MEDECINS EUROPEENS
EUROPEAN DOCTORS

Ms Ursula von der Leyen
President of the European Commission

European Commission
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cc: Ms Stella Kyriakides
Commissioner for Health and Food Safety

European Commission
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Brussels, 18 November 2022

Availability of medical devices in the European Union

Dear President von der Leyen,

We are writing to express European doctors' concerns regarding future disruptions in the availability of medical devices and ask you to take decisive action to avert this risk.

According to the information collected from CPME members, that is national medical associations across Europe, countries such as Germany, Sweden, the Netherlands, Austria, Finland and Denmark have already registered the limited availability of some medical devices and expect major disruptions in the near future.

This concerns key types of medical devices, in vitro diagnostics, medical imaging and monitoring, and various ICT systems referred to as medical devices. Alternatives are often more expensive, if available at all. In some countries, up to 75% of medical devices are at risk of becoming unavailable. Doctors fear that existing stocks of medical devices, especially those that are manufactured and used in limited numbers, may be significantly diminished.

One of the main reasons indicated by the national medical associations was the inadequate implementation of the Medical Devices Regulation 2017/745 and the limited capacity, or even absence, of the Notified Bodies.

This situation is unacceptable from the point of view of patient safety and quality of care. For European doctors, medical devices are indispensable tools for the effective provision of safe and evidence-based patient care.

We would like to take this opportunity to acknowledge the work done by the Medical Devices Coordination Group and the position paper 2022-14. Progress announced at the last MDCG meeting in October indicates that the challenge is being taken seriously. However, data collected from Notified Bodies are increasingly worrying. If we maintain the current rate of certification of medical devices, only half of them will be available after May 2024.

While European doctors are supportive of the Medical Devices Regulation's objectives of enhancing rigorous pre-market assessment and market surveillance to increase patient safety, we urge you to consider all necessary measures to avoid putting health of European patients at risk. If no other solution to increase the capacity of Notified Bodies and to make economic operators comply with MDR rules can be found, legislative steps must be considered. This includes permitting time-limited the continued use of selected classes of medical devices which do not present unacceptable health risks under the certificates issued under the Council Directives 90/385/EEC and 93/42/EEC until the MDR certification is processed beyond what is currently foreseen in the Regulation. A blanket extension for all classes should be avoided, as high risk and invasive devices should remain subject to the more stringent certification foreseen by the new Regulation. We also recommend that adequate steps are taken to resolve similar challenges arising with regard to the In Vitro Diagnostic Medical Device Regulation.

Yours sincerely,

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CPME President

Ms Sarada Das
CPME Secretary General