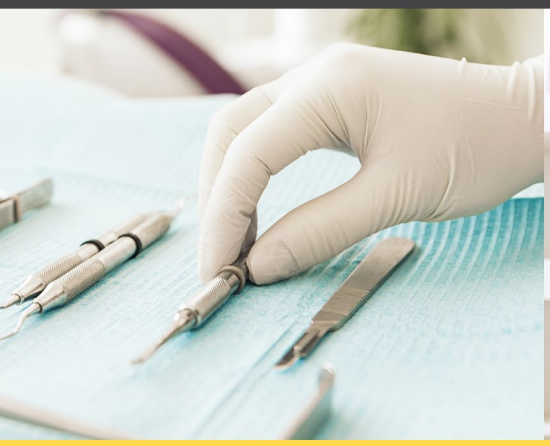
EU

# Understanding Europe's New Medical Devices Regulation (MDR)

## Key changes contained in the proposed MDR and their impact on manufacturers




**Authors**

Evangeline Loh, Ph.D., RAC (US/EU)
EMERGO
Vice President of Global Regulatory Affairs
evangeline@emergogroup.com

Ronald Boumans, MsC
EMERGO
Senior Global Regulatory Consultant
rboumans@emergogroup.com



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# Europe: Getting Consensus from 28 Countries with 28 Opinions

**A Note to Readers**
This white paper is based on the consolidated version of the Medical Devices Regulation (MDR) that has been adopted by the European Parliament and the Member States in June 2016. This text has been described by one of the stakeholders as 'Tentatively Agreed Consolidated Compromise Text', which illustrates the delicate nature of this document. There is a small possibility that some changes are made by the European Commission's Legal Services when this compromise gets a final review for legal inconsistencies. In general it can be expected that most, if not all of the requirements in this version will be in the final version that will be published at the beginning of 2017.

Since 1987 and the inception of the first Directive concerning medical devices, the European Community has expanded into a behemoth union with 28 countries (Member States). Considered in the broader sense, the Community now encompasses 33 stakeholders and over 600 million inhabitants[1]. This ill-managed expansion impeded the governability, and led to dis-harmonization in the implementation of the Medical Devices Directive (MDD) 93/42/EEC. Tension between the desire to harmonize and Member States' refusal to transfer their sovereign rights, paired with differences in interpretation of the MDD, further led to discrepancies between Competent Authorities (CA). These factors also contributed to a non-level playing field for Notified Bodies (NB).

Many of the weaknesses of the MDD were identified as early as 2002 by the Medical Device Expert Group[2]. Directive 2007/47/EC modified the MDD and Active Implantable Medical Devices Directive (AIMDD) 90/385/ EEC in an attempt to address these concerns. Among other elements, this Directive inserted a definition for clinical data and greatly expanded Annex X on Clinical Evaluation.

Member States made desperate attempts to improve their coordination and enforcement efforts through the MDEG, CMC, COEN and MSOG. Member States also attempted to harmonize NBs in several key areas (e.g. clinical evaluation) through NBOG and NB-MED, and to create an operationally sound essential European database (EUDAMED). Nevertheless, these endeavors were only partially successful, most notably in the area of shared information about vigilance. The NBs also championed a Code of Conduct[3] in the hopes of self-policing. Currently most TEAM-NB members have signed this Code of Conduct, others may do the same. However, the number of NBs actively certifying medical devices or IVDs is dropping rapidly.

In addition, the amazingly rapid development of hybrid technologies and highly bureaucratic procedures for resolving disputes made the text of the Medical Devices Directives seem obsolete much earlier than anticipated. Finally, at least for the EU Commission, the 2010 PIP breast implant fraud scandal in France could not have come at a more opportune time. The concerns raised in the PIP scandal expedited the process of renewal and generally satisfied the proponents who wanted more national control.

In September 2012, the European Commission published the initial proposals for the Regulations for medical devices (MDR)[4] and In Vitro Diagnostic Medical Devices (IVDR)[5]. In April 2014 the European Parliament came up with a total of 347 amendments for the proposed MDR[6] and 254 amendments for the proposed IVDR[7]. The European Council responded in September 2015 to the proposals adapted by Parliament. All these documents have not yet led to a final 'First Reading' version , which can be voted on by the European Parliament.

As the Commission, Parliament and Council apparently couldn't agree on the final document, a so-called trilogue was started. In the trilogue, Parliament and Council discuss their positions, facilitated by the Commission. The trilogues started in October 2015 and resulted in a compromise in June 2016. The compromise text was made publicly available in June 2016.

