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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Content

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. They shall be applied after the graduated transitional periods, ranging from six months to five years, have ended for different stakeholders.

Guidance documents are necessary to support the implementation of the forthcoming medtech Regulations, as these make provisions for implementing and delegated acts. Common specifications are required and the functioning of the medical device database, Eudamed, is a 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 the research, in particular clinical trials; related aspects of the Regulations and their implementation; and the relevant modules in Eudamed.

2 Abbreviations

EC	European Commission
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
IVDR	In Vitro Diagnostics Regulation (EU) 2017/746
KlinV-Mep	Swiss Ordinance on Clinical Trials for Medical Devices
MDCG	Medical Device Coordination Group
MDD	Medical Device Directive 93/42/EEC
MDR	Medical Device Regulation (EU) 2017/745
MDSAP	Medical Device Single Audit Program
MepV	Swiss Ordinance on Medical Devices
MIR	Manufacturer Incident Report
MPEUAnpG	German Medizinprodukte-EU-Anpassungsgesetz
NANDO	New Approach Notified and Designated Organisations
NB	Notified Body

3 COVID-19 impact on MDR implementation and notified bodies capacity

COVID-19 has not only led to the delay of the application date of the MDR, but also increased the demand for devices. With this rise in demand, there is a growing need to ensure that products intended for COVID-19 patients are rapidly available. As it can take several months for a notified body to assess and certify a device, the European Commission (EC) has called on notified bodies to give priority to essential medical devices in the fight against COVID-19. This priority will be based on a list that is to be agreed with the member states. The EC has published the results of its survey on the availability and capacity of notified bodies to carry out conformity assessments for COVID-19 related medical devices and in vitro diagnostic medical devices.

COVID-19 has severely compromised the MDR implementation. Potential delays in the notified body conformity assessment of products must be addressed to avoid device shortages for patients. The updated state of play of joint implementation plan for the MDR includes a series of measures the EC has put in place to monitor the availability of devices to prevent or remedy potential device shortages:

- Request regular reporting by the industry and notified bodies; monitor market developments and activities performed by notified bodies. These steps will help detect possible delays that could result in a shortage of devices in the market.
- Examine different means for taking measures to ensure the availability of safe and critical medical devices and provide guidance, as appropriate.
- Provide for mechanisms to communicate between National Competent Authorities and the EC on availability, the potential shortage risk, and the measures taken to ensure the availability of safe and critical medical devices.

As travel restrictions and quarantine orders relating to COVID-19 make it difficult for onsite audits to happen in the near future, MedTech Europe has published a position paper calling upon the EC and its Member States to allow notified bodies to conduct audits under MDR and IVDR in a virtual mode.

4 Implementing and delegated acts & guidelines

4.1 New European Commission medtech webpages

The EC has launched a new medical devices website, which is hosted on the portal of the Directorate-General for Health and Food Safety (DG SANTE).

There are three main pages on the European Commission's new medtech webpages:
- Overview
- Information on the current medical device directives
- Information on the new medical device and IVD regulations

4.2 Another update of the MDR/IVDR implementing measures rolling plan issued

Another update of the MDR and IVDR implementing measures rolling plan was issued in June, following the legislative procedure to defer the MDR date of application and the information that Eudamed will be postponed. The rolling plan lists several upcoming implementing acts & decisions. The following are scheduled for 2020:

MDR:
- Common specifications for products without a medical purpose
- Definition of detailed arrangements necessary for the setting up and maintenance of Eudamed

IVDR:
- Setting up of expert laboratories
- Rules to facilitate fulfilment of tasks by EU reference laboratories
- Fees for EURL services
- Common specifications for IVD Class D

4.3 Updated state of play of joint implementation plan for the MDR issued

According to the latest state of play of joint implementation plan on actions considered necessary to ensure the sound functioning of the new framework for medical devices under the MDR, the following actions are in work:

- EUDAMED: making the actor registration module available in Q4; providing guidance on administrative and technical solutions in the absence of Eudamed
- Expert panels: Appointment by end of July 2020; making panels available by Q4.
- Standardisation: New request to CEN/CENELEC from Q1 2021

4.4 Declaration of interest form for expert panels available

The declaration of interest form for expert panels includes two parts: personal details and the public declaration of interests. Declarations of interests of appointed experts will be published on the EC's website.

