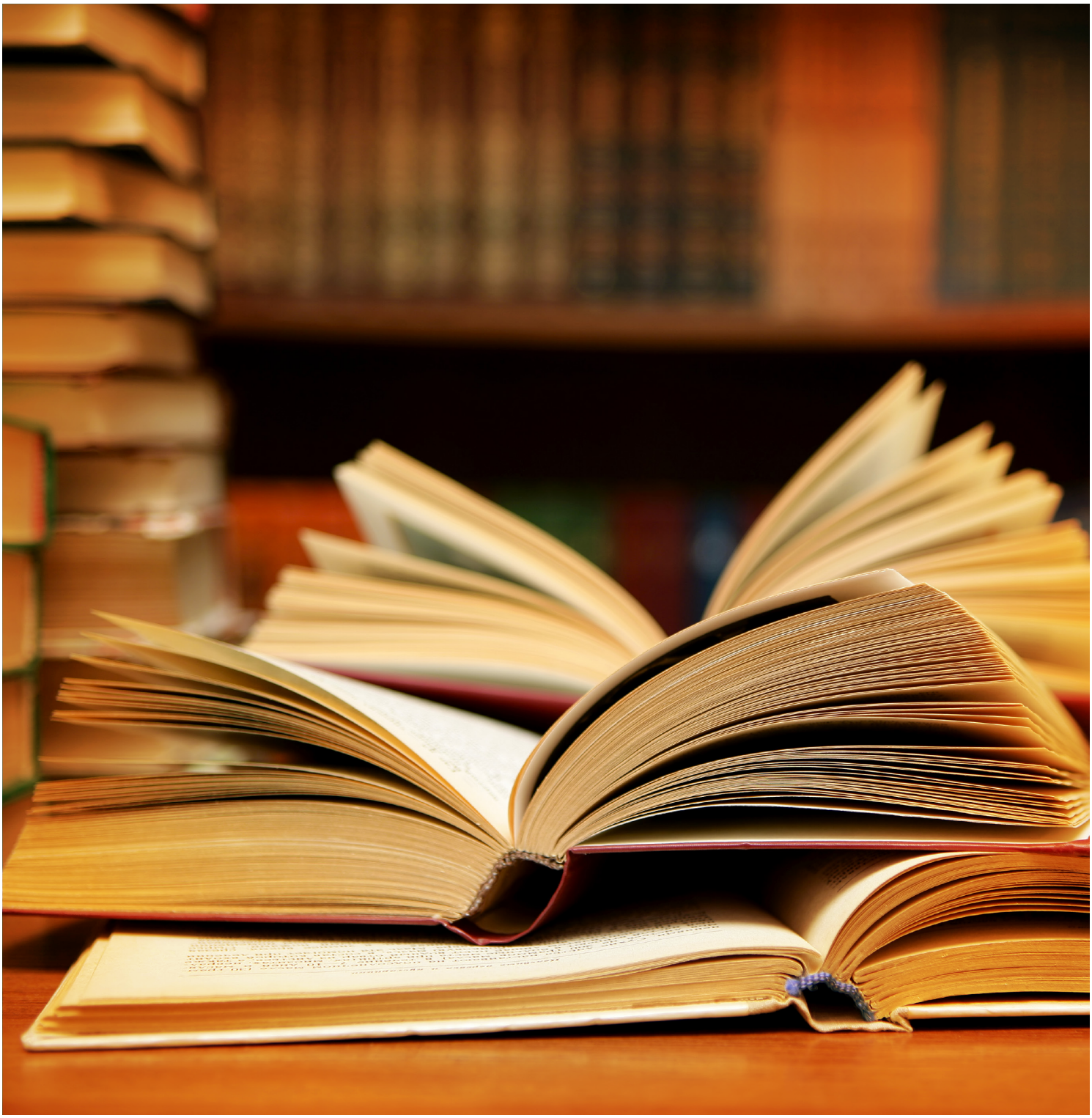


IMPLEMENTING

MEDICAL DEVICE REGULATION

COCIR VIEWS ON THE WAY FORWARD

COCIR SUSTAINABLE COMPETENCE IN ADVANCING **HEALTHCARE**

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

IMPLEMENTING THE MEDICAL DEVICE REGULATION[1]

COCIR VIEWS ON THE WAY FORWARD

EXECUTIVE SUMMARY

This document provides a strategic overview of the impact of Medical Device Regulation (MDR) impact on our sector and is addressed to all parties involved in implementing the MDR. It outlines COCIR's views on four key strategic areas, set out in the following sections: **1 GENERAL FRAMEWORK**, **2 PRE-MARKETS**, **3 POST-MARKET** obligations and, **4 RELEVANT ACTORS** in the implementation of the MDR. The objective is to clearly communicate the genuine impact of the MDR and to ensure its full implementation.

