Joint Implementation/preparedness plan on the new Medical Devices Regulation 2017/745 (MDR)

11 March 2020

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1. Context

A **new legislative framework** on medical devices[1, 2] was adopted by the Council and the European Parliament in April 2017. This new framework sets high standards of quality and safety for medical devices and aims at ensuring the smooth functioning of the internal market. The new regulation on medical devices (MDR) applies from 26 May 2020 (which is the focus of this analysis due to its shorter application deadline) and 26 May 2022 for the *in vitro* diagnostic medical devices regulation (IVDR).

The short transition period for the application of the new legislation is the result of a compromise in the interest of patient safety, and in response to scandals with defective medical devices in the past. It aims to ensure that the strengthened requirements of the new framework apply as soon as possible. The **implementation of the regulations has proven to be a very challenging task** for the whole sector and all concerned: stakeholders, the European Commission and Member States. Ensuring patient access to safe and efficient medical devices should be at the forefront of the implementation efforts.

Member States and the Commission have together with concerned stakeholders, **a joint responsibility** to ensure that the new legislation is operational from 26 May 2020. Many tasks have to be accomplished by the Commission to ensure a harmonised approach and smooth application of the MDR. Other tasks are best done by Member States to ensure that provisions are effectively applied and enforced at national level. In this respect, the Medical Device Coordination Group (MDCG), composed by experts designated by Member States, was established to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of the MDR. Together with its sub-groups, MDCG serves as a platform to facilitate cooperation between Member States and the Commission, to ensure a coordinated approach and to collect feedback and input from relevant stakeholders. Meetings between MDCG and stakeholders are organised at regular intervals in order to ensure appropriate stakeholder consultation.

Member States and the Commission have been working very hard to ensure effective implementation of the new rules. **Significant progress** has been achieved and a lot of work is under way. For example, a number of implementing acts have been adopted by the Commission and numerous guidance documents have been endorsed by the MDCG to facilitate coherent and effective implementation of the Regulations. Significant efforts have also been undertaken in terms of designating notified bodies. Despite this, notified body availability and capacity under the MDR remain a key challenge.

The short transition period represents a significant challenge also for **stakeholders** such as manufacturers, notified bodies and authorised representatives. EU stakeholder organisations have reported that careful planning and preparations have enabled a vast majority of their

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.)

[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance.)

members to take the measures needed for compliance with the MDR as from the application date, but a lot of uncertainty remain.

In order to meet the remaining challenges related to implementation of the MDR, it is essential that **all actors** involved further step up their efforts and work closely together to have an operational system in place in May 2020 and also engage thereafter in continuous work requiring careful setting of priorities and possible reallocation of resources over the months and years to come.

This paper sets out a **joint Commission and Member States plan, including concrete priority and contingency actions** which are considered essential in order to have an operational system in place by May 2020. Contributions and calls from stakeholders have been considered.

An objective of this document is to **respond to the call from the Council** (EPSCO) on 9 December 2019, where a significant number of Health Ministers called for a readiness check and to the MDCG meeting on 13 December 2019 where representatives underlined the need to define a list of key priorities of actions to be finalised by May 2020.

The priorities set out in this document have been identified based on the **objectives of public health, patient safety and transparency**, which are key to the new legislation and should continue to guide the priority setting also beyond 26 May 2020. These priorities are necessary to ensure focusing the limited resources across the Commission and Member States on priority items and to provide information and clarity to stakeholders in a transparent manner. It should be recognised that focusing on a more limited set of jointly agreed priorities could result in temporarily less resources being put into other areas.

It should be noted that most actions mentioned in this paper have already been identified as priorities and work is on-going. The main aim of this paper, however, is to agree on where to focus these limited **resources in the shorter term to ensure delivery by May 2020**. While these shorter-term priorities are necessary at this point in time, they must be seen in the wider context of an overarching plan with medium and longer-term actions to provide for effective implementation of the MDR and operation of the regulatory system.

The unique challenges related to ***in vitro*** **diagnostic medical devices, where the magnitude of change is even more significant, need to be fully recognised** although the date for application of this legislation (IVDR) is two more years away. There is a need to carry out a similar exercise also in preparation of this.

