Biomedical Alliance in Europe

Biomed Alliance statement on finding a balance between implementing PFAS restrictions and the need for continuous access to life-saving devices

Clinicians and researchers very much welcome the important steps the EU has taken during the current legislative term to enhance the outdated legislative framework to protect citizens from harmful exposure to the numerous chemicals in our environment. One key element has been the PFAS restriction proposal which is instrumental in reducing, and in the longer term, phasing out all PFAS from our environment.

The negative effects of PFAS on human health and the environment are well documented. Existing peer-reviewed studies provide ample evidence for the association between child exposure to Endocrine Disrupting Chemicals (EDCs) and the onset of numerous illnesses including endocrine cancer, obesity, disturbed timing of puberty, impaired fertility, neurodevelopment alterations and numerous rare diseases'.[1] 'In addition, certain PFAS can lead to numerous health problems in adults, including cancers and reduced fertility[2]. Since these 'forever chemicals' do not or hardly break down in the environment, the clinical community believes it is essential that we reduce the use of PFAS across all sectors, including in medical devices and in-vitro diagnostic devices (IVDs).

In specific cases, exemptions to the rule should be granted, but these should be kept to a minimum and only be of a temporary nature.

Obligations of manufacturers

A potential uniform restriction of PFAS under REACH for all sectors, and within the same timelines, may impact the availability of life-saving medical devices for European patients. Some manufacturers currently argue that they will not be able to meet the deadlines for the restriction of PFAS, as they indicate there are insufficient alternatives available and they will not be able to phase out the substance in time. They claim that this may lead to a large number of, sometimes life-saving, devices and IVDs that could disappear from the EU market endangering the lives of European patients

It is nonetheless essential that manufacturers speed up their efforts to phase out their dependence on PFAS and to find alternatives. The importance of their sector for preserving human health must not be used as an excuse to continue the status quo.

A task force made of independent chemists, toxicologists, endocrinologists, paediatric endocrinologists and epidemiologists should be created to evaluate the possibility of alternative and

[1] ADD ESPE STATEMENT

[2] See e.g.: European Environment Agency: https://www.eea.europa.eu/en/about/contact-us/faqs/what-are-pfas-and-how-are-they-dangerous-for-my-health

safer substances and check the implementation of innovative research protocols for identifying molecules that can replace PFAS in the short term.

Next steps

We must take a balanced approach, by on the one hand phasing out PFAS as quickly as possible, while on the other ensuring that the supply of essential devices is not disrupted. This depends on a careful evaluation of existing alternatives, increased research into viable new alternatives, and facilitating the use of exemptions for a limited time period in case essential medical devices are about to disappear from the market.