1. GENERAL FRAMEWORK

1A. DEFINITIONS: Proper implementation requires that clear definitions are available. COCIR recommends using the existing definitions in other legislation, guidance or international standards, thus avoiding additional effort that brings no benefits to patients.

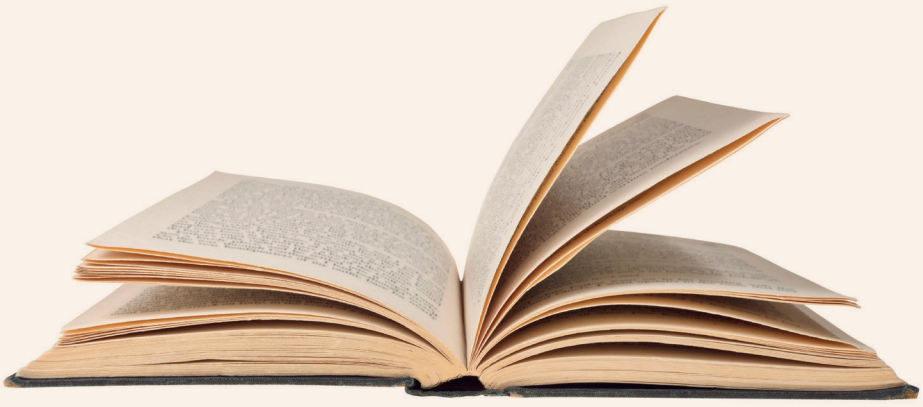
1B. SCRUTINY PROCEDURE: Although COCIR fully supports the concept of increased scrutiny, it is vital to clarify the process for establishing the group and selecting the experts.

1C. UDI & EUDAMED: COCIR supports the principle of a European-level database. However, timely implementation of its function is crucial. The aim should be convergence between EU UDI, IMDRF, and US FDA formats at a global level.

1D. DELEGATED AND IMPLEMENTING ACTS: COCIR stresses that timely adoption of the relevant Delegated and Implementing Acts is of utmost importance in ensuring that businesses are able to adapt their internal processes to comply with the Regulation.

1E. HARMONISED STANDARDS AND COMMON SPECIFICATIONS: COCIR believes that Harmonised Standards, finalised and published promptly, will - in most cases - be sufficient to support industry in complying with the MDR. Common specification should only be adopted exceptionally, where no standard is available, e.g. in specific clinical areas. Relevant stakeholders, including industry, should be involved during the drafting of the Common Specifications.

1F. TRANSITION PERIOD: Manufacturers will understandably require a reasonable preparation period. Three years will only be sufficient if they can make meaningful preparations throughout this period, beginning with the timely and sufficient availability of Notified Bodies, implementing legislation, guidance and Harmonised Standards.



1 European Commission on the MDR https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en

2. PRE-MARKET OBLIGATIONS

2A. CLINICAL EVALUATION: Clinical evaluation terms, such as “sufficient clinical data” or “effective”, need to be clarified. The IMDRF paper on clinical evaluations should be used to achieve global convergence for software.

2B. MEDICAL DEVICE SOFTWARE: Within the MDR, the majority of medical device software will move from class I to IIa to higher. This will lead to a major change, from self-certification to certification involving a Notified Body. Medical device software demands specific attention regarding classification, interpretation of different rules, clinical evaluation and the implementation of UDI.

2C. CHEMICALS: Clarification is still needed on labelling; COCIR urges avoiding any potential overlap with other EU legislation in the environmental policy field.

3. POST-MARKET OBLIGATIONS

3A. POST MARKET SURVEILLANCE AND VIGILANCE: COCIR remains concerned by the 15-day reporting timeline. It urges working to avoid duplicating administrative efforts for reporting by the various types of economic operator.

3B. REPROCESSING: COCIR looks forward to commenting on the draft Implementing Act.

4. RELEVANT ACTORS

4A. STAKEHOLDER CONSULTATION: Stakeholders - including industry - should not be relegated to an observer role under the MDR but should remain as active contributors. The newly created Medical Device Coordination Group (MDCG) should identify a mechanism for meaningful and early involvement by industry.