This paper has been developed by and constitutes the joint views of members of the MDCG and relevant Commission Services. The **MDCG meeting at a higher level** on 11 March 2020 is invited to endorse this document.

2. Priority areas and actions

a. EUDAMED

The Commission informed in October 2019 that the establishment of the **EUDAMED database is postponed**. The delay of the database does not prevent the application of the new Regulations as such, but represents important challenges for all actors involved. The MDR and

IVDR stipulate that the relevant obligations of the Regulations which are related to EUDAMED shall continue to generally apply also in this situation, while the information exchange shall take place in accordance with corresponding provisions and means established under the current Directives. Some rules related to the application of the new EUDAMED are as a consequence also postponed.

The Commission services and Member States are working closely to identify harmonised **administrative practices and technical solutions** to facilitate the exchange of information until EUDAMED is functional, in particular for cases where such exchange would be difficult to achieve based on the corresponding provisions under the current Directives. Guidance documents are being prepared in this respect with the aim of being endorsed by MDCG before 26 May 2020.

The Commission services are pursuing the **development of EUDAMED with the highest priority to deliver the actor registration module** by May 2020 and other modules in a gradual manner thereafter, working towards full functionality by May 2022. The actor module will be deployed from 26 May 2020 and an MDCG position paper is under preparation with the aim of explaining the issuing of Single Registration Numbers (SRNs) and to **encourage a common approach across the EU to record actors' data**.

Priority actions:

- Release and make available the actor module of EUDAMED allowing the Economic Operators to obtain a Single Registration Number (SRN) once the concerned Competent Authority has verified the registration request and executed the issuing (Commission services).[3]
- Endorse an MDCG position paper on the use of Single Registration Numbers (SRNs) and call for a common approach on the issuance of SRNs across the EU (MDCG)
- Endorse guidance on harmonised administrative practices and technical solutions in the absence of EUDAMED (MDCG).
- Endorse a fact sheet listing the information which will be available to the public in accordance with transparency obligations / requirements once EUDAMED is fully functional (MDCG).
- Provide regular updates to Member States and stakeholders on the development of EUDAMED towards full functionality (Commission services).
- Establish a sub-group on EUDAMED under MDCG to facilitate the work on the focus, establishment, management and maintenance of EUDAMED both at policy and technical level (Commission services).

b. Placing safe devices on the market after 26 May 2020

One concern related to the implementation of the MDR is the **potential risk of shortages and disruption of supply of critical medical devices** due to the lack of capacity for certification by notified bodies or the risk of reduced product portfolios. It is difficult to quantify the size of this challenge as no specific data has been presented by the industry.

[3] Indicates main responsible actor.

Currently, **a dozen notified bodies are designated under the MDR**. Their role is to assess the conformity of all medium and high-risk devices against the MDR requirements before they can be placed on the market. Additional designations are in the pipeline. While it is not possible to predict an exact number, it can be reasonably estimated that the number of designated notified bodies will significantly increase in 2020.

Transitional provisions established in the MDR allow for devices that were lawfully placed on the market under the current Directives (Directive 90/385/EEC and Directive 93/42/EEC) to continue to be placed on the market also after the application of the MDR and until May 2024 at the latest, under certain conditions. In order to allow manufacturers to fully benefit from this transitional period, the 55 notified bodies designated under the current Directives have an important role in reviewing and renewing existing certificates, when necessary. Such renewals have to be finalised before 26 May 2020.

It should also be noted that the scope of the transitional period was clarified by the **corrigendum** exercise finalised in December 2019, allowing class I devices pursuant to Directive 93/42/EEC, for which the declaration of conformity was drawn up prior to 26 May 2020 and for which the conformity assessment procedure pursuant to the MDR requires the involvement of a notified body, to benefit from the transitional period. The correction is estimated to have significantly alleviated pressure on notified bodies and to have ensured continued availability of certain essential devices (e.g. re-usable surgical instruments).

