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NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	Implementation of the Medical Device Regulation *- 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 9 December 2022.

ANNEX

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

At the EPSCO Health Council on 14 June 2022, Health Ministers expressed their concerns that severe challenges related to the implementation of **Regulation (EU) 2017/745 on medical devices** (MDR) threaten the continued availability of certain medical devices needed for health systems and patients and may jeopardise the access of innovative medical devices to the EU market ([1]). Health Ministers called on the Medical Device Coordination Group (MDCG) to propose solutions to address, as a matter of urgency, immediate challenges related to insufficient capacity of notified bodies to certify medical devices in accordance with the MDR within the remaining transition period that ends on 26 May 2024 and the level of preparedness of manufacturers.

The Commission committed to report back to the EPSCO Council on 9 December 2022 and to present further proposals for solutions if needed.

([1]) See Commission information note circulated as Council document 9910/22 of 9 June 2022.

1. State of play

At present, 36 notified bodies ([2]) are designated under the MDR. This is six more than on 14 June 2022. Further 26 applications for designation as notified body are currently being processed; three of them are in an advanced stage ([3]).

Based on the feedback received from notified bodies ([4]) to the latest survey in October 2022, notified bodies have received 8,120 applications from manufacturers and have issued 1,990 certificates under the MDR. According to a rough estimation presented by notified bodies to the MDCG on 17 November 2022, the number of MDR certificates issued by May 2024 may reach around 7,000 if the current rate of certificate issuance continues with no changes to current conditions. This is in stark contrast to 22,793 valid certificates issued under Council Directives 90/385/EEC and 93/42/EEC that will expire by 26 May 2024 at the latest. Of those 22,793 certificates, 1,387 certificates will have expired by the end of 2022, 4,311 certificates will expire in 2023 and 17,095 certificates in the first five months of 2024.

As regards **Regulation (EU) 2017/746 on in vitro diagnostic medical devices** (IVDR), the number of notified bodies designated remains low with only eight notified bodies designated so far; ten applications for designation are in progress, two of them in an advanced stage ([5]).

Pursuant to the data provided by notified bodies ([6]) during the survey in October 2022, notified bodies have received 822 applications from manufacturers and have issued 268 certificates under the IVDR. 1,551 valid certificates issued under Directive 98/79/EC will expire by 26 May 2025 at the latest. Of those 1,551 certificates, 38 certificates will have expired by the end of 2022, 165 certificates will expire in 2023, 482 certificates will expire in 2024 and 866 certificates in the first five months of 2025.

([2]) Publication in NANDO of the designation of the 36th notified body is expected to take place on 8 December 2022.

([3]) In those three cases, the joint assessment team has already reviewed the applicants' corrective and preventive action plan.

([4]) This includes data from 30 notified bodies designated under the MDR.

([5]) Publication in NANDO of the designation of the 8th notified body is expected to take place on 23 December 2022. In the two advanced cases, the joint assessment team has already reviewed the applicants' corrective and preventive action plan.

([6]) This includes data from all seven notified bodies currently designated under the IVDR.

2. Actions undertaken since the June 2022 EPSCO Council

Following the calls expressed at the June EPSCO Council, the MDCG endorsed a position paper (MDCG 2022-14) on 25 August 2022, laying out 19 non-legislative actions within the current regulatory framework with a view to enhancing notified body capacity, access to notified bodies and manufacturers' preparedness in order to support a successful transition to the MDR and IVDR.

Several of the actions listed in MDCG 2022-14 do not need further implementation, such as the status of guidance documents, or have already been implemented, such as a MDCG position paper on "hybrid audits" ([7]), and new MDCG guidance on appropriate surveillance with regard to devices covered by certificates according to the IVDD ([8]).

The MDCG has adopted a revision of MDCG 2019-6 with a view to removing obstacles to the employment of qualified personnel by notified bodies ([9]). On 26 October 2022, the MDCG taskforce on orphan devices held a stakeholder workshop to discuss a definition for 'orphan' devices and possible solutions for the regulatory challenges related to those devices. On 1 December 2022, the Commission adopted two delegated acts deferring the timing of the first complete re-assessment of notified bodies in order to free capacities both for designating authorities and notified bodies ([10]). Work on other actions is on-going, such as revision of the guidance on sampling of devices, on appropriate surveillance and on significant changes under the MDR, the provision of additional guidance regarding the practical application of clinical evidence requirements to legacy devices and the possibility for notified bodies to issue certificates subject to conditions, and clarification of what kind of dialogue between notified bodies and manufacturers before and during conformity assessment processes is permitted and should not be considered consultancy service. Some actions, namely those aimed to foster capacity-building of existing and new notified bodies, to facilitate access of small and medium-sized enterprises (SMEs) and first-

([7]) To be published after finalisation of the text following endorsement by written procedure that ended on 28 November 2022.

([8]) 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.

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

([10]) Commission Delegated Regulation (EU) …/... 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) …/... 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 now subject to a three months scrutiny procedure by the European Parliament and the Council.

time applicants to notified bodies and to increase preparedness of manufacturers, will be supported in the framework of the 2022 EU4Health Work Programme ([11]). While it does not seem to be feasible to quantify the exact impact of the actions laid out in the MDCG position paper 2022-14, the Commission considers that the message transmitted by the position paper, as well as the measures already taken are making a real difference. It is therefore important that the MDCG, with the support of the Commission, pursue its work to implement also the remaining actions.