4B. ECONOMIC OPERATORS (Manufacturers and Others): COCIR recommends that roles and responsibilities between manufacturers and other types of economic operators be clarified, to keep administrative efforts to the minimum required.

4C. NOTIFIED BODIES: As the number of medical devices undergoing certification will increase, and it is uncertain which Notified Bodies will be designated and when, it is vital to guarantee sufficient and timely Notified Bodies capacity to ensure a smooth transition.

DETAILED BRIEFING

The Medical Device Regulation (MDR) was adopted in May 2017 and will enter into application on 26 May 2020. The Regulation aims to harmonise the European market for medical devices, building on the Medical Devices Directives.

The implementation process is now at a critical phase, with secondary legislation being drafted. As one of the main industry stakeholders, COCIR is actively involved at this stage, through a detailed analysis of the impact on businesses and through working with Member States[2] and the European Commission towards successful implementation.

Although it does not introduce any radical changes, the MDR implements a series of additional rules and requirements, also increasing compliance demands at industry level. COCIR seeks a timely implementation that will not prevent or slow innovative devices entering the market and will help our members prepare for Spring 2020.

1. GENERAL FRAMEWORK

1A. DEFINITIONS

The MDR has a broader scope than the Medical Device Directives, encompassing, among others, a number of aesthetic devices. By introducing new roles and responsibilities for all economic operators, the MDR now combines all necessary elements in a single legislation. The Regulation also now includes several definitions that have been changed since the previous MDD; the most important changes cover the amended definition of a medical device. We also note that a number of other relevant definitions are required or need further clarification. COCIR recommends using the existing definitions in other legislation, guidance or international standards. This will avoid additional unnecessary efforts that will add to the industry burden without bringing benefit for patients and/or users.

1B. SCRUTINY PROCEDURE

The new Regulation introduces a new pre-market scrutiny mechanism that involves a pool of experts at European Union level. This requirement was introduced to ensure stricter ex-ante control for high-risk devices (class IIb[3] active devices intended to administer/remove a medicinal product and III implantable devices). Although COCIR supports the ambition for greater scrutiny, it is vital to understand the process being used to establish the group and select the experts. To target the scrutiny process more effectively, it should only apply to novel devices.

2 Competent Authorities for Medical Devices (CAMD) http://www.camd-europe.eu/
3 See Annex VIII Classification Rules for definitions of different classes

1C. UDI & EUDAMED[4]

Two of the major additions in the new Regulation are the obligation to provide a device traceability system based on a Unique Device Identification (UDI) and the creation of a comprehensive EU database of medical devices. For the UDI format, COCIR believes it important to align EU efforts with those at the global level, thus contributing to converging systems and reducing the administrative burden for manufacturers. The IMDRF guidance on medical device identification[5] as well as the experience of the US FDA in implementing UDI, provide useful resources. In practical terms, establishing a UDI helpdesk to guide medical device manufacturers, as currently being considered by the European Commission, would be valuable.

COCIR welcomes the establishment of EUDAMED as a comprehensive European-level database. This database is required to be functional by 25 March 2020. To support the European Commission and the Member States, COCIR is currently contributing to the technical work of the EUDAMED Steering Committee and providing expertise to its seven associated expert groups[6]. TThe overall recommendation is the early setup of EUDAMED, as the Regulation normally does not foresee any minimum period between point when EUDAMED becomes functional and the application of the obligations of economic operators.

One point of concern could be the possibility for the national competent authorities to ask for fees related to the effort undertaken; not only related to EUDAMED and registration of the economic operators, but also for their assessment relating to vigilance activities. COCIR urges competent authorities to communicate their plans for fee requirements publicly and in a timely manner to allow manufacturers to budget accordingly

1D. IMPLEMENTING AND DELEGATED ACTS

The regulators will need to adopt implementing and delegated acts that clarify and set up the various requirements of the Regulation, including UDI and EUDAMED. The MDR provides the potential for up to 80 implementing measures, including 18 that are mandatory, with the final number adopted at the discretion of the European Commission. For Delegated Acts, COCIR is particularly concerned by the potential for regulatory uncertainty. The European Commission should thus only use this potential where absolutely necessary. In addition, the Delegated Acts should clearly define the processes and be easily understandable. Timely adoption of implementing acts is of the utmost importance, as businesses need sufficient time to implement the new requirements before the enforcement date. Developing a Delegated or Implementing Act requires establishing a transparent process that allows stakeholders, particularly industry, to become involved in the drafting process at an early stage in order to leverage their specific expertise.

