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Submitted:

https://comments.echa.europa.eu/comments_cms/AnnexXVRestrictionDossier.aspx?RObjctId=0b0236e1885e69de

Rolle, 19 September 2023

Comments for Annex XV "Per- and polyfluoroalkyl substances (PFAS)"

Dear Madam, Sir,

Recently EFORT (European Federation of National Associations of Orthopaedics and Traumatology) was consulted by the European Society of Sports Traumatology, Knee Surgery and Arthroscopy (ESSKA) about concerns raised by the proposed European restriction on PFAS. This new legal provision on PFAS may inadvertently cause significant problems for the continuing availability of essential medical devices. Although we have not yet had the opportunity to thoroughly research the extent of the use of PFAS in medical devices, some illustrations of PFAS use in a clinical setting are:

- Endoscopes: PFAS are used to create the seal between the metal scopes and cannulas in endoscopes (e.g. minimal invasive arthroscopic surgery, abdominal surgery). This tight PFAS connection is essential to have maintain a sterile working environment. Concerning arthroscopic knee surgery alone, about 8 million procedures are performed annually in the EU, not taking into account the other joints, or the whole field of general and gynaecological surgery using these devices.
- Medical devices in body contact need to be biocompatible which fluoropolymers prove to be.
- Electrosurgical medical devices need high disruptive strength, high creep resistance and high electrical resistance currently provided by PFAS.

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We fully agree with the underlying environmental concerns, though note that the issue is persistence in the environment and not toxicity, therefore we hope that an informed withdrawal of PFAS from the ecosystem should be possible, allowing devices for which no suitable alternative is available to continue being manufactured and used until such time as a replacement that is effective for surgical use has been found. PFAS resistance to chemical attack, electrical resistance, compatibility with tissues and low friction qualities have allowed the development of instruments that resulted in a huge expansion in the range of surgical procedures that can be done minimally invasively, reducing complications in patients, hospital stay and healthcare costs.

We urgently seek your reassurance that the PFAS use in medical devices has been considered in detail and that the law will not impact negatively on these medical devices with unintended consequences on patient care.

Yours sincerely,

Mr. David Limb
EFORT President 2023/2024

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