MedTech Europe
from diagnosis to cure

PFAS in the medical technologies sector

MedTech Europe's preliminary views on the Restriction pre-publication

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About MedTech Europe

The European trade association for the medical technology industry including diagnostics, medical devices and digital health.

MedTech Europe
from diagnosis to cure

OUR MEMBERS

140+ multinational corporations*

50 medical technology associations

*medical devices, diagnostics and digital health

Specificities of the medical technology sector

About medical technologies

- Over **500,000** products, services and solutions are available
- **Medical devices** (e.g. surgical equipment, hospital beds, contact lenses, (active) implantable devices)
- **IVDs** (e.g. reagents, assays, analytical instruments)

Sectoral legislation MDR/IVDR

- Medical technologies are invasive and/or come into contact with the human body and are **strictly regulated** for their safety, design, performance, quality, risk management
- Certain requirements exist for the **justification and labelling of chemicals** used in medical technologies

Complexity of technologies & supply chain

- Individual devices differ greatly in complexity; it is not uncommon for routinely used devices to have **hundreds and thousands of components and parts** → E.g. laboratory/diagnostic machines for blood testing and analysis
- Supply chains of up to **30 tiers from materials to the final device** exist
- The average depth is smaller (e.g., **four to six tiers** for a seemingly simple product like an elastic bandage)

PFAS in the medical technology sector

Why PFAS

Properties such as **chemical** and **heat resistance**, **lubrication** and **biocompatibility**

PFAS is either a **component** of the final medical device or IVD, or a **processing aid** used during upstream manufacturing

PFAS substances are often key to achieving the required high **performance** and **durability** of the products in the various use areas

Alternatives

Without PFAS, these medical technologies would not be able to perform their intended purpose

Sometimes, the alternative is another type of PFAS - the functionalities of PFAS make them preferred over alternatives

A non-PFAS would likely lead to e.g.

- discontinuation of life saving procedures (e.g. stenting, heart valve repairing and replacement, catheters, implants, and capital equipment used in related procedures) and IVD uses (e.g. instruments, IVD testing kits)
- increased incidence of puncture wounds
- increased incidence of device malfunction and the inability of the surgeon to sufficiently visualize the surgical site
- inability to manufacture critical medical technologies

Examples of where PFAS can be found in Medical Devices and IVDs

Medical Devices

- Ophthalmic endotamponades - in **surgery** to reposition a detached **retina**
- **Blood contact invasive devices** – e.g. grafts/covered stents, catheter tubings for infusion of medication and IV fluids and drug eluting stent (DES) – **blood flow** within/between **arteries** and **veins** and for DES to control drug release to inhibit the vessel re-narrowing
- Medication contact components - **minimise drug-device interactions**
- Surgical sutures: pledgets made of PTFE serve as suture abutments when suturing soft tissue. They are essential in **heart valve operations**
- Fluoropolymers, like PTFE and PVDF, are used in several components for the **treatment of serious acute and chronic diseases**
- In hernia meshes for rapid **healing** of **hernia**
- **Cleaning** of medical devices as cleaning solvents in vapor degreasing applications

IVD Instruments & Reagents

- IVD testing kits for hemostasis products which **detect blood coagulation**
- **Heat-transfer agent** in IVD clinical chemistry diagnostic testing instruments, which is essential to the **functioning** of the instrument
- Surfactant properties in *in vitro* diagnostic assays, which allow **measures of various parameters** such as magnesium concentration in serum, plasma and urine
- Fluoropolymers like PTFE and PVDF are used in several components for **analytical instruments**
- In device part of an integral **drug-device combination**
- **Other**: Coating on the dispense tip, tubing and tubing connectors, distributors, seals and gaskets, syringe pump valves, O-rings and sealants

MedTech Europe's Preliminary Views on the Pre-publication Dossier

- MedTech Europe welcomes the **(conditional) derogations** proposed for the many essential medical technologies using PFAS
- **Laboratory diagnostics** are given a derogation, though some IVD uses fall out of the scope
- Multiple medical device derogations are '**to be confirmed**' after the public consultation
- Even if IVDs and medical devices obtain the necessary derogations, we rely on our **suppliers** to also have derogations, for the components, they supply us with

- No derogations are proposed for longer than 13.5 years, this creates the assumption that everything can be **substituted** and that is not the case, e.g. no alternative for PTFE
- The challenge with a long list of derogations for uses we stated as *known*, is that the list is **not exhaustive**
- The **multiple regulatory initiatives** running in parallel (PVC, BPA, PFAS, etc.) lead to substitution requirements that are **heavy on R&D**

Actions foreseen by the medical technology sector

- ✓ Collecting **data** in order to substantiate the 'conditional' derogations.

- ✓ Assessing whether:
  - ✓There are missing derogations for **IVDs and medical devices.**
  - ✓There are missing derogations for **components** that our suppliers supply us with (e.g. lubricants, PCB, other electronics).

- ✓ Working with our value chain:
  - ✓**end users** to understand if there is more that can be done on the reporting requirements/ end-of-life management of PFAS-containing technologies e.g. in hospitals, laboratories.
  - ✓**supply chain** to understand what a realistic transitional period is needed for the components identified to be containing PFAS.
  - ✓**partner associations** globally to collect data and communicate the impact.

Concluding remarks

- PFAS are used in a range of **critical medical technologies**
- Due to the expected **broad impact** of the PFAS restriction, numerous technologies and services could be affected in parallel
- PFAS often have no **alternative**, and where there is, it tends to be another PFAS
- We are working to collect additional data to support the dossier submitters' work and ensure continued access to medical technologies
- We are engaging with our **value chain**: global network, end-users and supply chain to understand better how to strengthen communication and actions on PFAS-containing medical technologies
- When considering a **transition** to a potential non-PFAS alternative, it is important to consider **patient well-being** and the timeline and requirements under **sectoral legislation**

Thank you!

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