MedTech Europe
from diagnosis to cure

MedTech Europe Reflection Paper on the European Commission 'European Chemicals Industry Action Plan'

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General Remarks

European Commission Chemicals Industry Action Plan of 8 July 2025

MedTech Europe welcomes the Chemicals Industry Action Plan[1], as a first step in recognising the ongoing challenges European industries, such as chemicals, are facing. Chemicals are used in many downstream sectors, including the medical technology[2] sector. The Action Plan lays down important proposals to alleviate the burden for the chemicals sector and indirectly, the entire value chain, of which medical technology manufacturers are a part. Some welcomed measures are:

- Commitment to publishing the **REACH** revision proposal by Q4 2025;
- Additional time for ensuring compliance with the revised **CLP** labelling requirements, as well as the proposal to amend several labelling requirements;
- Commitment to providing further clarity on **PFAS** later in 2025 and 2026, whilst ensuring continued use in critical applications under strict conditions where no alternatives are available;
- Reinforced resources and predictable budget for **ECHA** in carrying out its (new) tasks;
- Support the innovation and strength of the chemical sector in the EU, of which MedTech members depend as downstream users for substitute materials with a reduced environmental footprint;
- Improved customs and market surveillance to ensure a level playing field.

We would like to take this opportunity to reflect on the proposed actions and bring additional points for consideration, as we find there are uncertainties that remain and that need to be addressed, in order to for the Action Plan to support the *entire chemical value chain*, including downstream users such as the medical technology sector.

Chemicals in medical technologies are used for specific purposes, as they are needed to meet specific design, performance, quality, functionality and safety requirements. In the implementation of these actions, we strongly encourage the European Commission to consider a value chain approach to also include the perspective, challenges, opportunities and specific needs of chemical downstream user industries.

The medical technology sector uses specialized chemicals that are critical to fulfil regulatory requirements for medical technologies and any change in substance availability could jeopardize the manufacturing of these devices and their supply to patients in need across the EU. As such, any change to the availability of substances (e.g. combination of regulation, litigation risk, lowering commercial demand, rising energy prices) will have strong impact on the medical technology sector, as we would potentially be unable to source the chemical and in the absence of an alternative, this would leave the medical technology manufacturer with limited choice as to how to continue producing the medical technology. Therefore, changes upstream to the chemical sector has trickling effects downstream that need to be considered.

MedTech Europe, represents manufacturers of medical technologies, which are devices used to diagnose and treat patient conditions. The contribution of medical technologies is ultimately to improve and extend people's lives. Because these technologies come into contact with patients, they are highly regulated by sectoral legislation, as elaborated further in this paper. As chemicals and materials form an integral part of devices, any policies or legislation on chemicals and materials has an impact on medical technology manufacturers in parallel to the sectoral legislation.

[1] Available at : https://commission.europa.eu/news-and-media/news/plan-stronger-eu-chemical-industry-2025-07-08_en
[2] Medical technologies include medical devices, *in vitro* diagnostic medical devices (IVD), Research-use Only (RUO), and the device part of a drug-device combination product and digital health.

Medical devices and IVDs are regulated by the sectoral legislation for medical devices and IVDs, namely the Medical Devices Regulation 2017/745 (MDR), and *In Vitro* Diagnostics Medical Devices Regulation 2017/746 (IVDR), respectively. While RUO are not regulated to the same extent as medical devices and IVDs, they are commonly developed using the same materials, manufacturing techniques, and performance expectations as IVDs. RUO devices often serve as precursors to clinically validated diagnostics. Medical technologies are used to diagnose and treat patient conditions, ranging from wounds, emergency therapy and surgery, and longer-term illnesses and conditions. The objective of medical technologies is to improve and extend people's lives. The contribution of the medical technology sector in diagnosing and treating patient conditions is on a daily basis, noting it has also played an instrumental role in the diagnosis of COVID-19 during the 2020 pandemic, as well, as the ongoing research and efforts into diabetes, cancer, and cardiovascular diseases.

This paper presents specific considerations around some of the announced actions and Simplification Omnibuses, namely the CLP Regulation revision, the proposed ECHA Founding Regulation, the REACH Regulation revision, PFAS clarity, and other elements of relevance to the medical technology sector.