1E. HARMONISED STANDARDS AND COMMON SPECIFICATIONS

The MDR has been designed to function under the New Legal Framework (NLF), which replaces the New Approach of 2008. This implies that it will be complemented by 'state of the art' Harmonised Standards covering the relevant legal requirements. All concerned stakeholders develop such standards in mutual agreement, through the ESOs and in line with the applicable European Regulation on standards 1025/2012. To benefit from international expertise, and to support international trade and enhance European industry's competitiveness, European Harmonised Standards should preferably be based on international standards.

4 Refer to detailed COCIR Impact Paper on Medical Software
5 IMDRF Guidance Unique Device Identification (IMDRF/UDI WG/N7 FINAL:2013) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf
6 The seven EUDAMED expert groups are (1) Registration of Economic Operators and MD, (2) Unique Device Identification, (4) Notified Bodies and EC certificates, (5) Vigilance, (6) Clinical Investigation, (7) Market Surveillance and Data Exchange.

The Medical Device Regulations contains a provision for an alternative for Harmonised Standards, namely Common Specifications. COCIR believes that this alternative can be a useful addition to the "regulatory toolkit" available to authorities, provided it is used with extreme care and only deployed in exceptional cases where no Harmonised Standards can be agreed upon. In addition, even in these exceptional cases, development of Common Specifications should primarily use international competence and be open to input from all stakeholders in a structured way from early in the drafting process. Proposals for the drafting process of device-specific guidance in the clinical area, where the structural involvement of stakeholders was only foreseen in the last-but-one step of the process, leads COCIR to believe that this will not be realised. COCIR therefore urges Commission and Member States to redraft these proposals to reflect this.

COCIR has long been involved in developing standards for use in regulatory contexts. Since 2010, COCIR has become increasingly concerned with the slow and burdensome process of standards harmonisation. Given that the new Regulations will require 're-harmonisation' of all standards, a practical process should be defined as a priority. This should include a Standards Request that allows all necessary standards to be harmonised. The future Standards Request should not exclude selected categories of standards, but rather include horizontal and product specific standards. This is particularly important since the General Safety and Performance Requirements in the Regulations have become even more complex than the Essential Requirements of the existing Directives. So far, more than six months after the publication of the Regulations, little is visible of the practical process needed. This unacceptable delay in the harmonisation of standards under the Medical Device Directive 93/42/EEC, including their listing in the Official Journal (OJ), concerns not only new standards but also revisions and amendments of previously Harmonised Standards. Over half of the OJ-listed standards no longer reflect the latest edition. This creates problems of legal certainty, as it conflicts with the legal requirement that "state of the art solutions" must be implemented.

COCIR therefore believes that if this issue for the Directives is not swiftly resolved, it is reasonable to expect that, come May 2020, the number of Harmonised Standards for the Regulations will be at an unworkably low level, risking proper implementation. A lack of Harmonised Standards will create space for conflicting national standards, threatening the single market and to varying safety levels across the EU, based on individual interpretations by the various Notified Bodies on how to comply with the General Safety and Performance Requirements, hence jeopardizing the key benefits of the New Legislative Framework.

1F. TRANSITION PERIODS[7]

The obligations of the MDR will apply from 26 May 2020 onwards (see Annex I). A three-year transition period is only sufficient for industry if economic operators are able to make full use of this time and if it is starting to run as from the availability of the implementing legislation. For many obligations, it will only be possible to undertake meaningful preparations only after other parts of the MDR have been implemented, e.g. once a NB has been re-notified, or once a delegated act or implementing act has been published. Otherwise, economic operators risk falling outside compliance, or even face punishment for factors outside their control. In addition, many third countries, medical device registration relies on CE marking. In these markets, it will be necessary to re-register medical devices due to updated labels, technical files, and declarations of conformity and EC certificates.

It is therefore of the utmost importance that all Delegated and Implementing Acts, guidance documents and Harmonised Standards are published in good time for economic operators to prepare their own processes and achieve compliance. Communication and awareness building will be critical in ensuring that all economic operators are aware of their obligations and the relevant deadlines. In addition, there should be a guarantee that there is sufficient capacity to allow manufacturers to obtain Notified Body certificates in a timely fashion.

