European Chemicals Agency
PFAS consultation

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Dear Members of the European Chemical Agency,

I have become aware that the proposed PFAS ban may have unintended consequences on well-established and irreplaceable mesh implants used for hernia treatment, which are made of Fluoropolymers. This concern has prompted me to compose this letter.

As a dedicated hernia surgeon for over 15 years, I can attest that all relevant medical guidelines recommend the use of mesh implants as the gold standard for hernia treatment. These implants serve a permanent load-bearing function and typically remain in the patient's body for an average of 25 years, and in some cases, up to 60 years. In the event of a mesh implant failure, reoperation is required in the majority of cases, which always carries higher risks of complications compared to the initial intervention.

I have employed polyvinylidene fluoride (PVDF) meshes in my research and clinical practice for approximately a decade. This material has consistently yielded highly favorable outcomes, surpassing those achieved with alternative materials. These superior results encompass not only a reduced incidence of recurrences but also a decreased occurrence of infections. As of today, I consider PVDF meshes to be my preferred method of choice, whether in open surgery or laparoscopic hernia procedures (1–3).

The main focus of the discussion concerning a potential PFAS ban is the substances' extreme durability ("forever-chemicals"). However, this very characteristic is the strongest argument against banning these substances for specific long-term medical implants, especially for hernia meshes. There is currently no equivalent alternative to fluoropolymers that meets the essential requirement of long-term stability.

Considering the relatively small quantities of material used (only a few grams per mesh implant) and the significant patient and socio-economic benefits, a ban on hernia meshes made of Fluoropolymers would be disproportionate and lead to severe negative consequences for patients and the healthcare system.

I acknowledge the environmental concerns related to different PFAS materials and support the initiative to critically assess their widespread use and seek alternatives. However, it is crucial to weigh these environmental concerns against the immediate negative impact a ban on certain medical devices could have on patients' health.

With patient safety in mind and in the spirit of proportionality, I urge the European Chemicals Agency to grant an indefinite exemption for mesh implants made of fluoropolymers, particularly PVDF. If you have any further inquiries, please feel free to contact me.

Sincerely yours,

1. Rodicio JL. SHORT-TERM OUTCOMES OF A MULTICENTRE PROSPECTIVE STUDY USING A “VISIBLE” PVDF ONLAY MESH FOR THE PREVENTION OF MIDLINE INCISIONAL HERNIA. Br J Surg [Internet]. 2021; Disponible en: http://doi.org/10.1093/bjs/znab396.006

2. Aguilera BC, Torres M da S, Rodicio J, Valle AF del, Moreno M, Amoza S, et al. PROPHYLACTIC MESH FOR PREVENTION OF INCISIONAL HERNIA IN HIGH-RISK PATIENTS: PVDF “VISIBLE” MESH BEHAVIOUR ON MRI. Br J Surg [Internet]. 2021;108(Supplement_8).

3. M. Garcia Munar, a. Suarez, E Contreras, J Iturbe, P del Val, L Garcia, C Ramos, L Sanz, Rodicio J. OPEN ABDOMEN´S REPARATION USING PVDF MESHES. EXPIRIENCE IN OUR CENTRE. Abstracts of the 25th Congress of the Spanish Society for Surgical Research, Barcelona, December 2019. Br J Surg. 2020;107 Suppl 1:5-20.