Questions and Answers: Commission proposes an extension of the transitional periods for the application of the Medical Devices Regulation

Brussels, 6 January 2023

What is the Medical Devices Regulation about?

The EU rules on the safety and performance of medical devices were created in the 1990s. In April 2017, the European Parliament and the Council adopted Regulation (EU) 2017/745 and Regulation (EU) 2017/746 to reinforce the regulatory framework for medical devices and *in vitro* diagnostic medical devices. The objectives of these Regulations are to achieve a high level of protection of health for patients and users and to ensure the smooth functioning of the internal market for medical device products. To achieve these objectives, and in light of issues identified with the previous regulatory framework, the Regulations set out a more robust system of conformity assessment to ensure the quality, safety, and performance of devices placed on the EU market.

The Medical Devices Regulation entered into force in May 2017 and became applicable on 26 May 2021. The transition period provided for in the Regulation will end on 26 May 2024. An additional 'sell-off' provision allows for the further making available until May 2025 of medical devices which are placed on the market before or during the transition period and which are still in the supply chain when the transition period has ended.

The Medical Devices Regulation is complemented by the Regulation on in vitro diagnostic medical devices that became applicable on 26 May 2022. In January 2022, the European Parliament and the Council adopted a staggered extension of its transition period, ranging from 26 May 2025 for high-risk *in vitro* diagnostics to 26 May 2027 for lower risk *in vitro* diagnostics, and to 26 May 2028 for certain provisions concerning devices manufactured and used in health institutions.

What are the main benefits for patients?

There are more than 500,000 types of medical devices on the market. Most people will need to use a medical device at some point in their lives. Medical devices range from simple contact lenses and sticking plasters to sophisticated pacemakers and hip replacements.

The Regulation has paved the way for a more patient-centred healthcare where transparency and patients' information and choice are a priority, and where patients can benefit from innovative, high-performing devices and new therapies.

The improvements, include:

- stricter ex-ante control for high-risk devices via a new pre-market scrutiny mechanism with a pool of experts at EU level;
- reinforcement of the criteria for the designation and oversight of Notified Bodies (a 'Notified Body' is an independent third party conformity assessment body) – more info below;
- inclusion of certain aesthetic devices that present the same characteristics and risk profile as analogous medical devices under the scope of the regulation;
- improved transparency through a comprehensive EU database on medical devices (EUDAMED) –more info below;
- a traceability system based on a unique device identifier (UDI);
- introduction of an 'implant card' containing information for patients with implanted medical devices;
- reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorising multi-centre clinical investigations;
- strengthening of post-market surveillance requirements for manufacturers;
- improved coordination mechanisms between EU countries on vigilance and market surveillance;

- a robust financial compensation mechanism to ensure patients are compensated for damage caused by defective devices.

Why does the Commission propose an extension of the transition period?

Despite important progress made in the implementation of the Regulation, the overall capacity of notified bodies remains limited for ensuring a successful transition to the new regulatory framework. In addition, many manufacturers are not sufficiently prepared to meet the robust requirements of the Medical Devices Regulation by the end of the current transition period. This threatens the availability of medical devices on the EU market. Without any legislative action, there is a risk of significant disruption in the supply of various medical devices on the market, affecting healthcare systems and their ability to provide care to European patients.

Which transition periods will apply?

The length of the proposed conditional extension of the transition periods depends on the type of device, with a shorter transition period for higher risk devices such as implants (until December 2027) and longer periods for medium and lower risk ones such as syringes or reusable surgical instruments (until December 2028).

Is the application of the entire Regulation postponed?

No. The Medical Devices Regulation has been applicable since 26 May 2021 and remains applicable. The proposed targeted amendment does not change any requirements of the Medical Devices Regulation in substance. It is limited to amending the transitional provisions to allow manufacturers and notified bodies additional time to transition from the previously applicable rules to the requirements of the Regulation, subject to specific conditions.

Which products will benefit from the extension?

The conditional extension applies only to those medical devices, such as pacemakers or syringes, that are currently already covered by the transition period. This means that the extended transition period applies only to 'legacy devices', i.e. those covered by a certificate or declaration of conformity issued under Council Directives 90/385/EEC or 93/42/EEC before 26 May 2021. Moreover, the application of the extended transition period will be subject to several cumulative conditions in order to ensure that only devices that are safe and for which manufacturers have already taken steps to transition to the Medical Devices Regulation will benefit from the additional time.