CLP Regulation Revision

The CLP Regulation has both direct and indirect applicability for medical technologies. This entails that the Omnibus Amendments will have varying degrees of impact, depending on the medical technology. To illustrate, Article 1(5)(d) of the CLP Regulation states that "*This Regulation shall not apply to substances and mixtures in the following forms, which are in the finished state, intended for the final user: medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC*".

- Situation for medical devices:

The scope exclusion applies only to those medical devices which are (1) substances and mixtures (2) in a finished state, (3) intended for the final user, and (4) which are invasive or used in direct physical contact with the human body. This however does not cover all medical devices, and therefore, CLP requirements for labelling, packaging, etc. do apply to those uses not meeting these criteria.

The sectoral legislation for medical devices (Medical Devices Regulation 2017/745 - MDR), has requirements on chemicals which are triggered by a CLP classification of a substance as a CMR 1A/1B or an Endocrine Disruptor, namely under MDR Section 10.4.1 to perform a risk-benefit assessment of that substance in the medical device present in 0.1% w/w, and to label accordingly. *(MDR CLP/labelling requirements: Sections 10.4.5, 14.7, 23.1, 23.2 (m), and Section 23.4 (u) of Annex I).*

- Situation for IVDs:

Whilst IVDs benefit from the scope exclusion in Article 1(5)(d), the exclusion does not apply to IVDs which are in a *semi-finished* state, hence, these need to fulfil all the CLP labelling requirements. Additionally, the sectoral legislation for IVDs – *In Vitro* Diagnostic Medical Devices Regulation 2017/746 - IVDR), specifies that when labelling, the relevant hazard pictograms and labelling requirements of **the CLP Regulation shall apply** (with derogation for label space).

Therefore, whilst there is a scope exclusion that benefits IVDs and some medical device, there are nevertheless CLP chemical assessment and labelling requirements under both sectoral legislation MDR and IVDR, for medical devices and IVDs.

Specific Recommendations:

- ✓ Considering CLP affects certain medical devices and semi-finished IVDs, **MedTech Europe supports the CLP amendments which ease the time to implement labelling changes**. It should be noted that companies whose products have been in scope of the CLP requirements, have been working towards compliance with those labelling requirements.
- ✓ MedTech Europe supports simplification but insists that safety and traceability must not be compromised. We seek to ensure that medical device regulations remain robust, even as chemical rules are streamlined. This is important because medical devices often contain chemicals or mixtures that must be traceable in case of adverse events or recalls. If simplification leads to gaps in data or unclear responsibilities, it could affect patient safety or regulatory compliance. **Including medical technology-specific examples in EU guidance would help avoid misinterpretation and ensure the sector's needs are considered**.
- ✓ Regarding 'Defence Readiness', **MedTech Europe recommends explicit provisions recognizing the critical medical use for humanitarian and defence needs** (e.g. medical/surgical supplies in defence/humanitarian contexts). (COM 531 Recital aligns with defence-specific simplifications, widening national exemptions) and public health emergencies (e.g. pandemics), where rapid access to medical technologies is vital.

ECHA Founding Regulation & Attribution of New Tasks (OSOA)

MedTech Europe welcomes the publication of the proposal for an ECHA Founding Regulation. Considering the role of ECHA in chemical assessment and regulation, and the growing tasks over the years stemming from the SCIP database, but also, the new tasks allocated under the 'One Substance, One Assessment' (OSOA) package, we considered it important for ECHA to have a stable, predictable, and sustainable finance model.

The new pieces of legislation ECHA will work on has direct implications for medical technologies, as they are in scope of e.g. Batteries Regulation, RoHS Directive, the phthalate guidelines assessment under the Medical Devices Regulation (MDR) Section 10.4.1.

Specific Recommendations:

