Healthcare Associations warn of risks from PFAS restriction approach - failure to assess the impact on the availability of human and animal medicines

Brussels, 31 October – The European Federation of Pharmaceutical Industries and Associations (EFPIA), the Association of the European Self-Care Industry (AESGP), Medicines for Europe, AnimalhealthEurope, Access VetMed, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), EuropaBio, Vaccines Europe and the Life Science Manufacturers Association (LSMA) today voice serious concerns that the European Chemicals Agency (ECHA) does not intend to conduct an individual assessment on the impacts on the healthcare sector as part of its proposed universal restriction on PFAS[1,2,3].

While the healthcare sector remains in scope of the restriction, ECHA has indicated that the 8 new sectors, including 'other medical applications', covering medicinal products and their manufacturing, will not be individually assessed during the preparation of the final opinions by the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC). The associations warn that this approach risks disregarding critical evidence and sector-specific data submitted during the consultation processes and carefully assessed by the five Dossier Submitters.

Excluding medicines from individual assessment, while keeping them within the overall scope of the restriction, prevents the European Commission from obtaining a full understanding of the public and animal health and socio-economic impacts. Sector-specific evidence and emission mitigation measures have not been adequately reflected in the current analysis. Furthermore, the European Medicines Agency (EMA) and national health authorities have yet to be consulted in the ECHA assessment process despite being best placed to assess substitution feasibility and the potential impact on medicine availability.

Medicines are essential products governed by a unique regulatory framework to protect patient safety. Failing to assess the healthcare sector separately could lead to unintended consequences for public and animal health.

The associations therefore urge ECHA and the European Commission to ensure a dedicated, science-based assessment of the newly identified 'other medical applications' impacting the human and animal health sector within the PFAS restriction process. The associations emphasise the need for proportionate, evidence-driven regulation that protects the environment, animal and public health, without disrupting access to medicines for human and animal patients. The associations reaffirm their continued commitment to engage constructively in the process and call for a proportionate, science-driven regulation that balances environmental protection with safeguarding human and animal health.

Cosignatories

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Association of the European Self-Care Industry (AESGP)

[1] https://echa.europa.eu/sv/hot-topics/perfluoroalkyl-chemicals-pfas
[2] https://echa.europa.eu/sv/-/webinar-consultation-on-pfas-draft-opinion
[3] https://echa.europa.eu/documents/10162/111425157/echa_update_pfas_en.pdf/6775e241-204e-af0a-a2d0-4c16ba2c138d?t=1756287349062

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