The Commission's version of 2012 was accompanied by an impact assessment. The following versions, and the negotiated compromise have not been assessed on their possible impacts. Doing that would have delayed the process even further. That represents, of course, a risk because the amended articles –and there are a lot of them – pose many uncertainties.

## 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 FDA and advanced by many international standards[8].

The life-cycle approach is illustrated by the incorporation of European guidance (MEDDEVs) into the regulation: Guidances on Authorized Representation, Clinical Evaluation, Vigilance, and Post-Market Clinical Follow-Up have been integrated into the proposed Regulation. According to the draft document, NBs would be placed under a strict regimen of supervision, although it remains unclear whether the intended sanctions 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 the Clinical Evaluation. Equivalence, currently used to justify referencing 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 lower risk medical devices.

For implantable medical devices and Class III devices clinical investigations will be expected since equivalence will generally no longer be an acceptable approach, although some exceptions can be made. This requirement will not be applicable for devices that have been lawfully placed on the market in accordance with the AIMD and MDD where their demonstration of conformance is based on sufficient clinical data and applicable Common Specifications (CS)[9]. NBs will require a high level of quality with regard to investigations and clinical evidence in general.

The proposed MDR attempts to make more transparent the time frames for review by various parties for different activities. In general, greater details are inserted into the document, and information from guidance and standards are codified. Finally, an attempt is made to concentrate the harmonization efforts between the Member States by means of a new regulatory body called the Medical Device Coordination Group (MDCG). The objective of the MDCG would be 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 which may consist of representatives of stakeholders. This may closely resemble the current MDEG structure.

## Organization of the Proposed Regulation

The draft Regulation combines medical devices and active implantable medical devices into one document. The proposed Regulation commences with an explanatory memorandum and the recitals which are explanatory in nature and not legally binding. One recital of particular interest, (4) acknowledges the guidance of the now defunct Global Harmonization Task Force (GHTF) and the International Medical Device Regulators Forum (IMDRF). It emphasizes the importance of "global convergence of regulations" and UDI as well as other areas which would benefit from global regulatory harmonization.

The consolidated version of the Regulation consists of 201 pages, plus 154 pages of Annexes. The highest article number is 97[10]. Recital 71 is the last recital. The proposed Regulation is further organized into ten Chapters which are comprised of Articles. The Chapters address the important concepts and identify weaknesses. The Articles reference 16 Annexes.

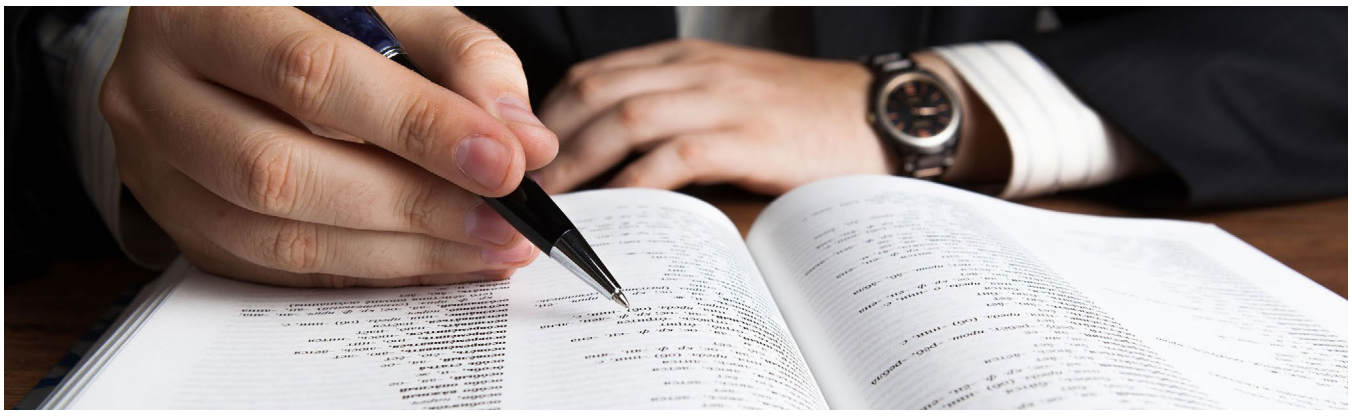
## Definitions and Scope of the Legislation

Article 2 has definition 50 as the highest number, but the Consolidated version contains in reality a total of 71 definitions. This section is significantly expanded (the MDD only contained 14 definitions).

