The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

CPME statement on survey on regulatory governance and innovation in the field of medical devices

The Standing Committee of European Doctors (CPME) welcomes the opportunity to provide input to the ongoing study on regulatory governance and innovation in the field of medical devices.

In relation to the survey questionnaire, CPME would like to comment on key points in coherence with its previous positions on this question.

- European doctors remain supportive of the objectives of the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR) to ensure rigorous pre-market assessment and market surveillance to increase patient safety. We note that there has been some progress on traceability of devices, however, it can still be developed further. The Commission should make sure that the gradual introduction of the EUDAMED database is not delayed beyond the new timelines announced by the Commission on 23 January 2024. We have also continuously underlined the need to prevent future disruptions in the availability of medical devices.
- In relation to governance, we underline the need for structures which ensure representation of health professionals to report on real-life practice. To this end, CPME is committed to continue its membership the Medical Devices Coordination Group and also its taskforce on orphan devices.
- We underline that there remain severe challenges with the implementation of the MDR and IVDR which require sustainable solutions. Our members, the national medical associations across Europe, continue to highlight the inadequate implementation of the MDR and IVDR and the limited capacity, or even absence of the notified bodies as one of the main reasons that access to medical devices is disrupted, with other factors which also deserve attention, such as commercial considerations, being obfuscated. The latest proposal to extend the

transition period further is expected to provide temporary relief and ensure much-needed continuity of patient care. However there is little progress on a long-term solution to enable a full implementation of the safety standards provided for in the legislation. We also welcome special attention for niche products and products with few or no alternative technologies.

- In relation to innovation, with a view to the suitability of the current legislative framework for a horizon of 5-10 years, it is not possible to make predictions into the future functioning of the legislation if it has never been fully implemented so far. CPME welcomes the intention of the Commission to advance the preparatory work for the evaluation of the MDR. We acknowledge the threats to the future availability of orphan medical devices and note industry's call for specific incentives; however, when considering incentives for orphan devices, the Commission should keep in mind the risk of artificial "orphanisation" of conditions which has been a strategy by the pharmaceutical industry to benefit from the incentives for orphan drugs. EU legislation and regulations (e.g. for AI, PFAS, etc.) which also affect medical devices should be kept in mind when the MDR and IVCR are evaluated and considerations are made as to whether further regulation is indicated.