7 Refer to detailed COCIR Impact Paper on Timeline and Transition

2. PRE-MARKET OBLIGATIONS

2A. CLINICAL EVALUATION[8]

The MDR aims to reinforce the rules on clinical evidence, including an EU-wide coordinated procedure for authorising multi-centre clinical investigations. The bar for demonstrating safety and performance has been raised significantly; however, there has been no indication of what quantity of supporting clinical data would be considered sufficient. This could prevent creation of a level playing field. Gathering clinical data is expensive and resource heavy, thus potentially obstructing market access for new and existing products and making it harder to bring innovation to market.

In addition, the amount and adequacy of clinical data may be dependent on the interpretation by the Notified Body (NB). The MDR, MDD, MEDDEV guidelines and Notified Body Operations Group (NBOG) guidelines all have different, ambiguous requirements for manufacturers and NBs. This increases the risk of non-coherent interpretation between competent authorities and NBs.

Guidance on conducting clinical evaluations has been developed at a global level in the framework of the IMDRF[9], including on clinically evaluating software. COCIR supports global convergence wherever possible to prevent barriers to trade. We expect this guidance to be used in the European Union, mapping it to the terminology in the MDR and MEDDEV.

2B. MEDICAL DEVICE SOFTWARE[10]

COCIR has been a long-standing and instrumental member of the European Commission expert group that develops dedicated guidance (MEDDEV 2.1) on medical device software. It is currently contributing to adapting existing guidance for the MDR. The new Regulation introduces several changes in rules and requirements that may have a specific impact on medical software.

One of the major changes introduced by the MDR refers to the classification of software and hardware medical devices that incorporate software, which could fall into higher classes than is currently the case under the MDD. This is due to the introduction of a new classification rule dedicated to software and hardware that incorporates software (Rule 11), but also due to changes to Rule 10 and the introduction of Implementing Rule 3.7. Applying the rules has become more complex than under the MDD, as multiple rules will now apply simultaneously for many medical devices. As the vast majority of software and hardware medical devices that incorporate software will now fall into higher classes (class IIa or above), this has major implications for manufacturers used to placing such products on the market as class I under the MDD. Rather than rely on self-certification, these manufacturers will now need to engage with Notified Bodies. This may have significant implications for cost and time-to-market, particularly as Notified Bodies are in short supply. To simplify the classification of software and hardware medical devices that include software, assure a common interpretation and maintain a level playing field, COCIR recommends developing guidance that integrates Rule 10, 11 and Implementing Rule 3.7 into a single scheme, based on the IMDRF framework for Software as a Medical Device. This should also be expanded to accommodate hardware medical devices that incorporate software and software accessories.

Medical software also poses a number of specific challenges for UDI. For software and systems packs, the rules of sequencing of the variable part of the UDI need clarification. If software defect fixes require a new UDI sequence, for example, this may lead to an overload of numbers.

8 Refer to detailed COCIR Impact Paper on Clinical Evaluation
9 IMDRF guidance documents http://www.imdrf.org/documents/documents.asp
10 Refer to detailed COCIR Impact Paper on Medical Software

2C. CHEMICALS

The provisions of MDR Annex I, 10.4 require manufacturers to justify using substances that are carcinogenic, mutagenic, toxic for reproduction (CMR) or Endocrine Disrupting (ED) substances in medical devices or in parts or materials where an exposure may arise (invasive devices and others). A number of critical elements have not been defined in the MDR; these will need further clarification from the EC.

Each year, substances can be reclassified as CMR or EDs. In the event of a reclassification, manufacturers should be given an appropriate transition time to take the actions required to evaluate use of a reclassified substance used in MDs. This should allow them to provide a justification for its continued use or to substitute it for a safer alternative. This process can take considerably longer given the complexity of redesigning devices. For devices that do not require an NB certificate, an 18-24 month transition time is the minimum for avoiding disruption in production and supply. For devices with an existing valid certificate, the change in classification of a substance should be considered at the time of the renewal of the certificate. Assuming they can demonstrate that the presence of the substance does not pose any risk to patients or users, manufacturers should not be required to update their technical documentation retroactively.

The EC should also provide clear guidance or provide a mandate to ESOs to clarify labelling obligations. Listing substances on the device or the package is impractical; it would be better to provide the information in the IFU or the accompanying documentation as is the case for existing EU legislation such as the REACH Regulation[11] Moreover, the MDR does not specify which standard should be used to name substances. The use of a recognised symbol for CMRs and EDs, as used for phthalates previously, could offer a practical and easy-to-use solution.