The definition of medical devices is extended to include products for cleaning, disinfection or sterilization. Previously, products used for cleaning, disinfection or sterilization were accessories to medical devices and hence accessories to cleaning, disinfection or sterilization products were not within the remit of the directive[11]. If cleaning, disinfection or sterilization products now become medical devices, their accessories will be covered by the Regulation. As these devices may rely on chemical reactions that could be considered pharmacological, immunological or metabolic, it is obvious they are listed after the exception made for the regular medical devices regarding this mode of action. Less clear is why this is also done with medical devices intended to control or support conception. It appears they may rely on a pharmacological, immunological or metabolic action.

The Regulation shall also apply to a specific group of devices that do not meet the exact definition of medical devices but may have a 'medical character'. These devices are listed in Annex XV and must meet in future specific CS to be defined by the Commission. A medical device incorporating an in vitro diagnostic medical device (IVD) will be governed by the MDR, although the requirements of the IVDR will apply to the IVD part of the device. This would imply that a Class I medical device incorporating a Class B, C or D IVD requires notified body involvement.

The definition of accessory is expanded to "assist" and not just "enable" [a device to be used]. Thus, the understanding of products which could be classified as accessories to medical devices is broadened. The term "label" is defined (Art 2(1)(11)). The label is the physical label on the device or on the package. The term Common Technical Specifications (CTS) was introduced in the EU Commission draft. The EU Council draft deletes the word "Technical" and simply refers to it as Common Specifications (CS). This term is borrowed from the In Vitro Diagnostic Devices Directive IVDD 98/79/EC and prescribes technical specifications which will be a mechanism to augment standards. Many definitions that can currently be found in the MEDDEVs have been added to the Regulation, like those concerning clinical evaluation and vigilance. An interesting detail is that software will still be considered an active device. One of the earlier versions of the Regulation had removed that. Also there is no longer a mention of 'standalone software' from Annex IX, Classification Criteria MDD; this is now referred to as 'software that are devices in themselves' or 'independent of any other device'.



# Chapter II — Placing Products on the Market

This chapter provides substantial definitions and responsibilities of the respective economic operators (EOs)[12]. This chapter delineates a demarcation between the responsibilities of the Authorized Representative (AR), the distributor and the importer. The 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)[13]. There is an article that describes the process to change an AR.

The person responsible for regulatory compliance is also introduced in this chapter. This highly educated and experienced person (though the compromise text decreased the number of years of experience originally proposed by the EU Commission) is intended to safeguard the regulatory compliance within the manufacturer or AR where he is working. Measures to ensure an injured patient can claim damage for defective products are also introduced in the EU Council draft. Article 8(9) requires the manufacturer to supply the competent authorities with all information necessary to demonstrate conformity, while at the same time these authorities are authorized to share that information with patients or their representatives claiming compensation. It is obvious this will have an impact on technical documentation.

As the AR is made jointly and severally liable for defective devices it can be expected that non-European manufacturers will face higher costs and more complex processes to enter the European market, compared to their European counterparts. This requirement may put further pressure on the willingness to share information with the authorities. The responsibilities of the importer and distributor are laid out, but there are no indications who would be liable in case they are not compliant to their obligations.

Reprocessing of single-use devices is handled in Article 15. This 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.

Article 3 of the MDD is retained as Article 4 (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 6 (1); compliance to EN harmonized standards published in OJEU presumes compliance to Annex I. Furthermore, Article 16 requires that patients with implantable medical devices be provided an implant card. These aspects included in the EU Commission draft are retained in the EU Council draft. Distance sales and Internet services are addressed in Article 5. 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 be regulated by this Regulation. This also means that an AR must be involved if the manufacturer is not based in Europe.

## General Safety and Performance Requirements (Annex I)

Annex 1, resembles the Essential Requirements (ER) of the current MDD. 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. The CS will also be used for this aim, introducing a possible conflict with international standards. Reduction of risk 'as far as possible' is explained as reducing 'without adversely affecting the risk benefit ratio'. Also the manufacturer is required to use a risk management system (section 1a). The number of Essential Requirements and the level of detail has increased. An initial count indicates that the new Essential Requirements Checklist would have more than 220 items to review.

Chapter 2 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 combination of substances intended to be absorbed or locally dispersed in the human body; Devices incorporating materials of biological origin; Construction of devices and interaction with their environment; Software in devices and software that are devices in 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, this includes software. Another addition by the Council (Section 19 .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.

MD

IVD

# Chapter III — UDI and Databases

The challenge[14] posed about 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 the users will all be responsible for the 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 (Article 26). It must be clear who the EOs are, where they are based and their relation with each other in terms of who supplied what to whom. Distributors and imports must work together with the manufacturer or authorized representative regarding traceability of devices. This will limit, if not eradicate parallel import into the EU. All these details will be registered. Yet the Regulation still allows for individual member states to set up their own registrations for high risk devices.


