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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	AOB for the meeting of EPSCO (Health) of 3 December 2024: Necessary reforms in the Medical Device and *In vitro* Diagnostic Medical Device Regulations: priorities / main points - Information from Croatia, Finland, France, Germany, Ireland, Luxembourg, Malta, Romania and Slovenia

Joint paper of Croatia, Finland, France, Germany, Ireland, Luxembourg, Romania, Malta and Slovenia

on necessary reforms in MDR and IVDR: priorities / main points

The Medical device regulation and the *In vitro* diagnostic medical device Regulation (MDR and IVDR) form an ambitious framework assuring product safety throughout the European Union. The implementation process is still a demanding task leading to a number of legislative postponements of entry into force and rescheduled transitional provisions. In the latest legislative action in 2024 IVDR transition times have been prolonged and on MDR/IVDR important provisions on EUDAMED and on a notification system for market interruption or discontinuation supply have been introduced.

These measures helped to spread the burden of implementation. In the new mandate of European Commission EU institutions have a chance to start a more comprehensive and fine-tuned legislative reform process responding to the experiences with MDR and IVDR on a broader basis including a robust impact assessment, cogniscent of the EU Commission's Targeted Evaluation and with a focus on public health value, infrastructure and resource needs. While legal measures may be necessary in advance of the completion of the targeted evaluation, these should be carefully considered, constructive and iterative.

Croatia, Finland, France, Germany, Ireland, Luxembourg, Romania, Malta and Slovenia would like to propose the following five key elements of such a reform of MDR and IVDR:

1. Reduction of administrative obligations of stakeholders

We want to reduce red tape to the extent necessary while assuring patient safety. Reporting obligations, validations tasks and inconsistencies in the conformity assessment process should be reviewed to avoid unnecessary formalities. In principle we want to uphold the re-certification every e.g., 5-years with a decision if the certificate can still be maintained but propose clarifying that re-certification should be an overview focusing on new aspects, safety aspects linked to post-market surveillance, vigilance and market surveillance and proportionate to the class of the risk (rather than a full repetition of the initial assessment); Post market surveillance systems should be clearly defined, implemented and enforced.

2. Centralisation of system management functions to the EMA

The system of MDR and IVDR needs stronger scientific, technical and administrative support. In our view, the EMA is in an excellent position to extend its unique knowledge base and expertise to medical devices. The role that a central entity could play to support the practical application and principles of the MDR and IVDR should be openly considered and discussed to ensure that the support from an agency also recognises the specificities of the medical technology sector. Therefore, we are in favour of setting up an EMA MDCG secretariat to support the practical applications and technical coordination of the system, development of MDCG guidance documents within a reasonable timeframe and transmitting certain administrative functions to the EMA, as this has already been done for the expert panels. The scientific and technical resources and capability needs for the system should be reviewed as part of the impact assessment and resource commitment to enhance scientific capabilities and supports for the MDCG and its subgroups by identifying a means to engage and utilise relevant scientific institutions including EMA. The EMA should also have a coordinating function for certain critical MD and IVD safety issues, as well as facilitating the coordinated assessment procedure for clinical investigations. In addition, more centralisation at the EMA level is needed for EUDAMED, where clear roles and responsibilities are defined.

3. Foreseeable and balanced certification procedures

Certification by notified bodies is the key element of product safety in MDR and IVDR. In the interest of early access to innovative devices and with a view to global competitivity appropriate, transparent and predictable timelines for certification (including stop-the-clock-options) should be introduced. The focus should be on providing necessary information whilst avoiding unnecessary formalities. With a view to increase comparability of notified bodies work EMA should also provide scientific and administrative orientation to the process of supervision of notified bodies; existing options in that regard should be explored.

4. Taking into account specific needs for medical devices intended for specific patient populations

Medical devices intended for specific patient populations play an important role in healthcare provision. Nonetheless, the development or commercial launch of those devices often are delayed or stopped due to a high administrative burden. The certification under MDR and IVDR system needs to be adapted to the specific needs of these product groups - especially avoiding an unnecessary burden for developing new products or keeping products on the market. A centralised entity, e. g. EMA, could be mandated with a process of defining product groups, providing advice and oversight to meet conformity assessment goals and post market surveillance/ clinical follow up objectives. Scientific support from an agency could also support provision of scientific data on well-established technologies and on sufficient level of clinical evidence for those devices. In addition, the process for harmonised standards should be made fit for the purpose.

5. Assuring a special pathway for innovations

The certification process by Notified Bodies is quite lengthy. For novel and innovative devices, a special and adapted pathway option could be envisaged. Specific pathways for technologies which are considered breakthrough or for those which address unmet clinical needs should be established with the scientific and advisory support of the EMA and the expert panels. In that context, we could take advantage of the „regulatory sandbox "-model currently being introduced in many areas of EU regulation. We need to identify a new path for product certification with a view on guaranteeing early access to innovations for patients in the EU and assuring global competitiveness of the MDR/IVDR system in the safest conditions for patients. The EMA could strengthen a coordinated scientific assessment with the coordination experts' panels and EU reference laboratories.

We consider a greater involvement of the EMA in an integrated and structured way in the MD /IVD sector would be beneficial for a better implementation of the regulatory framework. In that process we need to avoid duplication of work streams. The upcoming impact assessment on an MDR/IVDR reform provides a suitable forum for this joint effort.