EU Sustainable Prosperity and Competitiveness:

Priorities for the EU Chemical Industry Package

Brussels, 20 December 2024

MedTech Europe envisions a future where healthcare systems are environmentally and financially sustainable, equitable and resilient to future crises. Building such resilient and sustainable healthcare systems requires a robust, competitive, and innovation-driven medical technology industry.

Chemicals are an important catalyst for innovation in medical technologies[1], as they often offer a unique combination of properties. The medical technology sector is committed to the highest standards of chemical risk management measures and is working with its suppliers to continuously improve the performance of its products and processes. We also share the ambition of the EU Chemicals Strategy for Sustainability[2] to boost innovation for chemicals that are both safe and sustainable by design.

At the same time, the medtech sector is **ensuring the timely availability of lifesaving and life-sustaining technologies to satisfy patients' many different health needs**. Medical technologies are regulated under the stringent sectoral legislation, i.e., Regulation (EU) 2017/745 on Medical Devices (MDs) and Regulation (EU) 2017/746 on *In Vitro* Diagnostics (IVDs) [3], which lay down requirements for the design, safety, quality, performance, alternatives assessment and validation of MDs and IVDs. These processes require time and R&D, in addition to the continuous search for alternatives for chemicals proposed for phase-out at EU level, in parallel.

The upcoming **Chemicals Industry Package** should:

- Create **a more efficient and coherent regulatory chemicals framework** that acknowledges the particularities of the medical technology sector where patient outcomes and the safety performance cannot be compromised, and where chemical legislation needs to be aligned with the sector specific MDR & IVDR regulatory system and timelines.
- **Simplify REACH for downstream users, article manufacturers and importers**, such as the medical technology sector, as these face the priority impact of REACH restrictions and authorisations and depend on supply of information and materials/components from their supply chain.
- Provide **greater long-term investment certainty** for Europe's world-leading chemical companies and downstream user industries for rejuvenating the attractiveness of Europe for medical technology innovation.
- Provide **clarity on PFAS** and especially those uses already considered critical, such as medical technologies, based on the recent ECHA progress report that promotes alternative restriction options as long as there is a lack of alternatives in the sector and emissions are properly controlled.
- MedTech Europe supports a proposal to "**align REACH with the priorities of simplification, burden reduction and competitiveness"** and confirms the need to review the dual system of authorisations and restrictions to substantially reduce the need for individual authorisations.
- Ensure sufficient **resources, human and financial, as well as expertise** to the **European Chemicals Agency** in executing its new tasks under the One Substance, One Assessment package.

We highlight the following specific recommendations for the Chemicals Industry Act to implement the Green Deal in Healthcare:

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[1] For the purpose of this paper, medical technologies include medical devices, *in vitro* diagnostic medical devices (IVDs), Research-use Only (RUO), and the device part of a drug-device combination product.

[2] European Commission, Chemicals Strategy website, available at: https://environment.ec.europa.eu/strategy/chemicals-strategy/implementation_en

[3] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices

1. Design **realistic transition pathways to safer alternatives** in medical technology applications: The restriction of substances used in validated medical technology should allow for realistic and appropriate transition and it should only apply to new products - and not on existing ones - to enable a smooth transition and alignment with the development cycle of new medical technologies. In the event of a derogation, the scope should also include their manufacturing processes, imports, and supply chain so that potential alternatives can be identified and validated for suitability from a technical and regulatory perspective in accordance with the MDR/IVDR. Where there are no alternatives, derogations are necessary to ensure that patients and healthcare practitioners can continue to access the necessary medical technologies. Options instead of restriction and derogation should also be considered where alternatives are not available and emissions/conditions are controlled.
2. Because of the need to meet rigorous patient safety, performance and quality requirements, **the process of finding alternatives cannot be a one-size-fits-all for all uses and all industries**. Even when an alternative is available from a chemical perspective, it may not be a substitute from a patient safety/quality/performance perspective. Recognising the diversity of industries and their unique challenges in substituting hazardous substances is crucial, including from a patient perspective.
3. Establish **better consistency between chemicals regulations such as REACH and other horizontal and vertical EU legislation**, including the sector-specific regulatory framework, as well as other EU legislation, such as the RoHS Directive, Occupational Health and Safety legislation, the Ecodesign Directive/new ESPR initiative or the new Batteries and Packaging Regulations.
4. **Shaping REACH should pursue these objectives by implementing a four-point action plan:**
    a. Designing realistic transition pathways to safer alternatives in medical technology applications.
    b. Improving REACH restriction and authorisation, including if any, a workable extended Generic Approach to risk management (GRA) and implementing the new Essential Use Concept (EUC). In particular, MedTech Europe recommends:
        i. For any new restriction and authorisation of a substance used in a validated medical technology, the revised REACH Regulation should lay down a realistic and appropriate derogation period of at least 10 years for new products, which should also include their manufacturing processes, imports, and supply chain. New restrictions and authorisations should, as mentioned above, not apply on existing products already placed on the market. Options instead of restriction and derogation should also be considered where alternatives are not available and emissions/conditions are controlled.
        ii. To make use of such derogations, a company specific management plan could be presented to the EU's Chemicals Agency and/or competent national authority on an annual basis, including details on the conditions of use and safe disposal.
        iii. A review clause should be included to re-evaluate the transition deadline two years before the expiry of the granted derogation. To give industry the necessary predictability, a derogation should remain valid until the review process is completed.
        iv. The introduction of substance restrictions should be accompanied by an enabling R&D framework that supports medical technology manufacturers in the challenge of finding use-specific, fit-for-purpose alternatives that are also satisfying the regulatory requirements such as the MDR/IVDR.
    c. Increasing overall regulatory coherence of REACH with other relevant EU legislation.
    d. Ensuring workable information requirements for registrants, downstream users as well as article manufacturers and their supply chains.

For further information, please see:

EU Sustainable Prosperity and Competitiveness: MedTech Europe Recommendations for implementing the EU Green Deal in Healthcare

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.www.medtecheurope.org.