**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. It is still unclear, however, whether EUDAMED will be fully operational once the MDR goes into effect.

The proposals attempt 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
- Economic Operators
- 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
- Notified Bodies, including specific data related to the notification procedure, their functioning, subcontractors etc.
- Device nomenclature

Part of the data in EUDAMED will consist of a 'summary of safety and clinical performance' for Class III and implantable medical devices. The manufacturer is required to compile a document that is clear for the intended user and, if applicable, the patient. The NB will assess this document and upload it to EUDAMED. The database will also contain data on vigilance and post-market surveillance.

EUDAMED will be accessible for EOs, NBs, Competent Authorities and Commission. These stakeholders will also upload that 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 this is not specified in this Regulation, it is expected that this will refer to the GMDN terms.

# Chapter IV and Annex VI — Notified Bodies

By far the greatest change is the metamorphosis of the NBs from an industry partner into a police-like extension of the Competent Authorities' 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 the corrective measures is transferred from the CAs to "peer-reviews" by multi-national teams (reference Articles 28, 29, 32, and 33). NBs are monitored to ensure they are competent and ethical.

For Class III implantable devices, plus Class IIb devices intended to administer and/or remove a medicinal product, the NB will be obliged to send their clinical evaluation assessment report to the relevant expert panel (through the EU Commission) (Annex VIII, Chapter II, Section 6.0). The expert panel may decide to issue an opinion on the application. Forming that opinion should be done 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 81a) 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 to be 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 VI. Both Chapter IV and Annex VI abound with language describing the demise of NBs and how to monitor the competence of the remaining ones. The competition to hire the person(s) responsible for regulatory compliance will be intense.

NBs are required to take out liability insurance to cover cases where the NB may obliged to withdraw, restrict or suspend certificates. NB will also have to make public a list of standard fees for their conformity assessment activities.

NBs will be accredited by the national Competent Authority in the Member State where they are based. This Competent Authority will do a review of such a request and pass their conclusions on 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 Competent Authority, will perform an on-site assessment, including sites in other Member States or outside the Union. There are strict timelines given for this process, but there are no consequences for the Competent Authority or the MDCG if they are not met.

**Note:** As Notified Bodies are required to have similarly competent staff for Technical File 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 is kept essentially the same, but it is recommended to do a thorough assessment of all devices and not to rely on the current classification. The definitions and basic principles have some minor changes.

The Classification Criteria (Annex VII) proposed by the European Commission included 21 rules. The most recent draft has a numbered 23 rules (though there are some numbering issues). Rule 3 now places substances in contact with cells, tissues or organs before administering in the body in Class III. Rule 4 also applies to invasive devices that come into contact with injured mucous membrane. Rule 6 keeps the reusable surgical instruments in Class I, but at the same time they get a similar status as sterile or measuring devices and Notified Body involvement is required: Class I r.

Surgical meshes are now in Class III. A new rule is introduced – currently Rule 10a – for classification of software. Software can be in all risk classes. Rule 17 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 21 places devices composed of substances absorbed or dispersed in different classes based on their level of internal exposure. Rule 23 places active therapeutic devices with an integrated diagnostic function, which significantly determinates the patient management by the device in Class III (e.g. closed loop systems or automated external defibrillators).

The MDCG is expected to provide expeditious conclusion of difficult cases. 8. Conformity assessment has been simplified (routes to conformity assessment Annexes VIII through X), 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 is largely based upon the GHTF STED guidance. (The GHTF is no longer active and its work has been taken over by the IMDRF. The STED document can be found on the site of IMDRF[15].) Annex IIa describes the technical documentation on post-market surveillance. This consists of the post-market surveillance plan and the post-market performance follow-up plan and the periodic safety report. Annex III describes the Declaration of Conformity (DoC).

Class I self-certified medical devices do not have a route to conformity assessment (Article 42(5)); the manufacturer must set up a quality system (Article 8.5), compile the technical documentation and sign the DoC.

## Annex VIII, Conformity Full Quality Assurance and Assessment of the 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 4.3 states NB audits and assessment at least yearly, on the quality management system and PMS. Section 4.4 adds that the NB is to perform unannounced inspections of manufacturer and 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.

As expected, the roles of clinical evaluation and clinical investigation become far more prominent. 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 tight criteria are introduced for demonstrating equivalence. The consequences of this are that more clinical data must be obtained from clinical investigations with the device. Implantable devices and Class III devices generally require clinical investigations, unless a rationale can be provided 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, the notified body has confirmed this is only a modification and the manufacturer has full access to the technical documentation of the older device.

