Medical Technology Industry stands ready to support work on the future of the Medical Technology Frameworks

Medical technology manufacturers fully support the objectives of the Medical Device Regulation (MDR) and *In Vitro* Diagnostic Medical Device Regulation (IVDR), which aim to *"establish robust, transparent, predictable and sustainable regulatory frameworks for medical devices and in vitro diagnostic medical devices, which ensure a high level of safety and health whilst supporting innovation"*. However to date, these objectives have not been fully met. The availability of medical technologies – both IVDs and medical devices – to patients in Europe is at stake and therefore broad and comprehensive reforms are needed in the short- and mid-term to support public health, patient safety, and the future sustainability of Europe's health systems.

The undersigned industry associations support Member States' calls for reforms of the current medical technology frameworks, expected to be discussed at the upcoming EPSCO Health Council meeting on 3 December 2024. Next to such broad and comprehensive reforms, COCIR, eurom, FIDE and MedTech Europe emphasise the urgent need for immediate (short-term) measures. Waiting for the EU Commission's ongoing targeted evaluation to conclude and full legislative proposals -likely to take years- is not an option for patients and health systems. With that in mind, we recommend the EU Institutions to implement the following:

<u>Short-term measures</u> - These should be implemented without delay and should have sufficient legal weight to achieve their intended objectives

- Bringing predictability to timelines and costs in technical documentation assessment and change control
- Introducing accelerated pathway for breakthrough innovation
- Adapting certification to follow a life-cycle approach, i.e. removing the requirement to renew certificates every 5 years
- Ensuring harmonised interpretation and application of MDR and IVDR requirements by developing technical documentation harmonised methodology
- Making sure that MDCG 2022-14 delivers on its original goals
- Enabling structured dialogues before and during conformity assessment
- Working towards enabling electronic instructions for use (e-IFU) for all medical technologies and embracing ditization more broadly
- Promoting global convergence of regulations, by for example joining/adopting the Medical Device Single Audit Program (MDSAP)

<u>Mid-term measures</u> - Based on the results of the EU Commission's targeted evaluation

Here amongst other points, we recommend the development of a sector specific, single and accountable governance structure with competences for medical technologies. It should address the current fragmentation of the governance system by improving efficiency, increasing predictability, course correcting and taking system level decisions. Concretely, we consider it crucial that such structure:

- Oversees the framework, designates and supervises Notified Bodies. Notified Bodies' approaches should be harmonized, transparent and consistent (including fees)
- Serves as point of contact, advice and early meaningful involvement of stakeholders which continues through the process of guidance development
- Integrates the different applicable legislative frameworks to medical devices and IVDs

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- Manages the dedicated pathways for innovative medical technologies and orphan/devices for unmet medical needs
- Promotes reliance on regulatory approaches compatible with the CE marking
- Offers an appeal system in case of disputes
- Ensures engagement with international organisations and initiatives (e.g. IMDRF, standard development)

COCIR, eurom, FIDE and MedTech Europe are fully committed to supporting the European Commission, and stand ready to collaborate with regulators, policymakers, and stakeholders to ensure that Europe remains a hub for innovation and that patients continue to benefit from the latest medical technologies.

Additional suggestions are described in

- MedTech Europe's position paper on The Future of Europe's Medical Technology Regulations
- COCIR's Position on the Future Governance Framework for the Medical Technologies Sector