EPF reacts to the European Commission Proposal on transitional provisions under the IVDR and roll-out of EUDAMED

The European Patients' Forum (EPF) notes the publication on 23 January of a European Commission proposal to postpone once again the deadlines for full application of the In Vitro Diagnostic Medical Devices Regulation (IVDR) and speed up the launch of some elements of EUDAMED, the European database on medical devices.

Transition of devices to the IVDR

In view of the reports of risks of shortages of essential in-vitro diagnostics (IVDs), EPF supports the main objective of this proposal, namely **ensuring that patients continue to have access to the diagnostic tests they need**. IVDs are a crucial part of patients' care, as they play an essential role in e.g. screening and diagnosing diseases, guiding treatment decisions, monitoring disease progression, and identifying disease predisposition. As a result, it is essential that these devices remain available and that healthcare systems have an accurate view of potential supply disruptions to mitigate impacts on patients. Reporting requirements may also help clarify the reasons for device shortages or withdrawals, namely because devices are unsafe or outdated, or due to delays and inefficiencies outside a manufacturer's control.

That said, we are concerned that this is the third time in four years that the EU institutions consider or proceed with an extension of the timelines for full implementation of one or both medical devices regulations. While some conditions are in place, we note that some devices would now benefit from a transition period of over 12 years, until December 2029. While we understand the complexity of this overhaul of the system, these timelines would likely not be considered proportionate in any other public health context.

The Medical Devices Regulation and IVDR were adopted as a result of clear shortcomings of the existing regulatory framework to ensure patient safety and a need to significantly strengthen requirements and oversight across the devices' lifecycle. The COVID-19 pandemic also reminded us collectively how important reliable diagnostic tests are to inform public health decisions and pandemic response. As such, **we call on <u>all</u> stakeholders to work together to identify and address the challenges that hinder implementation of the regulations and to step up their efforts to make the system work for patients.**

Availability of EUDAMED

EUDAMED has the potential to considerably improve traceability of devices across their lifecycle and to facilitate post-market surveillance by competent authorities. It will also increase the overall transparency of the system for patients and healthcare professionals. In that sense, we welcome the decision to speed up the launch of EUDAMED and call on all stakeholders to do their utmost to ensure it is a well-functioning and fit-for-purpose tool. We also look forward to continued work with all parties to ensure that all relevant documents that can contribute to better patient information become available on the public site.

ABOUT EPF

The European Patients' Forum (EPF) is an umbrella organisation of patient organisations across Europe and across disease areas. Our 79 members include disease-specific patient groups active at the EU level and national coalitions of patients representing 21 countries and an estimated 150 million patients across Europe. www.eupatient.eu

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