3. POST-MARKET OBLIGATIONS

3A. POST MARKET SURVEILLANCE & VIGILANCE[12]

COCIR considers a robust post-marketing phase a key element in any balanced regulatory framework. The MDR introduces a number of changes in the post-marketing requirements, such as timing of vigilance reporting, Post Marketing Surveillance (PMS) planning and implementation, the introduction of new requirements such as the Periodic Safety Update report (PSUR) as well as additional roles and responsibilities for distributors and importers.

COCIR recognises and agrees with all economic operators' involvement in the post-marketing surveillance system. It also supports the obligatory reporting of complaints to manufacturers. Nevertheless, the Regulation requires that such notifications occur systematically for all suspected incidents and through all economic operators involved (manufacturer, importer, Authorised Representative). This means that all corrective maintenance activities of distributors will lead to multiple reports to the manufacturer, creating enormous transactions traffic and many duplicated records as well as risking confusing identification. It would also oblige distributors to disclose customer files, which could lead to the manufacturer gaining a dominant position. COCIR therefore considers that, while not explicitly set out in the Regulation, economic operators can agree between each other to sub-contract incidents reporting to the manufacturer and that manufacturers should be able to delegate part of the incident pre-evaluation to distributors.

11 REACH Regulation (EC 1907/2006) on chemical substances http://ec.europa.eu/environment/chemicals/reach/reach_en.htm
12 Refer to detailed COCIR Impact Paper on Post Market Surveillance

The timeline for reporting serious incidents has been decreased from 30 to 15 days. This timeline presents a major challenge to the industry, as more than 50 per cent of events require more than 15 days to be investigated[13]. This means that many unnecessary initial reports may need to be reported to Competent Authorities.

COCIR supports maintaining a post-marketing surveillance system during the lifetime of the medical device, as both patients' and users' safety needs to be guaranteed. We understand that the PMS plan must be designed to be proportionate to the risk class during the 'entire lifetime'" of a device (being the '"expected lifetime'" as defined by the manufacturer). However, the Post-Market surveillance Clinical Follow-up (PMCF) should also be defined in proportion to the device lifecycle status.

3B. REPROCESSING

COCIR looks forward to contributing to the draft Implementing Act for the reprocessing of Single Use Devices as medical devices. As the decision and responsibility for managing the reprocessing of devices is the responsibility of the Member States, this creates the potential for divergent interpretations and misunderstandings. These include cases where the manufacturer may have commercial relations both with Member States where reprocessing is allowed and Member States where it is not. Such divergence could also create confusion in relation to third countries that could decide by themselves whether or not to admit a reprocessed product. It should also be considered that in the post marketing surveillance process, the flow of information stops before the reprocessing. Thus, the risk-benefit analysis would be limited to a short period compared to the full lifecycle of the device.

4. RELEVANT ACTORS

4A. STAKEHOLDER CONSULTATION

CCOCIR believes that the currently established Medical Device Expert Group (MDEG), including all stakeholders as contributors, has demonstrated its value over the years. Under the MDR, stakeholders, including industry, should not be relegated to an observer role but rather should remain as active contributors. The newly-created Medical Device Coordination Group (MDCG) unfortunately is only comprised of Member State representatives. It is important that there is a mechanism to allow the expertise and knowledge of industry to be linked to the Member States. This is particularly important when drafting implementing measures, common specifications and guidance documents; industry needs to be involved at an early stage.

4B. ECONOMIC OPERATORS[14]

The Medical Device Regulation introduces the new role of 'economic operator', determining the respective tasks of actors in the supply chain, including manufacturers, importers and distributors. Most of the manufacturer's requirements are already covered in the preceding sections (see also Annex II), showcasing the increased efforts needed to show compliance. In addition, manufacturers are required to have at least one qualified person available in their organisation responsible for ensuring regulatory compliance. SMEs do not need to have such a person within their organisation but do need to have somebody permanently and continuously at their disposal.

13 GHTF/SG2/N54R8:2006 guidance document on adverse event reporting http://www.imdrf.org/documents/doc-ghtf-sg2.asp
14 Refer to detailed COCIR Impact Paper Economic Operator

While understanding the reasoning behind the new importers and distributors obligations in the MDR, COCIR is concerned by the substantial administrative burden and duplication of efforts caused by the specific way the EU New Legislative Framework (NLF) has been implemented in the MDR. The obligations go far beyond the receiving goods good practices and the NLF requirements (see Annex III). COCIR understands that, while not explicitly set out in the MDR, it is sufficient for importers to implement good practice, including documentary verification, that using sampling methods for physical checks. In addition, where economic operators belong to the same organisation (but are different legal entities), they should be able to agree on sub-contracting between each other's verification activities, with the provision that adequate control and monitoring is in place.