To avoid having to perform clinical investigations with 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 that are currently placed on the market. If these devices comply with the current requirements for clinical data, and with possible future CS. Data concerning clinical investigations need to be entered in 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.

## Articles 60a

The information modalities focus on the reporting of Serious Adverse Events during clinical studies, input by NBs about certificates, Summaries of Safety and Clinical performance, Vigilance Reports, and Market Surveillance. Also a periodic (annual) safety update report must be created. This report must evaluate the benefit to risk determination, PMCF data and sales volumes and numbers of the population that use the device. Periodic reports of Class III and implantable devices must be uploaded to EUDAMED for review by the NB and then be available to the Competent Authorities.

Manufacturers are required to report a serious incident (or Field Safety Corrective Action (FSCA)) to the database 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 61). The EU database will be used to share these vigilance reports to the following (Article 66a): Member State where the incident occurred, Member State(s) where the FSCA is undertaken, for FSCAs Member State where the manufacturer (or their Authorized Representative) is based in the EU, and for all vigilance reports to the NB. It is expected that FSCAs and FSNs will be made publicly available, and it can be expected this will 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 Field Safety Notice (FSN) needs to be submitted for review “except in case of urgency” (Article 63(5)). 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 84 ensures confidentiality of certain information but it is likely that patients seeking compensation will get access to detailed information about the device[16]. Also, article 1(8a) 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 78-81a

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[17]. 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 6(1) and 7(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.) The MDCG will play an important role in developing standards, CS and scientific guidelines. However, it should be noted that this will introduce a system where the MDCG is empowered with significant responsibilities[18].

## Transitional Provisions

The Regulation will apply three years after its formal publication in the Official Journal of the European Union (OJEU). It is expected that if the draft regulation is approved and published in OJEU in January 2017 (entry into force), it would become mandatory in January 2020 (date of application). Certificates issued under the current system may remain valid until they expire. However, Notified Bodies may issue certificates to the MDD or AIMDD up until the date of entry into force, that are valid for five years to allow for a smoother transition period (Article 94), though at the latest become void four years after application of the MDR. 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 that have been accredited before the date of application can start issuing certificates under the Regulation.

## Closing Remarks

Member States have the possibility to levy fees to cover costs associated with this Regulation. The fees must be transparent and on the basis of 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 87 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. It is evident that this Regulation is vastly more "legal" in nature than its predecessor, which had more of a "good will" approach in many ways. This will have consequences for staffing at Competent Authorities, Notified Bodies, and the Economic Operators, 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.

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## About the Author

**Evangeline Loh, Ph.D., RAC (US/EU):** Evangeline is Vice President of Global Regulatory Affairs at Emergo. Evangeline's areas of expertise include European CE Marking, clinical evaluation reports, vigilance, and device classification in markets worldwide. She previously worked for Cook Medical and holds a Ph.D. in pharmacology from The University of Texas Health Sciences Center at San Antonio.

## About the Author

**Ronald Boumans, MsC:** Ronald Boumans is Senior Regulatory Consultant at Emergo's office in The Hague. He previously served as Inspector of Medical Technology at the Dutch Healthcare Inspectorate (IGZ), and his areas of expertise include European medical device legislation, Competent Authority supervision, and CE Marking requirements.

References:

1 This includes the 28 official EU member states, plus Norway, Iceland, Lichtenstein, Switzerland, and Turkey by way of a Customs Union Agreement.

2 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52003DC0386:EN:HTML

3 http://www.team-nb.org/wp-content/uploads/2016/03/Code-of-Conduct-Medical-Notified-Bodies-v3-4-31-12-2015.pdf

4 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012PC0542&from=EN

5 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012PC0541&from=EN

6 http://data.consilium.europa.eu/doc/document/ST-12040-2015-REV-1/en/pdf

7 http://data.consilium.europa.eu/doc/document/ST-12042-2015-INIT/en/pdf

8 This is also a concept noted globally among many regulatory authorities.

9 See art. 49.2ab on page 125.

10 The final version will require some extra editing before it will be a consistent document. E.G. all recitals, articles, definitions etc will be renumbered and some inconsistencies will be edited out.

11 MEDDEV 2.1/1

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

13 The Council also added to the definition of Economic Operator the assembler of procedure packs or systems and the person sterilizing procedure packs or systems.

14 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.

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

16 Art. 78(2), each MS appoints one member and one alternate member to the MDCG.

17 This was verbally communicated at a stakeholders' meeting in April of this year, hosted at the Dutch Permanent Representation in Brussels

18 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.