- ✓ Given the increased role of ECHA in sustainability legislation, which is of direct impact to medical technologies, MedTech Europe asks that when allocating the resources for ECHA, that it has the **necessary expertise to handle the new responsibilities** envisaged in the targeted amendments to RoHS and the Medical Devices Regulation (MDR) , i.e. in **specific technologies** (**electronics, medical devices, and IVDs**) and their **respective legislation** (i.e. MDR and IVDR).
- ✓ Considering the increased role of ECHA in medical technologies' assessment, we encourage there to be **stronger alignment between MDR/IVDR and ISO 10993** (biocompatibility testing standard). We therefore recommend establishing a closer cooperation and alignment between ECHA and health authorities (e.g. Notified Bodies, DG SANTE MDCG Environment TF, etc.) to ensure biocompatibility evaluations and substance assessments are coherent.
- ✓ MedTech Europe overall notes that the proposal heavily focuses on upstream actors, whereas medical technology manufacturers are downstream users of chemicals. We therefore recommend the **inclusion of downstream user needs**, especially in the medical technology sector, through structured stakeholder involvement in ECHA committees.
- ✓ MedTech Europe supports transparency and quality improvements, but sees the risk of implementation gaps. MedTech Europe asks for **predictable implementation timelines**, **transitional guidance**, and **regular impact assessments** for downstream sectors.
- ✓ Budget flexibility is relevant, however it runs the risk of deprioritizing tasks related to medical uses. MedTech Europe recommends ensuring **dedicated resources or minimum allocation** for health-critical substance evaluations (Articles 17-19).
- ✓ Reclassification of substances used in sterilization or production could affect device compliance. MedTech Europe recommends **risk-benefit frameworks** and maintain or expand **exemptions for medical applications** where no safe alternatives exist.

REACH Revision

MedTech Europe welcomes the confirmation that the REACH revision proposal will be released in Q4 2025. Chemicals are an important catalyst for innovation in medical technologies, 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 to boost innovation for chemicals that are both safe and sustainable by design.

At the same time, the medical technology 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 MDR/IVDR, 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.[3]

MedTech Europe represents manufacturers of medical devices, *in vitro* diagnostic medical devices (IVDs), drug-device combination products, digital health, and Research Use-only products (RUO), as well as material and component manufacturers. As such, MedTech Europe members find themselves in various positions in the supply chain. Given this variety in the medical technology sector's membership in MedTech Europe, different companies are impacted by different requirements under REACH, also based on their portfolio, e.g. companies upstream can be registrants, but also have some Authorisation and Restriction obligations. Downstream users tend to be mainly Authorisation holders and are impacted by Restrictions.

Medical technology manufacturers are mainly downstream users of materials and components. Therefore, medical technologies are largely dependent on materials and components that are supplied to the medical technology sector from upstream via a complex multi-tier supply chain that can reach up to 30 tiers. As mainly downstream users, medical technology manufacturers do not have the oversight on when and what the suppliers can provide and the technological know-how as confidential business information is mostly owned some tiers upstream. Manufacturers of medical technologies use the same components as other sectors, e.g. electronics industry, but are seriously affected by early obsolescence of components (if drop-in replacements are not available), as re-design of medical technologies involves retesting, sometimes clinical trials, and gaining approval from Notified Bodies, before re-designed products can reach patients and hospitals, per our stringent sectoral legislation.

The process of testing and re-design can take several years, if there is a viable alternative available in the first place. A manufacturer would first needs to be supplied with a feasible technical candidate alternative, should such exist, and from there, begin testing for compatibility, safety, performance, etc.. These stringent requirements ensure that the final medical technology yields the same or better performance, safety and quality assurances, to diagnose and treat patients. **Thus, an "alternative" can only be deemed as such if a candidate technical alternative exists and this candidate alternative has been successfully implemented in line with the medical technology sectoral requirements**. What this entails in practice for the medical technology sector is that sufficient time is needed, so that feasible alternatives can be sourced and then tested and validated in line with sectoral requirements.

[3] For more information on MedTech Europe's views on the REACH revision, please consult our paper at the link here: https://www.medtecheurope.org/wp-content/uploads/2025/01/241220_mte_chemical-industry-package_final.pdf

The medical technology sector is dependent on the supply of materials and components and their candidate alternatives from its upstream suppliers, the sector is also dependent on the *supply of information on the presence of REACH-regulated substances (e.g. SVHCs).* Whilst this is to be communicated along the supply chain (Article 33 REACH) and declared in technical documentation, as medical technology manufacturers often do not produce the material and/or component, they depend on the timely communication of this information. However, not all products are impacted by REACH Article 33 requirements (e.g. imported articles). Once the information is made available, the medical technology manufacturer must then also update the technical documentation across the wide portfolios and update relevant (digital) tools e.g. SDS, labelling, SCIP, etc. Some technologies can have dozens to over a thousand components (e.g. IVD analyzers).

