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COVER NOTE

From:	European Economic and Social Committee
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To:	General Secretariat of the Council
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain in vitro diagnostic medical devices *- Opinion of the European Economic and Social Committee*

Delegations will find attached the opinion adopted by the European Economic and Social Committee on the above-mentioned proposal. Other language versions, if needed, will soon be available on the following website: https://dmsearch.eesc.europa.eu/search/opinion .

OPINION

European Economic and Social Committee

Medical devices/Eudamed

Proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain in vitro diagnostic medical devices
[COM(2024) 43 final – 2024/0021 (COD)]

INT/1060

Rapporteur: **Danko RELIĆ**

Referrals	Council of the European Union, 19/2/2024 European Parliament, 26/2/2024
Legal basis	Articles 114 and 168(4) of the Treaty on the Functioning of the European Union
Section responsible	Single Market, Production and Consumption
Adopted at plenary	20/3/2024
Plenary session No	586
Outcome of vote (for/against/abstentions)	165/1/1

1. Conclusions and recommendations

1.1 The European Economic and Social Committee (EESC) calls for the transitional periods for certain high-risk in vitro diagnostic medical devices (IVDs) to be extended. This is important because of the need to prevent shortages and maintain essential healthcare services, particularly in areas such as blood or organ donations and life-threatening infectious diseases.

1.2 The EESC calls for a pragmatic, consistent framework to provide advance warning about supply disruptions and foster collaboration among manufacturers, independent conformity assessment bodies ('notified bodies') and regulatory authorities; this will ensure a high level of transparency and preparedness across the EU.

1.3 The EESC stresses the need to involve healthcare professionals in reporting shortages, and calls for a system that includes reports from both manufacturers and healthcare professionals in order to improve the timeliness and accuracy of shortage notifications.

1.4 The EESC is in favour of a gradual roll-out of the European database on medical devices (Eudamed): this will enhance transparency and monitoring and ensure that devices meet the highest safety and efficacy standards without first waiting for all modules to be completed.

1.5 The EESC emphasises the need for comprehensive training programmes for all stakeholders in the medical device sector, including 'train-the-trainer' programmes; this will ensure widespread dissemination of regulatory and technical competencies.

1.6 The EESC highlights the importance of SMEs in the medical device sector due to their dynamic and adaptable nature, and calls for support mechanisms such as subsidies and simplified compliance pathways to enhance their innovative capabilities and competitive edge.

1.7 The EESC suggests that an EU-wide platform be set up to facilitate dialogue between stakeholders, including SMEs, healthcare professionals, manufacturers and regulatory bodies; this will make it possible to address challenges and share best practices in medical device innovation and regulation.

1.8 The EESC calls for enhanced support for and development of national agencies in charge of medical devices; increased resources and capacity building must be provided to ensure that these agencies can effectively monitor and manage medical device regulations within their jurisdictions.

1.9 The EESC considers that it is crucial to involve civil society organisations in the regulatory process, particularly those representing patients and relevant associations of manufacturers and distributors; this will ensure comprehensive and patient-centric regulations.

2. The European Commission proposal

2.1 The EESC takes due note of the European Commission's proposal to amend Regulations (EU) 2017/745 and (EU) 2017/746 on medical devices and in vitro diagnostic medical devices (IVDs).

This initiative is very important as the medical device industry is undergoing significant transformations, driven by technological advances and the pressing need for enhanced patient safety and access to innovative healthcare solutions.

2.2 The proposal aims to address critical challenges within the regulatory framework, ensuring that medical devices and IVDs available on the market meet the highest safety and efficacy standards.

2.3 The main objectives of the proposal are to:

- extend the transitional period for certain IVDs to prevent shortages, particularly of high-risk IVDs crucial for carrying out tests in blood or organ donations, blood grouping for transfusions and life-threatening infectious diseases;
- require manufacturers to issue advance notice before discontinuing the supply of critical medical devices and IVDs to ensure that users and relevant authorities have the opportunity to seek alternatives;
- enable a gradual roll-out of the electronic systems within Eudamed; this will enhance transparency and monitoring of devices on the EU market without waiting for all six Eudamed modules to be completed.

