29 January 2026
EMA/14601/2026

Highlights of the meeting on the impact of chemical and environmental policies on the healthcare sector and availability of medicines

19/12/2025 – chaired by Melanie Carr, Head of Stakeholders and Communication

1. Welcome and introduction

The Chair and the EMA Executive Director welcomed a delegation from the AESGP, AnimalhealthEurope, EFPIA and Medicines for Europe to the meeting. The delegation had requested the meeting to discuss the potential impact of certain chemical and environmental policies on the availability of medicines for human and veterinary use.

The importance of basing the discussion on data, science-based evidence and identifying a constructive way forward that could minimise the impact on the supply and availability of medicines was emphasised. Industry was asked to engage early with the relevant competent authorities in case bans and/ or restrictions are leading to shortages or withdrawals are anticipated. industry confirmed it has engaged by providing technical science based data in relevant consultations and discussions.

The Agency confirmed its ongoing collaboration with the European Commission (EC) and the European Chemicals Agency (ECHA), as well as its intention to explore the possibility of holding a joint EMA/ECHA meeting with stakeholders.

The industry delegation welcomed the opportunity to discuss these matters directly with the Agency.

2. PFAS restriction proposal under the REACH regulation

The industry provided an overview of ongoing and planned activities (including a project from the Innovative Health Initiative (IHI) due to start in 2026) to support a robust socio-economic assessment of the potential impact of PFAS (per- and polyfluoroalkyl substances) restrictions on the pharmaceutical sector. Given the potential impact and the lack of currently available alternatives to

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

PFAS, the importance of the Agency's dialogue with the Risk Assessment Committee (RAC) and the Socio-Economic Assessment Committee (SEAC) was highlighted.

The Agency acknowledged the concerns made, confirmed the involvement with ECHA at the initial stages of the public consultation and its availability to participate as an observer to future meetings of the SEAC and RAC. The EMA also confirmed that Members States are aware and monitoring via the informal HMA/EMA Horizontal Legislation Task Force and provided insight on the activities linked to sustainability of manufacturing of the Quality Working Party, Biological Working Party and Quality Innovation Group.

There was agreement on the need to raise awareness on the impact of horizontal legislation (such as chemical and environmental legislation) on medicines and ensure the perspectives of organisations representing patients and consumers can be taken into account.

Industry was invited to continue the engagement with ECHA and the EC via the existing channels, including the upcoming ECHA public consultation in Q2 2026.

3. Urban Waste-Water Treatment Directive

Industry expressed concerns regarding the expected costs for the pharmaceutical and cosmetics sectors, which are mandated to finance most of the costs for the removal of micropollutants from wastewater based on the extended producer responsibility system set out in the Urban Waste Water Treatment Directive (Directive (EU) 2024/3019), noting the risk that marketing authorisation holders may no longer be able to market medicines in the EU due to the expected related costs.

The Agency acknowledged the concerns and confirmed it has been consulted as part of the EC impact assessment study during the preparation phase of the legal proposal for a Directive as well as post adoption, on the preparation of the implementing acts from work led by RDC on technical aspects, including hazardousness and biodegradability, focusing mostly on hazard/risk assessment and technical explanations about the ERA under pharmaceutical legislation.

It was agreed to keep monitoring the topic and discuss, as required, in the margins of the Industry Standing Group (ISG).

4. Packaging and Packaging Waste Regulation (PPWR)

The Agency acknowledged the industry's need for greater clarity on the requirements as well as possible exemptions of Regulation (EU) 2025/40, ahead of the date of application of 12 August 2026, in order to ensure adequate and correct implementation. The Agency invited Industry to continue to seek clarity from the relevant competent authorities at national or EU level (including environment agencies). The Agency confirmed its labelling experts have submitted some interpretation questions to the EC.

It was agreed that the topic would be kept under close monitoring and any developments discussed as needed at future ISG meetings.

5. Conclusions and next steps

The open dialogue on shared concerns relating to the potential impact of environmental legislation on medicines for human and veterinary use was welcomed. Both parties acknowledged the ongoing interaction and agreed on the next steps.