Despite the progress achieved over the last months in terms of designation of notified bodies under the new MDR (and IVDR), **concerns remain, for the shorter term, about the capacity of the notified bodies**, both in certifying devices under the MDR and in reviewing and renewing existing certificates under the Directives. There is therefore a risk that the validity of existing certificates will gradually expire as from 26 May 2020 without being immediately replaced by a certificate under the MDR, which could potentially lead to shortages of devices essential for healthcare. The number of devices concerned is difficult to estimate, but information from notified bodies indicate that a vast majority of devices are already engaged in the procedures of certification or have already been re-certified. At this point in time, it has not been possible to receive more precise data. For the medium term, the situation is expected to normalise.

An additional factor to be taken into account by stakeholders is the possibility that the EU – **Switzerland Mutual Recognition Agreement** will not be updated by 26 May 2020. In such case, in order to place products certified by Swiss notified bodies on the EU market, manufacturers will need to have certificates issued by EU notified bodies. For products of Swiss origin or products from third countries having their authorised representative in Switzerland, EU authorised representatives and registration according to the MDR will be required.

An additional uncertainty is the timing of the inclusion of the new Regulations in the customs union agreement with **Turkey**.

As a last resort, in the exceptional circumstances when conformity assessment procedures have not been carried out, but the use of the devices is in the interest of public health or patient safety or health, a National Competent Authority can allow the placing on the market within their territory according to Article 59 of the MDR (**national derogations**). Such national derogations have to be communicated to the Commission and to other Member States. Under

exceptional cases, the Commission may decide to extend those national measures to the territory of the Union for a limited duration. If, nevertheless, non-compliant devices are identified on the market, National Competent Authority shall take appropriate **market surveillance measures** in accordance with the MDR.

In practice, the application of the means to ensure availability of safe and critical devices to stay on the market need to be carefully considered with a view to ensuring **high protection of public health and patient safety through a sound application of the legal framework**.

Priority actions:

- Endorse guidance on the application of the transitional period, notably in relation to the interpretation of conditions concerning "significant changes" in accordance to Article 120(3) of the MDR (MDCG).
- Endorse guidance on the consultation of relevant authorities for legacy devices with ancillary substances or manufactured using TSE susceptible animal tissues (MDCG).
- Endorse guidance on how affected manufacturers of some class I devices can make efficient use of the transitional provisions in Article 120 (3) and (4) of the MDR (MDCG).
- Request regular reporting from industry and notified bodies and monitor market developments and activities performed by notified bodies aiming at detecting possible delays that could lead to shortage of devices on the market (Member States and Commission services).
- Examine different means to ensure availability of safe and critical medical devices and provide guidance, as appropriate (Member States and Commission services).
- Provide for mechanisms to communicate between Member States Authorities and the Commission on availability, potential risk of shortages and measures taken to ensure availability of safe and critical medical devices. (Member States and Commission services).

c. Clinical evaluation and Expert Panels

In order to ensure patient safety and a high level of public health, clarification is needed on how to apply provisions covering **clinical data, clinical evaluation, investigations and post market clinical follow up** requirements for high risk medical devices and for well-established devices already on the market. Clarification is required for manufacturers, notified bodies and national competent authorities as a common approach is needed to ensure that the strengthened clinical requirements under the MDR are applied in an adequate manner.

The work to set up the **Expert Panels**, which will play an important role in supporting the assessment of certain high-risk devices, is advancing. The Commission Implementing Decision (EU) 2019/1396 regarding the designation of expert panels in the field of medical devices was published on 10 September 2019. The call for expression of interest for experts was published on 27 September and ran until 24 November 2019. More than 700 applications were received. The Commission services are currently finalising the selection of experts and expect to be able to publish their names and to establish the panels before 26 May 2020.

Due to uncertainty regarding the volume of work to be expected and to ensure the best quality possible, it is suggested to initially limit the tasks of the panels to the **clinical / performance**

evaluation consultation procedures and to progressively phase in other functions, e.g. consultations and ad hoc advice, in the years to come.