3. General comments

3.1 As pointed out in previous opinions[1], the EESC considers that health is a primary concern for Europeans. Medical devices and IVDs play a critical role in disease prevention, diagnosis and treatment, and are essential for maintaining health and improving the quality of life of people affected by illnesses and disabilities.

3.2 The EESC points out that the sector is important to the European economy, due to its innovation capacity and the creation of high-skilled jobs. The highest level of health protection must be ensured and due regard given to the sector's ability to stimulate innovation and economic growth.

3.3 The EESC underscores the importance of enhancing safety and efficacy standards for medical devices and IVDs within the EU. By calling for a robust regulatory framework, the Committee aims to ensure that all medical devices and IVDs on the market meet rigorous safety protocols and deliver on their therapeutic promises. The proposal's emphasis on comprehensive testing, evaluation and post-market surveillance reflects this commitment to patient safety and product effectiveness.

4. Regulatory framework, market surveillance and economic impact

4.1 The EESC supports the strategic extensions of and amendments to the transitional periods for medical devices and IVDs stipulated by the European Union's regulatory framework.

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1 OJ C 195, 18.8.2006, p. 14.
Proposal to amend Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices | EESC (europa.eu).
OJ C 152, 6.4.2022, p. 85.

Acknowledging the essential role played by these devices in ensuring the health and well-being of Europe's people, the EESC emphasises the need to ensure that measures are in place to prevent potential shortages of crucial medical and diagnostic devices. This applies particularly to high-risk devices used in critical healthcare applications such as blood and organ donation testing, blood grouping for transfusions and life-threatening infectious diseases.

4.2 The EESC recognises the proposal's potential to drive innovation in the medical device industry by establishing rigorous safety and efficacy standards which will boost both consumer confidence and competitiveness in the global market. It highlights the crucial role of SMEs due to their agility and adaptability which enables them swiftly to address potential shortages of medical devices and IVDs. However, as SMEs can find it difficult to cope with stringent requirements, the EESC calls for support mechanisms such as subsidies and simplified compliance pathways. It also recommends fostering dialogue between manufacturers, regulatory bodies and stakeholders in order to smooth the transition to the new regulatory framework, thereby enhancing SMEs' innovative capabilities and competitive position.

4.3 The EESC recognises that Eudamed is instrumental in enhancing transparency, regulatory oversight and market surveillance. It therefore calls for a proactive approach to deploying and mandating Eudamed's modules, ensuring that the database fully supports the safety, efficacy and monitoring of medical devices across the EU.

4.4 Recognising that there is still no harmonised approach to monitoring supply disruptions, the EESC supports the introduction of obligations for manufacturers to proactively inform relevant authorities, healthcare institutions and professionals of any foreseeable supply interruptions. Given the devices' crucial role in essential healthcare services and the fact that patient health is dependent on the availability of these devices, this initiative aims to enable timely mitigating action and to facilitate the search for suitable alternatives.

4.5 The EESC is also in favour of an obligation to inform the regulator of potential shortages, with this information being publicly disclosed to ensure market transparency. Transparent information on shortages must be provided to enable all market participants, including SMEs and healthcare professionals, to respond and adapt efficiently. This is especially important for smaller markets where the impact of shortages can be more pronounced, and will foster a more resilient healthcare system.

4.6 The EESC suggests that reporting obligations on shortages include healthcare professionals and not solely manufacturers. Reports from several sources can make notifying shortages significantly more effective. Engaging healthcare professionals in this reporting mechanism could greatly improve the timeliness and accuracy of the information received, thereby enhancing the market's ability to respond swiftly and effectively to any supply issues.

4.7 The EESC encourages the European Commission and the Member States to foster cooperation between manufacturers, independent conformity assessment bodies and regulatory authorities; this will make it possible to establish a pragmatic and consistent framework for providing advance warning, ensuring a high level of transparency and preparedness across the EU. Additionally, it emphasises the importance of supporting the development of national agencies in charge of

medical devices. This approach aims to strengthen the overall healthcare infrastructure, ensuring that local situations and needs are addressed properly and aligning healthcare infrastructure with EU-wide standards of safety and efficacy.

4.8 The EESC highlights the need for strategies enhancing supply chain resilience and preventing shortages that could impact patient care. By promoting equitable access and addressing economic and logistical challenges, the EESC supports efforts to ensure that advances in medical technology are accessible to all patients, irrespective of their geographical location or socio-economic status.

