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NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	Implementation of the Medical Device Regulations *- Information from the Commission*

Delegations will find in Annex an information note from the Commission on the above mentioned subject to be raised under "Any other business" at the meeting of the EPSCO Council (Health) on 14 March 2023.

ANNEX

Update regarding the state of play on the implementation of the Medical Devices Regulations

Following the EPSCO Health Council on 9 December 2022, the Commission presented a proposal for a targeted amendment of **Regulation (EU) 2017/745 on medical devices** (MDR)[1] and **Regulation (EU) 2017/746 on in vitro diagnostic medical devices** (IVDR)[2] on 6 January 2023[3].

The signature after the formal adoption of the proposed amending Regulation by the European Parliament and by the Council is planned for 15 March 2023.

The legislative initiative and complementary non-legislative actions respond to calls from Health Ministers expressed at the December EPSCO Council to swiftly extend the MDR transition period as outlined in the Commission information note[4] and to support the sustainability of the regulatory system with complementary actions.

1. Forthcoming legislative changes

The amending Regulation will provide for the following main changes:

(1) Extension of the MDR transition period until 31 December 2027 and until and 31 December 2028 depending on the device's risk class to be determined in accordance with the MDR classification rules. The extension is subject to several conditions to ensure that only safe devices, for which the manufacturer has submitted an application for MDR conformity assessment by 26 May 2024 at the latest, will benefit from the extended transition period.

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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 (OJ L 117, 5.5.2017, p. 1).

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 (OJ L 117, 5.5.2017, p. 176).

3 Commission proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices, COM(2023) 10 final, 2023/0005(COD).

4 Council document 15520/22 of 6.12.2022

(2) Extension of certificates' validity, provided the conditions for the extension of the transition period are met. Also certificates that have already expired after 26 May 2021 may be considered to be valid if additional conditions are met.

(3) Transfer of appropriate surveillance to MDR notified bodies by 26 September 2024 at the latest.

(4) Introduction of a temporary derogation until 26 May 2026 from requirement for quality management system certificate for class III implantable custom-made devices, subject to conditions.

(5) Removal of the 'sell-off' date in MDR and IVDR, allowing devices that have been placed on the market before or during the transition periods and which are still in the supply chain to be further made available without time limitation.

2. Developments since the 9 December 2022 EPSCO Council

At present, 38 notified bodies are designated under the MDR. This is two more than on 9 December 2022. Further 26 applications for designation as notified body are currently being processed; 7 of them are in an advanced stage[5].

Under the IVDR, 10 notified bodies have been designated so far. This is also two more than on 9 December 2022. Further 9 applications for designation are in progress, 3 of them in an advanced stage[6].

[5] In those advanced cases, the joint assessment team has already reviewed the applicants' corrective and preventive action plan.

[6] In those advanced cases, the joint assessment team has already reviewed the applicants' corrective and preventive action plan.

With the entry into force of the two Commission delegated acts[7] deferring the timing of the complete re-assessment of notified bodies, capacities of notified bodies and national designating authorities have been freed that can be used, in the former case, for the conduct of conformity assessment procedures and, in the latter case, for the designation of applicant conformity assessment bodies.

3. Further actions

- **Gaining momentum in designation of notified bodies**

It is crucial that, at the latest by the beginning of 2024, as many applicant conformity assessment bodies as possible are designated, increasing not only the overall number of notified bodies but also their geographical distribution. For that purpose, the Commission has called upon all actors involved in the assessment, designation and notification of conformity assessment bodies to make all efforts to speed up this process, while preserving the level of requirements to be met by notified bodies under the Regulations.

The Commission is offering its assistance to national designating authorities to gain efficiency in the process. The Commission has also offered additional supports to national designating authorities and applicant conformity assessment bodies in relation to the corrective and preventive action phase of the joint assessment procedure (the most lengthy phase of the process). At the same time, the Commission notes that for 6 applications, designating authorities have not yet submitted their preliminary assessment reports , which are needed to launch the joint assessment phase. The Commission therefore calls upon all designating authorities to submit outstanding preliminary assessemnt reports without undue delay. According to the relevant MDCG best practice guide[8], the estimated time to complete such a preliminary assessment is three months but current waiting times for submission vary from a few weeks to 18 months, in some cases up to 24 months. The Commission also commits to shorten its reaction time wherever possible.

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7 Commission Delegated Regulation (EU) 2023/502 amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the frequency of complete re-assessments of notified bodies (OJ L 70, 8.3.2023, p. 1); Commission Delegated Regulation (EU) 2023/503 amending Regulation (EU) 2017/746 of the European Parliament and of the Council as regards the frequency of complete re-assessments of notified bodies (OJ L 70, 8.3.2023, p. 3).