In addition, the Commission proposes the introduction of a transition period until 26 May 2026 also for class III custom-made implantable devices, such as patient specific implants for bone reconstruction. Those devices are currently not covered by the Regulation's transitional provisions. While manufacturers of class III custom-made implantable devices are required to comply with all applicable Regulation's requirements since 26 May 2021, they will now be given more time to obtain certification of their quality management system by a notified body. Also in this case, the transition period only applies if the manufacturer has lodged an application before 26 May 2024 resulting in the signing of a contract with the notified body before 26 September 2024.

Will the additional transition periods compromise public health or patient safety?

No, on the contrary. The application of the extended transition periods will be subject to several cumulative conditions, in order to ensure that only devices that are safe and for which manufacturers have already taken steps to transition to the Medical Devices Regulation will benefit from the additional time.

The transition to the new rules has been slower than anticipated. The COVID-19 pandemic, global supply chains disruptions, limited capacities of conformity assessment ('notified') bodies and limited preparedness of economic operators are causing a risk of shortages of life-saving medical devices for patients.

The overall goal of the proposed amendment is to maintain patients' access to a wide range of medical devices while ensuring the transition to the new framework.

The Commission proposes to delete the 'sell-off' date – doesn't this allow low quality devices to remain on the market for a very long time?

The 'sell-off' date is the end date after which devices already on the market but not yet with the final user should be withdrawn. Removing such 'sell-off' date will further reduce the risk of shortages and prevent unnecessary disposal of safe medical devices with a positive impact on both patient safety and the environment.

Only devices that were in compliance with the previous legislative requirements (i.e. the EU medical

devices directives) will benefit from this provision; the safety of those devices have been checked when they were placed on the market. Together with the cumulative conditions for the extension of the transition period, this provision will ensure that, after 26 May 2024, only medical devices for which the manufacturer submits an application for conformity assessment to meet the requirements of the new system may be placed on the market. As soon as such conformity assessment is finalised, the manufacturer has an interest in selling its newly approved devices.

Moreover, devices with a limited shelf-life cannot be made available after expiry of the shelf-life. The existing safeguards in the Regulations such as market surveillance activities and reporting and analysis of serious incidents ('vigilance') will apply also to those devices in order to protect patients and users.

What is the role of Notified Bodies?

Unlike medicinal products, medical devices, including in vitro diagnostic medical devices, are not subject to a pre-market authorisation by a regulatory authority. Instead, medium and high-risk devices are subject to a conformity assessment procedure involving an independent third party known as a 'notified body'.

Notified bodies are designated and monitored by the Member States and act under the control of the national authorities. Since 2013, assessments of notified bodies are performed by a joint team of members from other Member States and the Commission. Under the new framework, the successful experience of these joint assessments for the designation of notified bodies is reinforced.

Why are there so few Notified Bodies?

Notified bodies are in most cases private for-profit entities. Their establishment is therefore market driven. So far, only 36 notified bodies have been designated under the Medical Devices Regulation. 26 applications for designation as a notified body are pending.

The Medical Devices Regulation has significantly tightened the requirements to be met by notified bodies. This has also an impact on the length of the designation process.

What else is the Commission doing to ensure full implementation of the Medical Devices Regulation?

On 25 August 2022, the Medical Device Coordination Group (MDCG), which is chaired by the Commission, endorsed a position paper[1] that lays out 19 non-legislative actions with a view to enhancing notified body capacity, access to notified bodies and manufacturers' preparedness and thereby support a successful transition to Regulation (EU) 2017/745 and Regulation (EU) 2017/746. Several of the actions listed in that position paper have already been implemented, such as a MDCG position paper on hybrid audits[2], new MDCG guidance on appropriate surveillance[3], and a revision of MDCG 2019-6, removing obstacles to the employment of qualified personnel by notified bodies[4].

On 1 December 2022, the Commission adopted two delegated acts deferring the timing of the first complete re-assessment of notified bodies[5]. This is expected to free capacities both for designating authorities and notified bodies.

Work is ongoing to implement the remaining actions listed in MDCG 2022-14, as they remain important also if the transition period is extended.