4.5 Commission guidance for expert panels on decision criteria in the clinical evaluation consultation procedure

The Commission guidance is intended to provide guidance for expert panels established under Article 106 of the MDR. It aims to ensure a consistent interpretation of the criteria to be applied when deciding whether to provide a scientific opinion.

4.6 Implementing Regulation (EU) 2020/1207 on common specifications for the reprocessing of single-use devices

The Implementing Regulation on Common Specifications (CSs) for the reprocessing of single-use devices has been published in the Official Journal. It enters into force on 29 August 2020 and will fully apply on the same date as the EU Medical Device Regulation. The reprocessor must assume all responsibilities of the original manufacturer who will no longer be mentioned on the label (but will continue to appear on the instructions for use). Whether it is permissible to reprocess single-use devices remains the decision of the Member States.

4.7 CEN/CENELEC reject MDR standards request

The standards bodies rejected the EC's Medical Device Regulation (MDR) and IVD Regulation (IVDR) standardisation request on 16 June. The latest state of play of joint implementation plan displays the EC's intention to submit another standards request in the first quarter of 2021.

4.8 Clinical evaluation assessment report template issued

The MDCG has published a guidance document, which explains the role of the notified body's clinical evaluation assessment report (CEAR) in assessing a device under the MDR. The CEAR will be used by notified bodies to document the conclusions of its assessment of the clinical evidence presented by the manufacturer in the clinical evaluation report (CER) and the related clinical evaluation.

4.9 Guidance issued for class III, high-risk, device-drug combinations under MDR

The MDCG issued a guidance explaining the process for transitioning CE certificates for devices containing an ancillary substance that could be considered a medicinal product or those manufactured using animal tissues under the MDR. The document explains differences of requirements between the Directives and the Regulation, including the 210-day timeframe for the competent authority or EMA to provide an opinion, the 60-day window for supplementary consultations and the statement that notified bodies might not issue a certificate if the opinion is unfavourable.

4.10 MDCG guidance on the use of MDSAP audit reports in the context of surveillance audits under MDR/IVDR

MDCG 2020-14 outlines how notified bodies can refer to Medical Device Single Audit Program (MDSAP) audit reports when planning surveillance audits under the MDR or IVDR.

4.11 Updated manufacturer incident report (MIR) form issued

The EC published a revised version of the MIR template, version 7.2.1 (Manufacturer Incident Report for Serious Incidents) in mid-June 2020. Only minor changes have been made to the previous version.

4.12 Updated guidance document on UDI for systems and procedure packs

The MDCG guidance on UDI for systems and procedure packs has been updated. The revision includes an additional example.

4.13 Guidance documents and Q&A document updated due to new MDR application date

In July 2020, four MDCG guidelines and one Q&A document to reflect the postponement of the MDR application date have been revised:

- MDCG 2019-10 rev. 1 Application of transitional provisions concerning validity of certificates issued in accordance to Directives 90/385/EEC and 93/42/EEC
- MDCG 2019-15 rev.1 Guidance notes for manufacturers of class I medical devices
- MDCG 2019-16 rev. 1Guidance on Cybersecurity for medical devices
- MDCG 2020-2 rev. 1 Class I Transitional provisions under Article 120 (3 and 4) – (MDR)
- Unique Device Identification (UDI) System – FAQs

5 Eudamed

5.1 Updated timetable for the release of the database in modules

The EC, in agreement with the Medical Device Coordination Group (MDCG), is going to make available the different Eudamed modules on a gradual basis as soon as they are functional. Deployment of the actor registration module is planned for December 2020 and will be voluntary to begin with. MDCG 2020-15 provides information on the use of the actor registration module and single registration numbers.

The module on UDI/device registration (second module) and the module on Certificates and Notified Bodies (third module) will become available by May 2021. Afterwards, the remaining modules will be displayed as soon as they are functional. The EC has published a video explaining the actor registration module on YouTube.

5.2 Fact sheet on MDR requirements for transparency and public information

A fact sheet lists information that will be made available to the public in accordance with transparency obligations of the MDR, considering that some requirements will be applicable only when Eudamed becomes fully functional. The fact sheet breaks down different types of information that will be publicly accessible based on whether it will be found within or outside Eudamed (but does not provide an exhaustive list).