8 MDCG 2022-13 Designation, re-assessemnt and notification of conformity assessment bodies and notified bodies.

- **Continued implementation of actions to enhance notified body capacity and ensure availability of medical devices and in vitro diagnostics**

Several actions agreed by the Medical Device Coordination Group (MDCG) in its position paper MDCG 2022-14 have already been implemented. Since the EPSCO Council meeting on 9 December 2022, the revision of MDCG 2022-4 on appropriate surveillance and guidance on the list of standard notified bodies' fees have been endorsed[9].

The Commission is committed to pursue its support to the MDCG to effectively implement the remaining actions listed in MDCG 2022-14. In the view of the Commission, the revision of the guidance on sampling of devices, of the guidance on significant changes under the MDR and of the guidance on summary of safety and (clinical) performance should be concluded as quickly as possible. Moreover, provision of additional guidance regarding the practical application of clinical evidence requirements to legacy devices in combination with the possibility for notified bodies to issue certificates subject to conditions is of particular importance. In addition, clarification regarding structured dialogues between notified bodies and manufacturers before and during conformity assessments appears necessary to enhance the efficiency and predictability of the certification process.

- **Pilot project on scientific advice for clinical development strategies for high-risk devices**

In February 2023, the European Medicines Agency (EMA), which on behalf of the Commission provides the secretariat of expert panels established under the MDR, has launched a pilot project enabling the expert panels to provide scientific advice for manufacturers of high-risk medical devices[10]. During the pilot phase, such advice should primarily be provided to manufacturers of orphan devices and/or that qualify as small or medium-sized enterprises (SMEs).

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9 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. MDCG 2023-2 – List of standard fees.

10 See Medical devices | European Medicines Agency (europa.eu)

- **Targeted support for SMEs**

In its position paper MDCG 2022-14 (action no. 13), the MDCG called upon notified bodies to develop schemes to allocate capacity for SME manufacturers and first-time applicants and to ensure their access to notified bodies for conformity assessment. To support notified bodies in meeting this objective, the Commission has set up a dedicated action under the EU4Health Programme[11]. The financed activity started on 1st of March 2023 and aims at developing material and activities to support market operators, in particular SMEs, in meeting the requirements of the MDR and IVDR. The action will benefit from the involvement of the European Enterprise Network for a targeted outreach to SMEs.

- **Tailored solutions for orphan devices**

Representatives of MDCG observer organisations, such as healthcare professionals and providers, patients, industry and notified bodies, have been invited to join the MDCG taskforce and to support the development of both short-term solutions for orphan devices within the current regulatory framework and a sustainable regulatory approach in the medium- and long-term.

- **Financial support through the EU funded programmes**

Under EU4Health, a survey gathering data on the implementation progress has been launched. Other actions financed by the EU4Health 2022 work programme have recently started such as the action to support increased capacity of notified bodies and market operators and the launch of a study on innovation and governance.

[11] EU4Health work programme 2022, Commission Implementing Decision C(2022) 5436 final of 25.7.2022, action HS-g-22-19.03.

Moreover, the 2023 work programme of the EU4Health Programme[12] will support the implementation of the MDR and IVDR with EUR 8.25 million. Among those actions are grants to EU reference laboratories to be designated under the IVDR, a call for proposals for a programme on orphan medical devices, in particular targeting paediatric patients, support to a technical secretariat for the Notified Bodies Coordination Group, technical and administrative support to the MDCG, joint assessments of notified bodies and ongoing support to Functional specifications for the European Database on Medical Devices (EUDAMED).

Other EU funded programmes such as HorizonEurope also include actions that support the implementation of the MDR/IVDR – Under the 2023-2024 HorizonEurope programme[13], EUR 10 million are dedicated to develop EU methodological frameworks to generate clinical data for demonstrating safety, performance and clinical benefit and thereby providing support in meeting the requirements of MDR and IVDR in this respect.

4. Assuring the sustainability of the regulatory framework

The Commission fully supports the Regulations' objectives to improve patient safety and device performance for the benefit of patients and public health. At the same time, it considers important to tackle structural issues before the end of the extended transition periods. These issues have appeared within the current regulatory framework and have a negative impact on patient safety, public health and medical innovation. Those are, for instance, related to orphan devices, small manufacturers' access to notified bodies, length and costs of conformity assessment procedures, interplay between clinical trials for medicinal products and performance evaluation studies for in vitro diagnostics. The Commission will gather further evidence for the comprehensive evaluation of the MDR and IVDR due by May 2027 (Article 121 MDR and Article 111 IVDR).

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12 Commission Implementing Decision C(2022) 8510 final of 21.11.2022.

13 Horizon Europe – Work Programme 2023-2024, Cluster 1 – Health, European Commission Decision (2022)7550 of 6 December 2022, action Horizon-Hlth-2024-IND-06-08.