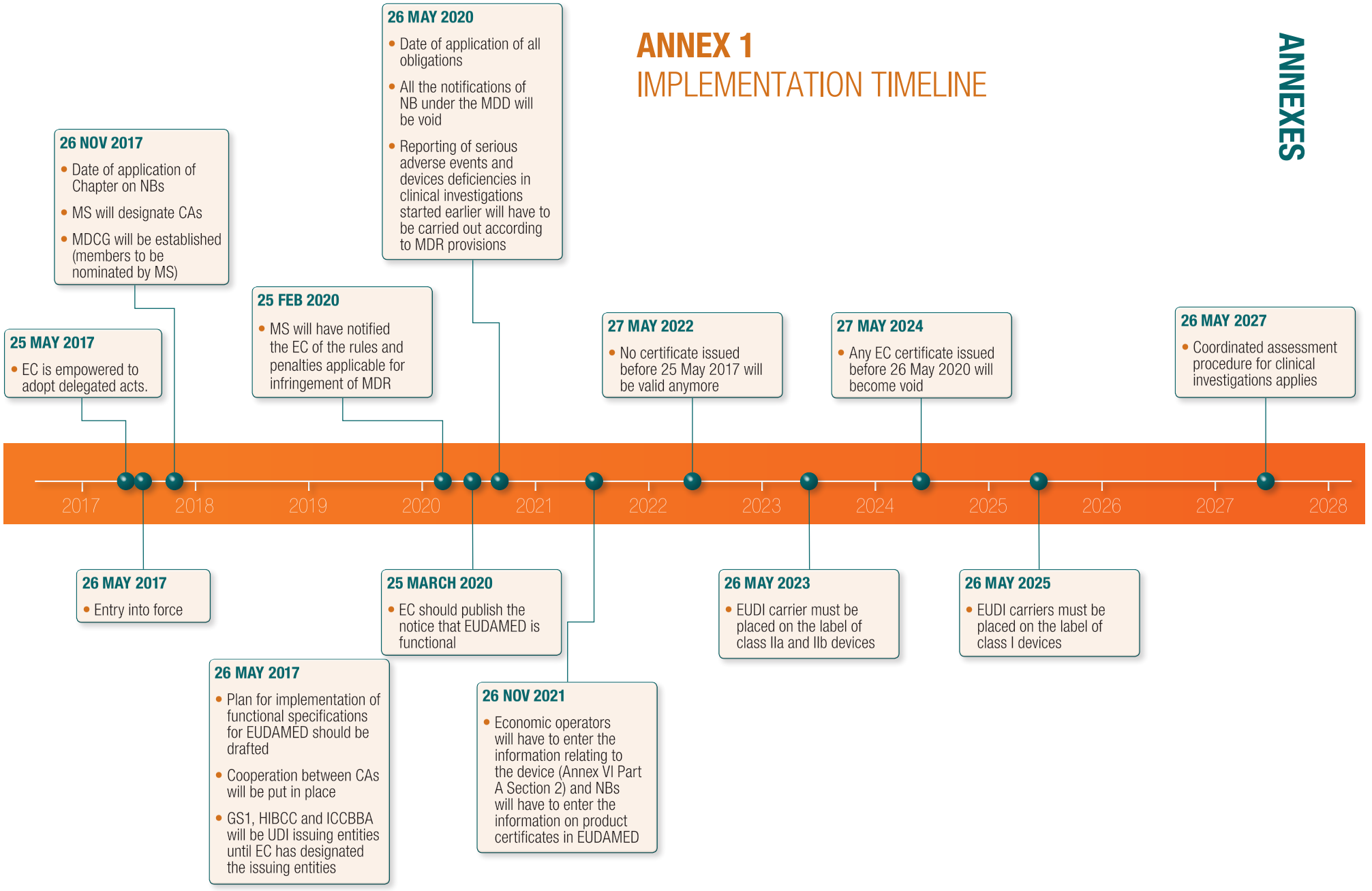
4C. NOTIFIED BODIES

Notified Bodies are vital stakeholders in implementing the MDR. As of 26 November 2017, conformity assessment bodies may apply for designation as Notified Bodies[15]. Given that the requirements under the MDR have become more complex and the scope has been broadened, COCIR expects the demand for Notified Bodies to increase.