At its extraordinary meeting on 17 November 2022, the MDCG agreed on a uniform and coherent approach to the use of market surveillance provisions as a bridging action before the transitional period would be extended by an amendment of the MDR. That approach is based on the application of Article 97(1) MDR by the competent authority of the Member State where the manufacturer is established in situations where a device is not in conformity with the MDR because its certificate issued under Directive 93/42/EEC or Directive 90/385/EEC expires before issuance of the necessary certificate(s) in accordance with the MDR. Application of Article 97(1) MDR will be subject to certain conditions and require the manufacturer to bring the non-compliance to an end within a reasonable period of time clearly defined by the competent authority. MDCG agreed to publish a paper describing that approach after the EPSCO Council meeting on 9 December 2022.

Further efforts are being made to support implementation in the longer-term through further actions (co-)funded under the EU4Health Programme. These include regular close monitoring of the market to get information on devices and certificates and launching reflections on how the MDR supports innovation, looking both at market aspects and governance ([12]) as well as supporting Members States in market surveillance activities through a Joint Action ([13]). The actions are expected to start in 2023.

([11]) See 2022 EU4Health Work Programme, in particular call for proposal HS-g-22-19.03.
([12]) See 2022 EU4Health Work Programme, in particular HS-p-22-19.04, 06, 07, 08, 09, 10 and 11 "Supporting the implementation of Regulations on medical devices and *in vitro* diagnostic medical devices".
([13]) See 2022 EU4Health Work Programme, in particular HS-g-22-19.01 "Direct grants to Member States' authorities: reinforced market surveillance of medical devices and in vitro medical devices".

3. Additional measures

Despite their full support for the MDCG position paper 2022-14, several Member States, some Members of the European Parliament and stakeholders consider that those actions will not be sufficient and are calling for additional measures, namely an urgent, targeted legislative initiative to amend the MDR. At the MDCG meeting on 24-25 October 2022, at the meeting of the Council Working Party for pharmaceuticals and medical devices on 28 October 2022, and at the extraordinary MDCG meeting dedicated to the transition to the MDR on 17 November 2022, a large number of Member States' representatives spoke in favour of an extension of the transitional provisions provided for in Article 120 MDR linked to certain conditions in order to give manufacturers and notified bodies more time to conduct the necessary conformity assessment procedures. Notified body representatives, who participated in a part of the extraordinary MDCG meeting on 17 November, agreed on the need to give them and manufacturers more time to transition to the MDR. They indicated that an extension until May 2026 for class III devices might be too short for some of those high risk devices, in particular for those subject to consultation procedures. Notified body representatives also pointed out that notified bodies will need to spend a significant amount of resources in order to fulfil their duties under the MDR (e.g. surveillance of issued certificates; change notifications; review of manufacturer's Periodic Summary Update Reports) that will increase the more MDR certificates are being issued. Hence, those resources would not be available for initial MDR certification.

The Commission has listened attentively to the concerns expressed by Member States, Members of the European Parliament and stakeholders, and, in light of the situation set out above, is ready to act upon these calls. The Commission will present the likely elements of a legislative proposal for a targeted amendment of the MDR and IVDR during the EPSCO Health Council on 9 December 2022.

Those likely elements are based on the input received so far from national experts and stakeholders and could include:

- an extension of the transitional period in Article 120(3) MDR with staggered deadlines depending on the risk class of the device. Those deadlines could be 2027 for class III and class IIb devices (i.e. devices with a higher risk) and 2028 for class IIa and class I devices (i.e. lower risk devices) that need the involvement of a notified body in the conformity assessment;

- if needed for legal and practical reasons (including for access to third country markets), the extension of the transitional period could be combined with an extension of the validity of certificates issued under Council Directives 90/385/EEC and 93/42/EEC by amending Article 120(2) MDR;

- conditions to be fulfilled in order to ensure that the extension applies only to devices that do not present any unacceptable risk to health and safety, have not undergone significant changes in design or intended purpose and for which the manufacturers have already undertaken the necessary steps to launch the certification process under the MDR, such as adaptation of their quality management system to the MDR and submission and/or acceptance of the manufacturer's application for conformity assessment by a notified body before a certain deadline (e.g. 26 May 2024);

- the removal of the 'sell off' provision in Article 120(4) MDR and Article 110(4) IVDR.

Having regard to the urgent nature of the legislative initiative and the need for a swift adoption by the co-legislators in order for the changes to have the intended effect in a timely manner, the Commission considers that amendments should be kept to what is absolutely necessary at this moment in time.

Progressively, the Commission will also tackle more structural issues that have appeared, such as for instance those related to niche devices.

By May 2027, the Commission will also undertake a comprehensive evaluation of the MDR. Should evidence demonstrate that the new rules do not achieve their objectives or have a negative impact on patient safety, public health or medical innovation, the Commission will consider proposing amendments where appropriate.

The Commission remains fully committed to taking its part of the joint responsibility of all actors contributing to full and effective implementation of the two Regulations on medical devices. They are the basis of the EU regulatory system governing those important health products, improving patient safety and device performance for the benefit of patients and public health