ESIP Statement
on the Implementation of
Regulation (EU) 2017/745 on Medical Devices

including on the Proposal for a Regulation amending Regulations
(EU) 2017/745 and (EU) 2017/746
as regards the transitional provisions for certain medical devices
and in vitro diagnostic medical devices

European Social Insurance Platform (ESIP)

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About the European Social Insurance Platform (ESIP)

The European Social Insurance Platform (ESIP) represents 45 national statutory social insurance organisations in 17 EU Member States and Switzerland, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

Statement regarding positions submitted by ESIP: ESIP members support this position in so far as the subject matter lies within their field of competence.

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Introduction

At the end of May 2017, the new European Medical Devices Regulation (Regulation (EU) 2017/745; MDR) entered into force. The main goals are to increase the safety of medical devices placed on the market, to raise the requirements for the clinical evaluation of high-risk devices, to establish transparency by implementing a central, partly accessible database (EUDAMED), and to harmonise the quality of Notified Bodies throughout Europe. This reform was necessary to adapt the classification, clinical evaluation and marketing rules of the old medical devices Directive from 1993 to today's state-of-the-art of technologies.

In the view of the European Social Insurance Platform (ESIP), **the MDR is an important step towards improving patient safety and the quality of treatments using medical devices.**

Since the Regulation came into force, several actors have raised concerns regarding the limited capacity of Notified Bodies and difficulties in accessing those, especially for small and medium entreprises (SMEs). In conjunction with stricter requirements and timelines, manufacturers argue that supply disruptions and/or market withdrawals of needed medical devices are to be expected, consequently exacerbating severe shortages, hindering the competitiveness of the EU market and most importantly patient safety.

ESIP Recommendations towards the implementation of Regulation (EU) 2017/745 on Medical Devices

In order to ensure availability of medical devices complying with the highest safety and quality standards according to the intended aim of the Regulation, it is crucial to:

- **Further support non-legislative solutions to strengthen the capacity of Notified Bodies in light of the challenging transition of ~ 25,000 former Directives certifications to MDR**

ESIP acknowledges that compliance with the new MDR quality standards in terms of personnel and infrastructure would be challenging for many Notified Bodies, resulting in delayed notification processes and therefore less opportunities to file successful applications for manufacturers and especially SMEs. We therefore **support measures to further strengthen the capacity of Notified Bodies** and we welcome the recommendations of the Medical Devices Coordination Group published in August 2022.

- **Avoid blanket extensions of the transition period and consider targeted derogations instead**

In our view, further general postponement would fail to provide an efficient solution to the identified problem, as simply prolonging the transition period may lead to further delays in filing an application for conformity assessment. Hence, the problem might not be solved but only postponed.

When necessary, **derogations for legacy devices could be considered for a limited period of time,** permitting their continued use until their MDR certifications are processed, **under the following conditions: that the manufacturer can prove that an application for a conformity assessment under the MDR has been submitted before 26 May 2024, and that the respective medical device does not present unacceptable health risks according to the Council Directives 90/385/EEC and 93/42/EEC**. Consequently, devices falling under the scope of Article 120 of the MDR (on transitional provisions) and subject to derogations from Article 5 (new rules for placing devices on the market and putting them into service), should be clearly identified.

- **Adopt transparent and harmonised measures at European level to address and prevent withdrawals of medical devices while maintaining high level of safety, quality and transparency**

ESIP acknowledges the current risk of supply disruptions and calls upon the Commission to consider and assess alternative mechanisms to ensure availability of medical devices, especially for very rare conditions, in all Member States and without compromising patient safety. For instance, ESIP invites to consider a **centralised EMA authorisation process for clearly defined device groups**, implying a streamlined consultation process, clearly defined authorisation conditions as well appropriate and standardised authorisation fees.

Concerns were raised particularly for specific devices for the treatment of rare disease conditions, such as e. g. balloon catheters for pediatric cardiology. Those might be withdrawn from the European market due to economic reasons, despite the urgent need to treat certain vulnerable patient groups and in the absence of treatment alternatives. Member States may authorise these products on a national level on 'duly justified imperative grounds of public health and patient safety', according to article 59, MDR, as a short-term solution to ensure patient access.

In the long term, however, **the problem of withdrawals should not be addressed by allowing market fragmentation through separate marketing authorisations on the national level**. In parallel, **appropriate safeguards must be foreseen to limit the use of these devices for those patients really in need**. Importantly, high safety and quality requirements as laid down in the MDR should be maintained especially for devices targeting vulnerable groups.

In this context, **ESIP calls upon the Commission to publish information about national marketing authorisations, together with a summary of safety and clinical performance of the devices in question, and information about validity periods of the authorisation.** National marketing authorisation holders should also be made responsible for justifying the grounds by which a conformity assessment could not be performed at European level.

- **Increase overall transparency**

ESIP observes that a clear and transparent report on the medical devices at risk of withdrawal from the EU market has not yet been produced. **More clarity and transparency are needed regarding the types of devices at serious risk of withdrawal/shortages, combined with the precise reasons for withdrawals. Furthermore, ESIP supports a thorough analysis of the root causes leading to supply disruptions, to be led by the Commission and in close cooperation with the notified bodies and manufacturers.** Transparency is key for ensuring safety and traceability of medical devices. This would be crucial to better target the necessary policy measures based on strong evidence.

Finally, **ESIP calls on the Commission to swiftly establish, implement and ensure public access to the European database on medical devices (EUDAMED).**