Specific Recommendations:

In view of these sectoral specificities and the high compliance costs associated with REACH requirements, MedTech Europe calls for the following points to be reflected in the upcoming REACH revision, to ensure a regulatory framework that is efficient and cost-effective, and allows companies to prioritize their resources into innovative solutions for patients:

- ✓ Designing **realistic transition pathways** to safer alternatives in medical technology applications, as often the substitution timelines under REACH are not compatible with the lengthy re-design and validation processes under sectoral legislation (MDR/IVDR).
- ✓ Simplify and provide clarity on new obligations in 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.
- ✓ 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.

PFAS Clarity

MedTech Europe is committed to a transition to feasible alternatives that meet patient safety requirements and also recognizes that this complex undertaking requires significant time. Accordingly, until such alternatives and their stable supply are identified and subsequently have successfully passed patient safety requirements, sufficient transitional arrangements should be available for critical medical technology applications where there is no suitable alternative and potential releases to the environment can be controlled.

PFAS uses in the medical and research technology sector, or its supply chain, occur due to their combination of different and essential properties, including chemical resistance, heat resistance, durability, lubricity, low dielectric constant and biocompatibility.

Given the need for such a combination of essential properties, there is often no known alternative available to the use of PFAS in many medical technologies, their (sterile) packaging, or upstream manufacturing processes. Often, the only proposed alternative is another type of PFAS. In addition, any alternative must also fulfil all other regulatory requirements for use in medical technologies, including, required validations, aging tests, change of tooling and production processes, biocompatibility tests, clinical trials for certain devices, regulatory approvals and registrations, according to sector specific legislation (i.e., MDR and IVDR). Without successful completion of such required regulatory assessments and the necessary time to carry them out, a potential alternative material is neither able nor allowed to replace a given PFAS for use in MDs, IVDs, Research-use Only devices (RUOs), the device part of a drug-device combination product, and other medical technologies.

The 2023 PFAS Restriction proposal would result in significant impacts on the quality and availability of treatments for patients in the EU. Due to the unavailability of suitable alternatives to PFAS that meet the sectoral requirements under MDR/IVDR, some medical technologies and services may become unavailable for patients and practitioners.

Companies have been working with their suppliers to map PFAS uses in medical technologies and continue to find further use cases as time goes on. Due to the sheer number of substances in scope of the Restriction proposal and highly complex multitiered healthcare supply chains sometimes involving thousands of suppliers, there is the high risk that uses of PFAS that have not been identified by the end of the ECHA consultation period would fall outside the scope of derogations and would therefore not be permitted for use.

Finally, the medical technology sector is constantly looking for ways to innovate state-of-the-art technologies and solutions. PFAS offer many benefits in medical technologies, due to the unique combination of properties they offer in a single material. The Restriction of this entire class of substances risks halting future medical technology innovation. Industry needs clarity and legal certainty regarding research priorities for alternative substances, since the discovery of viable alternatives to the thousands of different PFAS substances cannot be accomplished and incorporated into medical technologies at the same time. A group of companies from the medical technology sector, together with the pharmaceutical sector, have made a proposal of close to 24 million euros in an upcoming project under the Innovative Health Initiative (IHI) on PFAS[4], (total project value is close to 50 million euros, as the industry contribution will be matched by the European Commission), where the three key priorities and targeted outcomes for the sector are:

[4] More information is available at the link here: IHI call 10 | IHI Innovative Health Initiative

- ✓ Better visibility over the presence of PFAS along the long and multi-layered supply chain;
- ✓ An assessment of alternatives tailored to the challenges with PFAS;
- ✓ Improving emission control and the end-of-life fate of medical technologies.

We note that in the November 2024 progress update on the PFAS Restriction, a third regulatory option is considered by the Dossier Submitters, which would still aim to reduce the PFAS emissions throughout the lifecycle, but with restriction options other than a ban. It is mentioned that this assessment is considered for, amongst others, medical devices.[5]

Specific Recommendations:

MedTech Europe welcomes the provisional actions laid down in the Chemical Industry Action Plan. However, more 'clarity' is needed on PFAS, as was alluded to in the Von Der Leyen Political Guidelines. PFAS are essential in many medical technologies due to their unique properties. **MedTech Europe urges any Restriction on PFAS in medical technologies to acknowledge:**

