INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

IMPLEMENTATION OF THE NEW EU MEDICAL DEVICE REGULATIONS MDR (2017/745) AND IVDR (2017/746)

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1 Introduction

The EU's Medical Device Regulation (EU 2017/745) and In Vitro Diagnostic Regulation (EU 2017/746) – MDR and IVDR, respectively – have entered into force on 26 May 2017. Both regulations are applicable for various stakeholder once the graduated transitional periods, ranging from six months to five years have come to an end.

Guidance documents are necessary to support the application of the forthcoming MedTech Regulations, as these make provisions for implementing and delegated acts. Common specifications and a functional medical device database, EUDAMED, are prerequisite for the full employment of the new regulatory framework.

ISS Integrated Scientific Services has been entrusted by the Federal Office of Public Health FOPH (Bundesamt für Gesundheit BAG) to report on the ongoing developments related to these Regulations as well as their implementation and further elaboration. Subsequent reports will be published at three-month intervals. The thematic focus of the reports will be on research, in particular clinical trials; related aspects of the Regulations and their implementation; and the relevant modules in EUDAMED.

2 Abbreviations

ANSM	National Agency for the Safety of Medicines and Health Products, France
CAMD	Competent Authorities for Medical Devices
EC	European Commission
EPSCO	Employment, Social Policy, Health and Consumer Affairs Council
EURLs	EU Reference Laboratories
FIMEA	Finnish Medicines Agency
IVDD	In Vitro Diagnostics Medical Devices Directive (98/79/EC)
IVDR	In Vitro Diagnostics Regulation (EU) 2017/746
MDCG	Medical Device Coordination Group
MDD	Medical Device Directive 93/42/EEC
MDR	Medical Device Regulation (EU) 2017/745
MPDG	Medizinprodukte-Durchführungsgesetz, Germany
NANDO	New Approach Notified and Designated Organisations
NB	Notified Body

3 Fear of medical device shortages calls for action

The growing fear that the MDR and IVDR implementation will result in many devices becoming unavailable in the EU seems to be confirmed by a recent survey which cites the new regulations as a contributor to these shortages. According to the results, legacy products, niche products, and orphan devices are the most affected. In its plenary session in November 2022, the EU Parliament approached questions on securing medical device availability across Europe. With decreasing numbers of available medical devices, patient care is deteriorating instead of improving based on the new regulations.

The European Commissioner for Health and Food Safety acknowledged that there is a serious risk of shortages of medical devices and that, in this context, the Commission is thoroughly assessing the potential need for legislative action to avert the threat of shortages of critical medical devices. Accordingly, the EC would present an update on the state of affairs, at the EPSCO meeting on 9 December 2022. Here, they will provide guidelines to address short-term issues, while also addressing the more structural problems that have emerged. The specific situation of so-called orphan devices for small patient groups is part of that ongoing assessment.

The Competent Authorities for Medical Devices (CAMD) share this view: At its 51st plenary session in October 2022, the CAMD published a statement on the current challenges in implementing the MDR. The CAMD recognises that contingency measures are required to solve immediate issues of implementing the regulations, but also advocates for a broader and more critical assessment of which factors are leading to the implementation challenges.

4 Implementing and delegated acts & guidelines

4.1 October update of rolling implementation plan published

The joint implementation plan for the IVDR as well as the implementation rolling plan were updated in October 2022.

4.2 Guidance on authorised representative according to MDR and IVDR issued

MDCG 2022-16 focuses on the role of the authorised representative who plays a pivotal role in ensuring the compliance of devices produced by manufacturers who are not established in the EU. The guidance includes details on topics such as registration and verification obligations, minimum tasks and responsibilities, liability and transitional provisions.

4.3 Revision of MDCG guidance clarifies the procedure for initial certification of specific types of IVDs

MDCG 2021-22 outlines the procedures for notified bodies to consult the expert panel for oversight of an IVD's clinical performance in the case of the first certification for a specific type of device. The first revision of this document makes minor changes to the text of questions 1 and 2 but adds six notes to clarify the meaning of "the first certification for that type of device".

4.4 MDCG issues background note to explain applicability of MEDDEV 2.7/1 rev. 4 for legacy devices

In addition to the MDCG 2020-6 guidance on sufficient clinical evidence for legacy devices, the MDCG issued a background note to clarify the relationship between the guidance and MEDDEV 2.7/1 rev 4 on clinical evaluation. This is not entirely new, as the appendix of MDCG 2020-6 notes that certain sections of MEDDEV 2.7/1 rev 4 are relevant to the MDR.

4.5 MDCG guidance on appropriate surveillance under transitional provision of IVDR

MDCG 2022-15 provides information on the appropriate surveillance for legacy IVD devices, such as the elements to be monitored by notified bodies as well as manufacturer's obligations regarding their quality management system.

4.6 First version of borderline and classification manual under MDR and IVDR published

The first version of the manual on borderline and classification for medical devices under the MDR and IVDR was published in October 2022. The working document includes information on the decisions to be made when products lie on the border between the regulation of a medical device and the other EU regulations to determine the primary or sole regulation that applies. The manual is not a legal document, the decision remains with national competent authorities and the national courts on a national level.

