EAHP statement on the calls for revision of the Medical Device Regulation and the In Vitro Diagnostic Medical Device Regulation

EAHP statement on the revision of the MDR and IVDR

Medical devices are an essential part of the delivery of high-quality healthcare and their procurement and management in the European hospital setting is often under the authority of hospital pharmacists.

Therefore, as an impacted stakeholder, the European Association of Hospital Pharmacists (EAHP) takes a particular interest in the implementation of the Medical Device Regulation (EU 2017/745) and the In Vitro Diagnostic Medical Device Regulation (EU 2017/746). EAHP especially welcomed the aim of the regulations to improve post-assessment vigilance and the traceability of devices and harmonising the approval procedures by notified bodies.[1] However, the implementation of the regulation has shown the complexities of the new framework and the limited predictability, efficiency and timeliness of access to medical devices for patients throughout Europe.

Moreover, the introduction of a more stringent risk classification system under the IVDR, combined with the consequent increased reliance of manufacturers on Research Use Only (RUO) products and the restrictions imposed on their use under the IVDR when intended for diagnostic purposes, has further complicated access to certain diagnostic tools, resulting in increased costs and delays.

The 2023 EAHP shortages survey collected information on shortages of medical devices in relation to the implementation of the MDR.[2] When asked about medical device shortages, 61% of respondent hospital pharmacists reported challenges accessing medical devices in their hospitals. The most common causes given were; supply chain problems, shortages or discontinuance of component, part or accessory of medical devices, and price of a medical devices. The implementation of the MDR and IVDR was the fourth most common response for hospital pharmacists. Communication of shortages was also seen as a problem for 37%

[1] European Association of Hospital Pharmacists. (2019). *EAHP opinion on the medical device regulations.* https://eahp.eu/wp-content/uploads/2024/03/eahp_opinion_on_the_medical_device_regulations.pdf
[2] European Association of Hospital Pharmacists. (2023). *EAHP 2023 Shortage Survey Report.* https://eahp.eu/wp-content/uploads/2024/03/shortages_survey_report_final.pdf

respondents who reported that they only receive information from manufacturers when asked.

Therefore, EAHP agrees that short-term measures are necessary to address pressing issues to ensure that patients and healthcare practitioners continue to have timely access to the medical devices they need, including:

- Improving the limited availability of orphan and paediatric devices;
- Ensuring the access to well-established technologies for which no health risks have been identified;
- Clarifying the notion of similarity in the clinical evaluation; and
- Ensuring a swift roll-out of the fully functional EUDAMED platform.

However, these should be separate from the in-depth evaluation process of the MDR and IVDR which must take the appropriate time to fully assess the impact and appropriateness of any new measures. EAHP welcomes the intention from policymakers to address regulatory challenges[3] as the application of the MDR and IVDR entails additional costs for manufacturers which can then have a cascading effect to either additional costs for hospitals or the disappearance of products and/or manufacturers and the risk of developing more monopolistic markets or markets far removed from Europe. Nevertheless, such changes must follow the appropriate process ensuring a clear rational and impact assessment to understand the public health consequences.

EAHP welcome the European Commission's decision to conduct a thorough evaluation of the impacts of the MDR and IVDR[4] and call upon policy makers to wait for the results from the evaluations to have a clear overview of the issues directly related to the implementation of the MDR and IVDR before performing any major legislative changes without due process. Public health and patient safety must remain at the core of the MDR and IVDR regulatory system.

[3] European Parliament. (2024). *Urgent need to revise the medical devices regulation.* https://www.europarl.europa.eu/doceo/document/TA-10-2024-0028_EN.pdf

[4] European Commission. (2024). *EU rules on medical devices and in vitro diagnostics – targeted evaluation*. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14155-EU-rules-on-medical-devices-and-in-vitro-diagnostics-targeted-evaluation_en