4.9 The EESC recognises the pivotal role of innovation in advancing healthcare outcomes through medical devices. It supports the proposal's emphasis on creating a regulatory environment conducive to innovation while also ensuring safety and efficacy. The Committee calls for a framework that balances the need for innovation with the imperative of patient safety; this framework should also facilitate the development of cutting-edge technologies that can address unmet medical needs and improve quality of life.

5. Stakeholder engagement and workforce considerations

5.1 The EESC emphasises the critical need for comprehensive training programmes for all stakeholders involved in the medical device sector, including SMEs, larger enterprises and regulatory bodies. It urges the European Commission to initiate and facilitate 'train-the-trainer' programmes to ensure that essential regulatory and technical competencies are adopted throughout the industry. This initiative is seen as a vital step in ensuring that all entities, regardless of size, are equally prepared and equipped to comply with the evolving regulatory requirements; this will keep up the EU's high standards of healthcare and patient safety.

5.2 The EESC emphasises the critical importance of addressing the impact of regulatory changes on workers and labour conditions within the medical device sector. It highlights concerns regarding job security, the need for reskilling given new technological and regulatory requirements, and the potential for increased work-related stress. The EESC calls for proactive measures to ensure that workers' rights and working conditions are not adversely affected.

5.3 With a view to mitigating these challenges, the EESC recommends engaging in constructive dialogue with trade unions and worker representatives to develop training programmes, support systems and transitional measures that safeguard employment and promote a healthy work environment. These efforts should equip workers with the skills needed to thrive in a rapidly evolving industry, ensuring that the transition to new regulatory standards strengthens the workforce and fosters positive labour relations.

5.4 The EESC recognises that healthcare professionals play a significant role in the medical device ecosystem, especially in light of the proposed regulatory changes. It understands that these professionals must stay abreast of the latest technological advances and regulatory standards in order to provide the best possible care.

5.5 Furthermore, as part of a broader, long-term strategy, the EESC stresses the need to establish uniform production conditions and consistent standards for manufacturers. This approach aims to

keep EU production vibrant and maintain market competitiveness. The Committee also points out that standards set for the EU must be respected by third countries and that bilateral agreements must be aligned with these standards. This strategy is integral to enhancing the resilience of the EU's medical device sector, ensuring high levels of safety, efficacy and quality across the board.

5.6 The EESC highlights the need for a supportive environment that allows healthcare professionals to voice concerns and suggestions regarding medical device usage and safety, and ensures that their invaluable frontline insights are built into regulatory discussions and decision making.

5.7 The EESC attaches great importance to involving civil society organisations, particularly those representing patients and relevant associations of manufacturers and distributors, in the regulatory process for medical devices. These organisations must have a voice in shaping regulations that have a direct impact on patient care and safety. This inclusive approach will ensure that the regulations are comprehensive and take into account the perspectives of all stakeholders in the medical device lifecycle, from production to patient use.

5.8 The Committee calls for greater transparency and inclusiveness, ensuring that patient representatives are actively involved in discussions on device safety, efficacy and accessibility. To facilitate this, the EESC recommends establishing formal mechanisms for patient advocacy groups; this will enable them to contribute to policy development and review processes and ensure that the patient perspective is consistently integrated into decision making.

6. Quality assurance and patient safety

6.1 The EESC emphasises the importance of ensuring that the medical devices made available to EU patients are of the highest quality. To achieve this, the Committee is in favour of reinforcing designated EU laboratories as they are vital for upholding stringent EU standards of quality and safety across medical products. This initiative underscores the commitment to maintaining excellence in the healthcare sector and safeguarding patient welfare.

6.2 The EESC strongly endorses EU4Health framework initiatives aiming to empower the EU to both enhance the medical devices market and prevent the entry and circulation of counterfeit medical products or those which do not meet EU standards. The Committee also calls for action to support programmes making economically unattractive medical devices and IVDs accessible to Europeans through tailored solutions. These efforts are crucial for addressing Europeans needs and ensuring fair access to high-quality healthcare solutions.

Brussels, 20 March 2024.

Olivier RÖPKE
The president of the European Economic and Social Committee

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