The MDR also introduces greater scrutiny of Notified Bodies, particularly those accredited for high-risk devices. It is therefore a concern that there would be a lack of sufficient and timely capacity of Notified Bodies, also during the transition period. For manufacturers to be able to implement the MDR there needs to be transparency and predictability on when Notified Bodies will be designated under the MDR and for which scope. This is lacking in the current NANDO database, which is completed retrospectively. COCIR proposes a centralised and easily-accessible overview of all accredited and de-notified Notified Bodies that will provide manufacturers with all required information.

15 Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017 on the codes for the designation of notified bodies http://eur-lex.europa.eu/eli/reg_impl/2017/2185/oj

ANNEX 1
IMPLEMENTATION TIMELINE



ANNEX 2
OBLIGATIONS OF THE MANUFACTURER

CONDUCT THE **CLINICAL EVALUATION**	MDR Articles 61 and 88
DRAW UP THE **TECHNICAL DOCUMENTATION** AND KEEP IT AVAILABLE FOR THE COMPETENT AUTHORITIES	MDR Articles 10 (4) and 10 (8), Annexes II and III
ESTABLISH, DOCUMENT AND MAINTAIN A SYSTEM FOR **RISK MANAGEMENT**	MDR Articles 10 (2) and 10 (3) and 61, Annexes I, Section 3, and XIV
DRAW UP THE **EU DECLARATION OF CONFORMITY** AND KEEP IT AVAILABLE FOR THE COMPETENT AUTHORITIES	MDR Articles 10(6, 8), 19, 20, 56
COMPLY WITH THE **UNIQUE DEVICE IDENTIFICATION** SYSTEM	MDR Articles 27, 29, 31
SET UP A **QUALITY MANAGEMENT SYSTEM**	MDR Articles 10(9), 27(3), 29, 83, 87, 88, Annex I Section 3
COMPLY WITH THE **LABELLING** REQUIREMENTS AND ENSURE THAT MEDICAL DEVICES ARE ACCOMPANIED BY INFORMATION IN RELEVANT LANGUAGE	MDR Annex I, Section 23
IMPLEMENT **VIGILANCE** SYSTEM FOR RECORDING AND REPORTING OF INCIDENTS AND FIELD SAFETY CORRECTIVE ACTIONS	MDR Articles 87 and 88
DEMONSTRATE SUFFICIENT FINANCIAL COVERAGE FOR **LIABILITY FOR DEFECTIVE PRODUCTS**	MDR Article 10
IMPLEMENT **REGISTRATION IN** CENTRAL DATABASE EUDAMED	MDR Annex VI, Section I
DESIGNATE AN **AUTHORISED REPRESENTATIVE** IF NECESSARY	MDR Article 11
DESIGNATE A **PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE**	MDR Article 15

ANNEX 3
NEW OBLIGATIONS OF THE OTHER ECONOMIC OPERATORS

(Showcasing potential for duplication of efforts between different economic operators)

NEW OBLIGATIONS	IMPORTER MDR Art. 13	DISTRIBUTOR MDR Art. 14	EU REP MDR Art. 11
Verify CE mark and Declaration of Conformity have been drawn up before placing a device on the market	**X**	**X** (sampling)	**X** (+ assessment route)
Verify Authorized Representative has been designated*	**X**		NA
Verify Label compliance & IfUs delivered (imported products)	**X**	**X** (sampling)	"Implicit"
Verify UDI assigned to the device*	**X**	**X**	**X**
Notify Manufacturer (and EU Authorized Rep. and Importer where relevant) on Non-conformity & complaints	**X** (excl. importer)	**X**	**X** (excl. importer & EU rep)
Notify Competent Authority on serious risk & falsified product	**X**	**X**	
Label imported product with importer's name & address	**X**		
Verify product registration in Eudamed*	**X**		**X**
Keep register of complaints, non-conforming products, FSCAs*	**X**	**X**	
Ensure storage & transport conditions comply with manuf. requirements	**X**	**X**	NA
Keep copy of DoC & CE certificates available to Competent Authorities	**X**		**X**
Keep a copy of the technical documentation available to Competent Authorities			**X**
Cooperate with CA & provide free MD sample (or grant access)*	**X**	**X**	**X**
Verify importer/Manufacturer comply with his obligations		**X** (importer)	**X** (mfr)
Ensure traceability (MDR Art. 25)	**X**	**X**	NA
Economic operator Registration in Eudamed	**X**		**X**
Terminate his mandate if manufacturer acts contrary to its obligations			**X**