Priority actions:

- Endorse guidance on clinical evidence needed for medical devices previously certified under Directives 93/42/EEC and 90/385/EEC (legacy medical devices) and on equivalence for well-established technologies. (MDCG).
- Nominate experts of the Expert Panels and publish a list of experts as well as provide information on a dedicated webpage on the functioning of the panels. (Commission services).
- Establish the Expert Panels for Clinical/Performance Evaluation Consultation Procedures (CECP/PECP) (Commission services).

d. Implementing Acts

The new legislation contains about 80 empowerments for different types of implementing acts, but only a limited number of these acts are necessary for rendering the legislation operational. **Implementing acts have already been adopted** on the designation of the twelve new Expert Panels, the setting of the new unique device identification (UDI) infrastructure and the list of codes for types of devices for specifying the scope of notified bodies.

Other **implementing acts are under preparation** and are expected to be adopted before 26 May 2020, notably the Implementing Decision on a standardisation request to CEN/CENELEC for MDR / IVDR harmonised standards and the Implementing Regulation on Common Specifications for the reprocessing of single-use medical devices. Also the Implementing act on devices without an intended medical purpose (Annex XVI MDR) is in the pipeline.

3. Monitoring

Monitoring of implementation/transition progress and market developments is considered crucial both ahead of May 2020 and beyond. In this respect, the Commission services intend to continuously request **regular updates** from industry and notified bodies and to cooperate closely with Member States and stakeholders to identify potential problems early and find adequate solutions. This includes both overall monitoring of progress of the transition from the current Directives to the MDR and more targeted monitoring as regards the availability of medical devices on the market and the capacity of notified bodies, the continued progress of notified body designation and other associated tasks, notably the processes of extension of scope and, in due course, their re-assessments. When required, the Commission services will make available **adequate mechanisms to communicate and coordinate** activities among Member States and with stakeholders.

4. Beyond 26 May 2020

The short terms priorities set out above should be seen in the context of continuous prioritisation by all actors involved beyond 26 May 2020 in the frame of an **overarching strategic plan for medium- and longer-term actions** that should be established to provide

for the most optimal implementation of the legal framework on medical devices within the limits of available resources.

From an operational perspective, the development of **EUDAMED** will continue based on the functional specifications made public in March 2019. Following the release of the actor module by 26 May 2020, Commission services will continue finalising the first set of modules, i.e. UDI/devices registration, the notified bodies and certificates modules, for subsequent deployment when functional. Input from MDCG and EUDAMED sub-groups is essential, in particular to ensure the timely and proper set up of the second set of modules, i.e. vigilance, clinical investigation and performance studies and market surveillance. It is therefore important that the relevant sub-groups prioritise and speed up their work in this regard, notably the sub-group on market surveillance. The newly established MDCG sub-group will support this process through facilitating the work on the focus, establishment, management and maintenance of the different EUDAMED modules.

Commission services are committed to keep MDCG regularly updated on the overall progress towards full functionality of EUDAMED. The full and mandatory operation of EUDAMED will be possible once the Commission has verified that EUDAMED has achieved full functionality and the related EUDAMED functional specifications are audited. A first draft of the required EUDAMED Implementing Act regulating details on the setting up and maintenance of EUDAMED is under preparation and can be expected to be adopted well in advance of the completion of EUDAMED.

Furthermore, cooperation and collaboration on **market surveillance and vigilance** is key to ensure that devices on the market are safe. More clarity is needed as regards certain aspects of the application of these requirements, such as those related to **periodic safety update report** (PSUR) implementation. A specific guidance document on **classification** rules should be finalised in 2020. In addition, the tasks and functions of the **Expert Panels** should be further developed by adding to the Clinical Evaluation Consultation Procedures other tasks listed in the MDR, including consultations and ad hoc opinions as deemed appropriate. Additionally, possibilities to develop common specifications for well-established technologies and other device types will be explored in the longer-term.

It is also vital, following the 26 May 2020, to focus on the **implementation of IVDR** to ensure effective application as of 26 May 2022.

Engaging in this type of prioritisation exercise in the medium and long term will require a more strategic role of the MDCG with increased coordination with and between MDCG sub-groups in a transparent manner and a common frame for coordinating information between all actors. Further reflections on the **most optimal governance function**, with the view to optimise resources and expertise might also be needed within the next year.

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