To: European Commission, DG SANTE
Attn.: European Commissioner for Health and Food Safety Stella Kyriakides
Address: Rue de la Loi 200
Postcode – City: 1049 Brussels
Country: Belgium

Brussels, 14 September 2023

Open Letter: Need for comprehensive structural reform to address healthcare access challenges resulting from the EU regulatory framework for medical technologies

Dear Commissioner Kyriakides,

We are writing to you on behalf of the European medical technology industry to **ask for your intervention to address systemic issues** to medical technology access for patients and health systems in Europe.

It is of paramount importance that we ensure that medical technologies continue to reach patients and health systems in a timely manner. **Delayed access** may become a reality as the latest state-of-the-art prevention, screening, treatment, and care services will not be available at the speed that some patients might need. Medical technology innovation is necessary for ensuring that the EU effectively combats emerging **health crises**, such as antimicrobial resistance, new strains of infectious disease, and non-communicable diseases. Beyond healthcare, innovation in medical technology design is critical if our industry is to respond to the calls of the EU and society at large for more **environmentally sustainable healthcare**. Finally, it is innovation that enables the benefits of **digital healthcare** to empower patients, and support care teams and the chronically overburdened health systems.

The Medical Devices Regulation (EU) 2017/745 (“MDR”) and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (“IVDR”) aim to provide “a robust, transparent, predictable and sustainable regulatory framework that ensures a high level of safety and health while supporting innovation”. Our industry is fully behind these goals.

Unfortunately, despite more than six years of implementation, these goals are still not fully achieved. It is apparent that there are structural issues in the regulatory framework which cannot be solved simply through its implementation. The regulatory framework is unpredictable, complex, slow and costly. The result is that medical technologies – both those already on the market and future innovations − struggle to reach European patients and health systems. When medical technology innovations that are available in other regions are not available in Europe, patients will pay the highest price. Yet there is a broad consensus that MDR and IVDR are causing certain products to no longer be available for medical care.[1]

1 For example, see MedTech Europe 2022 survey reports for MDR and IVDR; more recent statement from European BioMedical Alliance and BCG publications https://www.bcg.com/publications/2022/us-ahead-in-medtech-regulation; https://web-assets.bcg.com/8c/f0/06744e8848ea9654bbd0765bf285/bcg-interstates-and-autobahns-mar-2022.pdf

We commend the European Commission's commitment to address structural deficiencies in the regulatory framework, including your call, Commissioner Kyriakides, during the 9 December 2022 EPSCO meeting to shape a regulatory environment that fosters innovation and ensures that Notified Bodies are enabled to focus on patient safety and less bureaucracy. Many Member States at the same EPSCO meeting also noted that structural changes to the regulatory framework will be needed.

Reaching the objectives of the IVDR and MDR in full will require **comprehensive change to improve efficiency, support innovation, and strengthen governance** – all while maintaining the highest standards of **patient safety**:

1. Europe needs a **more efficient and fit-for-purpose CE marking system**, taking the best of the current framework while improving resource efficiency among manufacturers, notified bodies and authorities. At the same time, it should improve predictability of conformity assessments and requirements over the certification lifetime, so that all actors can plan, prepare, and allocate resources efficiently. Such improvements to the current system should result in reduced administrative burden and costs. The system should be reactive and able to adapt as needed to external changes. Examples of concrete measures include but are not limited to:

    a. Efficiency gains through overhaul of the governance system,

    b. Predictability and transparency of deadlines and costs for all regulatory processes,

    c. Remove the limited validity of certificates, making it more efficient and risk-based,

    d. Bring the EU into the MDSAP programme

2. Europe needs a **system that supports innovation for medical devices and diagnostics**, by incorporating an explicit innovation principle aimed at swiftly connecting the latest medical technologies to European patients and health systems. The EU can achieve this by establishing well-resourced platforms for early dialogue with developers on evidence expectations, and by making dedicated and fast-track assessment pathways available for medical technologies **innovations that address unmet medical needs, life-threatening or highly debilitating conditions, and orphan and niche indications**. We owe it to the patients we collectively serve to ensure they have ongoing access to the latest and best care possible.

3. To put all this into practice, Europe needs a **single, dedicated accountable structure to oversee and manage the regulatory system**. It should designate and oversee Notified Bodies. The structure should be empowered to take system-level decisions to ensure efficiency and agility including providing support for SMEs. This includes the implementation of accelerated pathways for innovative technologies, and the enabling of Union-wide derogations in times of crisis to address unmet needs. Such an approach will greatly strengthen, harmonise and empower the assessment and certification processes carried out by Notified Bodies.

Commissioner Kyriakides, we stand ready to work together with you and the European Commission services to address this pressing situation and work toward the comprehensive structural reform necessary to achieve the stated objectives of the regulations.

We ask that you formally elevate the need for comprehensive structural reform within Europe's health policy debates. Existing fora, such as the Heads of Medicines Agencies (HMA), the MDCG, Study on Governance & Innovation and other areas, should be fully leveraged to bring together all medical technology stakeholders to jointly craft solutions, with clear actions and milestones mapped out to ensure these solutions are enacted as swiftly as possible.

We would welcome a meeting to further discuss the needed comprehensive structural reform of our regulatory system, and to elaborate on the possible solutions to improve efficiency, innovation and governance.

Only together can we deliver on the original goals of the IVDR and MDR to develop an effective and fit-for-purpose regulatory system for the benefit of European patients, health systems and society.

Yours sincerely,