

(English version)

**Question for written answer E-002391/26
to the Commission
Tomislav Sokol (PPE)
(10 June 2026)**

Subject: Impact of the proposed PFAS restriction on the availability of critical medical devices in the EU

Evidence submitted by stakeholders in the medical technology sector to the European Chemicals Agency consultation on the proposed restriction on PFAS (per- and polyfluoroalkyl substances) highlights that fluoropolymers play a critical role in numerous key medical devices, including vascular grafts, catheters, guidewires and surgical meshes. These materials are used because of their unique properties such as biocompatibility, durability, and resistance to degradation, which are essential to ensuring clinical performance and patient safety.

The current Annex XV restriction dossier acknowledges that, for many of these applications, no technically and clinically viable alternatives to fluoropolymers exist. The potential for substitution is considered to be low.

Concerns have been raised that the proposed restriction could lead to reduced availability of established therapies, increased reliance on more invasive procedures that carry higher risks for patients, and higher healthcare costs due to complications, longer hospital stays or repeat interventions.

In this context:

1. What actions is the Commission taking to comprehensively assess the impact of the proposed PFAS restriction on the availability, safety and performance of critical medical devices and their role in clinical pathways?
2. If the Commission identifies a risk to the availability of such medical devices, what regulatory or policy measures does it intend to take to prevent disruption to patient access?
3. What steps will the Commission take to ensure the long-term availability of these essential medical technologies in the EU?

Submitted: 10.6.2026

**Answer given by Mr Várhelyi on behalf of the European Commission
(20 August 2026)**

The restriction dossier submitted to the European Chemicals Agency (ECHA) by five national authorities in 2023 on per- and polyfluoroalkyl substances (PFAS), the so-called ‘Universal PFAS restriction’ is still being assessed by ECHA. Medical devices is one of the sectors assessed in detail during this process ⁽¹⁾.

In that context, the availability of alternatives to PFAS and the socioeconomic impacts of the restriction options are evaluated by ECHA’s Committee for Socio-Economic Analysis (SEAC).

The public consultation on SEAC’s draft opinion was closed at the end of May 2026 and SEAC will finalise its opinion considering the received comments.

Once finalised, ECHA’s final opinions will be a basis for the Commission to prepare a restriction proposal, taking into account all relevant information.

As the Commission announced in the Chemicals Industry Action Plan ⁽²⁾ where adequate alternatives in terms of performance and safety are not available, the continued use of PFAS in industrial applications may be allowed for critical applications, such as health, under specific conditions until acceptable substitutes are found.

⁽¹⁾ See <https://echa.europa.eu/documents/10162/5dfb5f74-b7c6-22bf-01b2-6f76a399e657>.

⁽²⁾ COM(2025) 530 final.