4.7 Updated guidance on safety reporting in clinical investigations and summary safety report form issued

The first revision of MDCG 2020-10 on safety reporting in clinical investigations under the MDR and the respective report form include several new sections. These sections include; completion guidelines, event details, revisions of definitions, clarification on filling in the reporting table, reporting duties, and the causal assessment.

5 EUDAMED

5.1 New EUDAMED playground version available

The new version 3.2 of the EUDAMED playground, which has now been made available by the European Commission, contains new developments for the market surveillance module (for authorities only) as well as improvements and bug fixes for all other modules. The changes made to the individual modules can be found in the newest release note.

6 Notified body designation

6.1 35 notified bodies designated under the MDR, seven under the IVDR

By the end of November 2022, there are 35 notified bodies designated under the MDR, while seven are designated under the IVDR.

The following additional NBs with MDR designation are listed in NANDO:

- MDR NB POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A., Poland
- ENTE CERTIFICAZIONE MACCHINE SRL, Italy
- INSTITUT PRO TESTOVÁNI A CERTIFIKACI, a. s, Czech Republic

The EC issued a summary outlining that the previously designated notified bodies cover over 80% of the designation codes.

7 Implementation activities on national levels

7.1 Germany: Amendments to MPDG provide clarifications on certain national requirements

The Medizinprodukte-Durchführungsgesetz (MPDG) has been amended to clarify the requirements on free sales certificates, insurance coverage and clinical trials.

7.2 Italy: Ministry of Health specifies domestic requirements for medical devices and IVDs

The Italian Ministry of Health has published two decrees that specify the national requirements left to the Member States by the MDR (Legislative Decree No. 137) and IVDR (Legislative Decree No. 138). A new guidance document specifies the modalities and timelines of the different economic operator's responsibilities in reporting serious and non-serious events and complaints as outlined in the decrees that establish the national requirements.

7.3 France: Drug delivery devices under old directive authorized by ANSM

To ensure the supply of cannulas used to administer diazepam to infants and children for the treatment of seizures, the French National Agency for the Safety of Medicines and Health Products (ANSM) authorised a company to manufacture the devices in compliance with the old directives on a temporary basis.

7.4 Slovakia: Procedure to apply Article 59 of MDR and IVDR issued

The Office for Standardisation, Metrology and Testing of the Slovak Republic issued a document explaining the procedure that applies to the decision-making process on introducing a product onto the market without a conformity assessment in an emergency as permitted by article 59 of the MDR and IVDR.

7.5 Finland: Distributors exempt from an annual device notification

In Finland, medical device distributors must notify the Finnish Medicines Agency (Fimea) of its activities, which include; distributing devices to retailers, health care and social welfare operators, other professional users and

making devices available on the market. However, due to a large number of devices to be notified, distributors are exempt from the obligation to submit device notifications in 2022.

8 Miscellaneous

8.1 First expert panel opinion on non-novel device issued

The expert panel issued its seventh opinion under the Clinical Evaluation Consultation Procedure according to the MDR context, which is the first expert opinion on a device that is not novel.

8.2 Team-NB issues seven position paper to push MDR and IVDR implementation

TEAM-NB has been recruited to develop position papers, which do not have any legal powers but provide additional guidance and cover the following topics:

- Off-label use
  While the MDR requires manufacturers to identify misuse or off-label use of their devices proactively, the terms "misused" and "off-label use" are not defined within the regulation. The document provides definitions, examples and scenarios related to these terms. The document also discusses to what extent off-label data can be used to expand the intended purpose/indications.
- Hybrid audits
  The present position paper describes the collective positions of the notified bodies on what to consider when making use of remote QMS audits as part of a hybrid audit.
- Transition periods for implementing MDCG guidances
  This position paper aims to establish a uniform approach with transition periods for implementing MDCG guidelines and other documents to standardise the implementation of such documents.
- Smooth transfer from one notified body to another
  Team-NB published a contractual agreement supporting companies who want to change notified bodies under the MDR and IVDR. The document provides information on the processes to be followed for a successful transfer from one notified body to another and defines the responsibilities of the involved parties.
- Best practice guide on technical documentation
  In a new position paper, TEAM-NB suggests a framework to make use of evidence from previous assessments and lists what is required in a technical documentation submission. While a full technical documentation in line with Annex II and Annex III of the MDR must be submitted, it is considered helpful if manufacturers indicate whether the evidence/data they have changed or not, the extent of the changes compared to what was previously reviewed/assessed by their notified body and refer to previous notified body reports.
- IVD class D measures in the absence of EU reference laboratories
  In a new position paper, TEAM-NB suggests a framework for the verification process for class D IVDs in the absence of designated EU Reference Laboratories (EURLs).
- Cybersecurity
  The ongoing digitalisation, its associated risks in health care, a confusing multitude of national cybersecurity requirements and guidances, have led to an increased fragmentation within the European framework. Team-NB addresses this issue by publishing a position paper that sets out recommendations for conformity assessments of cybersecurity.

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