Barbora East, MD, PhD, FEBS AWS, general surgeon
III. Department of Surgery of 1st Medical Faculty of Charles University, Motol University Hospital in Prague, Czech Republic

Dear Members of the European Chemical Agency,

I am medical doctor and dedicated hernia surgeon at Motol University Hospital in Prague, Czech Republic. I am member of the board of the European hernia society, where I serve as the Secretary for Quality and president elect for the upcoming 2024 annual congress of the European Hernia Society hosted in Prague.

I have received information about a potential ban of numerous mesh implants made of fluoropolymers including PVDF. This ban would affect many well established and, in many ways, unique implants for which there are no equivalent alternatives available on the market:

1. Hernia meshes must provide permanent reinforcement of the abdominal wall or groin area over the patient's lifetime. Extensive scientific research [1-5] and clinical studies [6-8] have demonstrated the safety and efficacy of PVDF hernia meshes, with positive long-term outcomes and low complication rates compared to available alternative materials.
2. Mesh implants made of PVDF are in many cases associated with specific operation techniques (chimney technique to treat parastomal hernia (DynaMesh®-IPST)) for which no alternative mesh implants are available. In the case of a ban, these important surgical procedures can no longer be performed.
3. Pre-shaped PVDF mesh (DynaMesh®-ENDOLAP 3D) has unique handling properties and leads to less foreign body formation in the groin area, making the most common operation safer and without causing chronic pain.
4. PVDF hernia implants are available as MRI-visible variants. There are no other mesh implants on the market with this specific feature, which represents a clinically relevant improvement in terms of patient safety. [9-13]

For these reasons and in the interest of patient safety, I call on the European Chemicals Agency to grant a time unlimited exemption for mesh implants made of fluoropolymers, in particular PVDF.

I will be happy to answer any questions you may have.

Sincerely yours,

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Barbora East, MD, PhD, FEBS AWS

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