introduced. NBs are already signaling they will not be able to process all this extra work, which may lead to compliant devices losing access to the European market.

It is important to note that EN ISO 13485:2016, which was released in March 2016, also becomes mandatory in early 2019, thus heralding a very busy 2017 and 2018 for all parties involved in QA/RA compliance.

About the Author

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References:

1 MEDDEV 2.1/1

2 Previously, only the manufacturer and AR were defined terms.

3 In the definition of economic operator also the assembler of procedure packs and the person sterilizing procedure packs and systems are mentioned.

4 The issue of who owns, manages and accesses the data will be addressed. However, the funding, language, adjudication of problems and irregularities, and who has the jurisdiction has not been addressed in the Proposal.

5 It is not clear what a device intended to remove a medicinal product would look like. However, there is a possibility that with these words the same devices are meant as mentioned in Rule 12 of the classification rules: '…and/or remove medicinal products, body liquids or other substances…'

6 http://www.imdrf.org/docs/ghtf/archived/sg1/technical-docs/ghtf-sg1-n011r17-conformity-to-safety-principles-medical-devices-021025.pdf#search="sted"

7 This was verbally communicated at a stakeholders' meeting in April 2016, hosted at the Dutch Permanent Representation in Brussels.

8 http://curia.europa.eu/juris/document/document.jsf?text=&docid=184891&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=218514

9 Creating standards and specifications could be considered 'creating rules' while the same organ is also interpreting these rules and supervising their application. This appears to be in conflict with the Trias Politica on which European law making is based.