6 Notified body designation

6.1 16 notified bodies designated under the MDR, four under the IVDR

The EC updated the state of play of the joint assessment of notified bodies in the medical devices field on 13 July 2020.

The following two additional NBs with MDR designation are listed in NANDO:
- GMed (France) has been designated as the 15th notified body under the MDR
- DQS Medizinprodukte GmbH (Germany) has been named the 16th notified body to be designated under the MDR

The following additional NB with IVDR designation is listed in NANDO:
- TÜV SÜD (Germany) has been designated as the 4th notified body under the IVDR.

7 Implementation activities on national levels

7.1 Belgium: FAMHP updates web portal in anticipation of MDR/IVDR

In anticipation of MDR and IVDR, the FAMHP has updated the 'My company' and 'My activities' applications on its web portal. This includes the separate displays of:

- Activities that will also be registered in Eudamed in the future: Manufacturing, authorised representative, importer, and system/package producer activities.
- Activities that will not be registered in Eudamed in the future: Activities involving custom medical device manufacturing, distributor, 'in-house' manufacturing of medical devices by healthcare facilities, exporter and home-care technicians installing medical devices (Article 59 of the Law of 15 December 2013).

7.2 Germany: National medical device legislation published in the Bundesgesetzblatt

The Medizinprodukte-EU-Anpassungsgesetz (MPEUAngG) was published in the Bundesgesetzblatt on 22 May 2020 (MPEUAnpG, BGBI, Teil I, Nr. 23 vom 22 May 2020, S. 960). This law primarily ensures the adaptation of the national medical device law to MDR & IVDR. The Zweite Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite (BGBI. Teil I, Nr. 23 vom 22.5.2020, S. 1018), among other things, contains the provision (Article 15) that the MPEUAnpG will not enter into force until one year later, on 26 May 2021.

7.3 Germany: BfArM and major functional units of DIMDI merged

The Federal Institute for Drugs and Medical Devices (BfArM) and major functional units of the German Institute for Medical Documentation and Information (DIMDI) were merged into one authority on 26 May 2020. The Medizinprodukte-EU-Anpassungsgesetz envisages transferring the tasks previously performed by the German Institute for Medical Documentation and Information (DIMDI) to the Federal Institute for Drugs and Medical Devices (BfArM). This transfer of tasks makes it necessary to adapt the DIMDI-Arzneimittelversorgung, the Verordnung über klinische Prüfungen, and the Bundespflegesatzverordnung.

7.4 UK: Health Research Authority reveals strategy to improve clinical trial transparency

The Health Research Authority has unveiled its 'Make it public' strategy on how it plans to improve clinical trial transparency in the UK. The strategy contains measures to strengthen compliance with existing requirements relating to the registration of clinical trials, reporting of results, and informing trial participants.

7.5 Switzerland: Revised Medical Devices Ordinance and new Ordinance on Clinical Trials approved

At its meeting on 1 July 2020, the Swiss Federal Council approved the revision of the Ordinance on Medical Devices (MepV) and the new Ordinance on Clinical Trials for Medical Devices (KlinV-Mep), which will be effective from 26 May 2021.

Swissmedic issued an information sheet on the derogations for the placing on the market and putting into service of medical devices that have not undergone a conformity assessment procedure. The information is valid and binding as of 1 August 2020.

8 IVD-specific issues

8.1 Joint paper includes key proposal for development of companion diagnostic guidance

MedTech Europe and the European Federation of Pharmaceutical Industries and Associations (EFPIA) released a 24-page paper that contains some 30 requests on how companion diagnostics should be regulated under the IVDR.

8.2 Medtech Europe issues position paper on IVDR transition

Medtech Europe urges the EU to complete the deployment of the new regulatory infrastructure required for the IVDR before the May 2022 deadline. As the pandemic impact on the IVDR implementation has been considerable, Medtech Europe is calling on the EU to postpone the date of application of the IVDR.

9 Miscellaneous

9.1 New not-for-profit association TEAM-PRRC launched

A new not-for-profit European association, TEAM-PRRC, has been launched to support the medtech regulatory experts who are soon appointed to the new role of Person Responsible for Regulatory Compliance (PRRC), in the context of the EU Medical Device Regulation (MDR).

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