On 9 December 2022, the MDCG issued a position paper[6], which sets out a uniform approach of competent authorities to applying market surveillance measures to bridge the gap between the expiry of certificates issued under Council Directives 90/385/EEC and 93/42/EEC and the issuance of a certificate under the Medical Devices Regulation. That approach is meant to be a temporary measure until the legislative changes in today's Commission proposal take effect. It contributes to avoiding disruption of supply of medical devices on the EU market. However, having regard to the number of certificates expiring in 2023 and 2024, it is not considered a sustainable solution for addressing the expected bottleneck of expiring certificates by 26 May 2024.

Further actions to support the implementation of the two Regulations are also (co-) funded under the 2022 and 2023 work programmes of the EU4Health Programme. These include: a targeted action to support capacity of Notified bodies with a specific focus on SMEs[7]; a Joint Action to support reinforced coordination between Member States on market surveillance[8]; a study to assess the current regulatory governance for medical devices and its impact on innovation[9]; a survey of key actors operating on the market namely notified bodies and manufacturers, including SMEs[10]; a program on orphan medical devices, in particular targeting paediatric patients[11]; dedicated support to strengthen coordination between notified bodies[12].

The Commission is also planning to make use of the Enterprise Europe Network to raise awareness on regulatory requirements and provide targeted support to SMEs active in the medical devices sector.

What is the state of play on the medical devices database, EUDAMED?

Eudamed is an essential element of the new regulatory framework and is a major step forward to ensure traceability and transparency in the medical device field. It will provide an overview of all medical devices available in the European Union. It will be composed of six modules related to: actor registration, unique device identification (UDI) and device registration, notified bodies and certificates, clinical investigations and performance studies, vigilance and market surveillance. It will integrate different electronic systems with information about medical devices and related companies (e.g. manufacturers).

The development of Eudamed is progressing, with the first Eudamed module on actor registration made available in December 2020. Since the beginning of October 2021, the second and third modules are available, namely the module on UDI/device registration and the module on certificates and notified bodies, except for the mechanism for scrutiny and the clinical evaluation consultation procedure functionalities (CECP) (the latter relevant only to medical devices such as implants and not in vitro diagnostics). The remaining modules as well as the functionalities for the mechanism for scrutiny and the CECP will be released when Eudamed is fully functional.

The Commission will continue to work in close cooperation with the Member States on this highly complex project.

For More Information

Press release: Public health: more time to certify medical devices to mitigate risks of shortages

Factsheet European Health Union: Supporting the transition to the new medical device framework

Proposal for a Regulation amending Regulation (EU) 2017/745

Medical devices – new Regulations

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[1] MDCG 2022-14 MDCG position paper Transition to the MDR and IVDR - Notified body capacity and availability of medical devices and IVDs (August 2022).

[2] MDCG 2022-17 MDCG position paper on 'hybrid audits' (December 2022).

[3] MDCG 2022-15 Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the IVDR with regard to devices covered by certificates according to the IVDD (September 2022); MDCG 2022-4 rev. 1 Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD (December 2022).

[4] MDCG 2019-6 Rev.4 Questions and answers: **Requirements relating to notified bodies (October 2022).**

[5] Commission Delegated Regulation (EU) …/... of 1.12.2022 amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the frequency of complete re-assessments of notified bodies, C(2022) 8640, and Commission Delegated Regulation (EU) …/... of 1.12.2022 amending Regulation (EU) 2017/746 of the European Parliament and of the Council as regards the frequency of complete re-assessments of notified bodies, C(2022) 8649. The delegated acts are available in the interinstitutional register of delegated acts and are subject to a three months scrutiny procedure by the European Parliament and the Council.

[6] MDCG 2022-18 MDCG position paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate.

[7] EU4Health Work Programme 2022, Call for proposals to support increased capacity of notified bodies for medical devices.

[8] EU4Health Work Programme 2022, Direct grants to Member States' authorities: reinforced market surveillance of medical devices and *in vitro* medical devices

[9] EU4Health Work Programme 2022, Supporting the implementation of Regulations on medical devices and in vitro diagnostics medical devices.

[10] EU4Health Work Programme 2022, Supporting the implementation of Regulations on medical

devices and in vitro diagnostics medical devices.

[11] EU4Health Work Programme 2023, Call for proposals for a program on orphan medical devices, in particular paediatric patients.

[12] EU4Health Work Programme 2023, Support for the technical secretariat for Notified Bodies Coordination Group.

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