- ✓ **An overall patient-centric approach** whereby patient safety needs are the priority when transitioning away from PFAS (where technically and economically feasible).
- ✓ **Take into consideration all the regulatory options** and where there is no feasible alternative and emissions can be controlled, those applications should be exempted.[1]
- ✓ **A realistic transition pathway to non-PFAS alternatives** that are reliable and feasible for medical technologies (including their manufacturing and supply chain) to avoid shortages of medical technologies for patients and practitioner
- ✓ **A differentiated approach to high risk and low risk PFAS** in line with Article 68.1 REACH, which requires a proof of "unacceptable risk" for enacting a REACH Restriction: high risk PFAS should be targeted first. Fluoropolymers have a proven history of use and safety in medical technology applications and differ distinctly from the broader PFAS group.
- ✓ **A safeguard mechanism** for cases where no alternatives will be available, and for newly identified non-derogated cases or potentially missed use cases to ensure quality and continued access to essential medical technologies containing PFAS or requiring PFAS for their manufacturing, as well as their upstream supply chain.
- ✓ **An inclusion of upstream suppliers and manufacturing in MedTech derogations:** Where medical technologies are granted the necessary derogations, these need to include the materials and components supplied to the MedTech sector as well as manufacturing processes and process aids to be workable.
- ✓ **An enabling R&D framework** that supports medical technology manufacturers in the unprecedented challenge of finding numerous use-specific, fit-for-purpose alternatives to PFAS MedTech applications that are also satisfying MDR/IVDR regulatory requirements without compromising patients' lives or health.

We recommend the continued the use of PFAS-containing medical technologies as long as alternatives are not available and/or have passed patient safety requirements and emissions can be controlled, to ensure patient access to indispensable technologies and treatments in the transition to PFAS-free alternatives.

[5] For more information on the MedTech Europe views on the proposed REACH Restriction of PFAS, please consult our position paper available at the link here: MedTech Europe Position on the Proposal for A REACH Universal PFAS Restriction - MedTech Europe

Other Recommendations

Below are several other items noted in the Chemical Industry Action Plan that will likely have an impact on medical technologies or are not yet described in sufficient detail to assess the potential impact on medical technology manufacturers, such as:

- MedTech Europe welcomes the recognition of multi-tier supply chains, however, in practice, many suppliers are unable to reliably identify e.g. PFAS content or other restricted substances. We **consideration for the need for EU-supported supplier tools, templates, and training (particularly for SMEs)** to improve transparency and reduce compliance gaps.
- The integration of REACH through the **EU Single Window Environment for Customs**. Recognizing the need for greater oversight to ensure compliant product are placed on the EU market, linking TARIC codes can indirectly increase burden on industry to demonstrate conformity based on rather broad HS code schedules. Given the critical nature of medical technologies, we suggest calling for priority customs clearance or streamlined procedures within the EU Single Window to avoid delays in patient-critical supply chains.
- Increased customs enforcement could create bottlenecks for compliant medical products. MedTech Europe requests **technical alignment between REACH and product regulations**, and **simple, digital data exchange mechanisms** to avoid supply delays. (Action 7 (Q4 2025)).
- Compliance burdens on non-EU suppliers may increase, affecting component sourcing. MedTech Europe should push for **clear guidance**, **transition periods**, and **supplier support tools**, especially for complex medical supply chains. (Action 6 (Q4 2025)).
- MedTech Europe supports tapping into the potential of the upcoming Circular Economy Act to further reinforce circularity in the sector.

Concluding remarks

Chemicals are of vital importance for the design and manufacture and functioning of a wide range of medical technologies used to diagnose and treat patient conditions on a daily and long-term basis. As users of chemicals, downstream sectors such as medical technology manufacturers are also impacted by any changes to chemical supplies' availability. Medical technologies fall under strict regulations, such as the MDR and IVDR, to ensure patient safety and device performance. Changes to chemical legislations often triggers requirements under sectoral legislation (e.g. substitution timelines) which should be taken into account due to its potential consequences for patient access and healthcare provisions across the European Union.

Therefore, whilst the Chemical Industry Action Plan puts forward actions and policies that are a step in the right direction for the chemicals value chain, we nevertheless see the need for further considerations and actions by the European Commission during its 5-year mandate, to ensure that sectors that are dependent on chemicals, also benefit from simplification, predictability, transparency and cost-effective solutions that will improve patient access and treatments.

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.