9 June 2026
EMA/133179/2026
European Medicines Agency

Highlights European Medicines Agency (EMA)-European Chemicals Agency (ECHA) joint meeting with Industry stakeholders

09/06/2026 – Chaired by Melanie Carr, Head of Stakeholders and Communication Division

1. Welcome and opening remarks

The EMA and ECHA Executive Directors welcomed all participants, highlighting their openness and commitment to listen to stakeholders and noting the close collaboration between the Agencies while respecting their distinct mandates. They emphasised the importance of continuous dialogue with industry to better understand challenges and perspectives, particularly in addressing the increasing fragility of pharmaceutical supply chains, with a continued focus on safeguarding public and animal health.

The ongoing cooperation of both Agencies with the European Commission (EC) and other EU bodies under the One Health approach was noted.

2. Agencies roles, policies and stakeholder involvement

A comprehensive overview of the responsibilities and engagement frameworks of both ECHA and EMA was provided, clarifying their respective processes and how industry stakeholders can interact with them.

ECHA's mandate to implement EU chemicals legislation and deliver independent scientific advice was outlined, highlighting that the "right of initiative" for action on specific substances lies with EU Member States or is mandated by the EC. It was also noted that stakeholder involvement is ensured through calls for evidence and consultations of interested parties, where industry and relevant stakeholders can contribute with evidence-based information. The importance for stakeholders to stay up to date with the latest information and of early engagement, including with the relevant competent authorities at the national level, was emphasised.

EMA presented its role in medicines lifecycle management including early development support, scientific review of marketing authorisation applications and safety/availability monitoring, inclusive of monitoring of supply chain impacting potential availability of medicines to patients. The potential

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impact of restrictions under the chemical and environmental legislations on the pharmaceutical and medical device industries, as well as on patient and animal health, was emphasised. This can be significant when restrictions apply not only to active pharmaceutical ingredients and excipients, but also to substances used in the manufacturing processes including machinery, containers, and packaging.

EMA described the long-standing collaboration with ECHA, noting that exchanges have increased in recent years under the One Health and One Substance One Assessment initiatives. Key touchpoints supporting this cooperation were presented, including mutual consultation on annual work programmes, proactive monitoring of planned or ongoing relevant assessments, and bilateral meetings. EMA described the interactions with ECHA in relation to the harmonised classification of talc as an example of the close collaboration between the two agencies, while respecting their different remits. The importance for industry to monitor the ECHA activities and to report to both agencies and to the EC any foreseen challenges and constraints on the supply of medicinal products and medical devices was stressed. EMA concluded by highlighting the need for decision-makers to strike a balance between environmental protection and safeguarding patient health and continuity of care, given the fragility of the pharmaceutical supply chain, especially in an uncertain geopolitical environment.

The European Commission underlined its strong commitment to the One Health approach, recognising the interconnection between human, animal, and environmental health. It highlighted its intent to foster robust cooperation across EU agencies, particularly through the "One Substance, One Assessment" initiative, which is expected to significantly enhance chemical safety, data integration, and regulatory efficiency. The EC stressed the importance of balancing environmental protection with the resilience of the healthcare and pharmaceutical sectors, which may be possible through proportionate risk management measures, innovation in sustainable alternatives, and policy decisions based on robust scientific assessments.

The Commission also reaffirmed its support for finding balanced solutions as regards the phasing out of per-and polyfluoroalkyl substances (PFAS) in pharmaceuticals and medical technologies and pointed to the public–private partnership funded under the Innovative Health Initiative Joint Undertaking as a key enabler in the search for non-PFAS alternatives. In addition, it expressed support for the development, validation, and uptake of non-animal methods in close collaboration with ECHA, EFSA and EMA, to strengthen science-based regulatory decision-making and facilitate the transition to non-animal alternatives.

Industry participants welcomed the joint EMA–ECHA meeting and expressed support for the EU Roadmap towards phasing out animal testing in chemical safety assessments. EMA and ECHA reaffirmed their commitment to the 3Rs principles (replacement, reduction, and refinement) and in minimising environmental impact, highlighting their relevance at both European and international levels. EMA highlighted the importance of considering medicinal products as a special case justifying a specific risk proportionate approach due to the potential impact on patients.

3. Industry presentation on stakeholder needs and expectations

Industry representatives from the human and veterinary pharmaceutical, medical device and manufacturing sectors highlighted the challenges arising from overlapping and evolving regulatory frameworks, stressing the need for greater coherence, early engagement, and sector-specific considerations to prevent unintended impacts on the availability of medicines and devices. The increasing complexity of the legislative landscape and its cumulative effects were identified as key concerns, recalling the importance of systematic cross-legislative impact assessments.

Emphasis was placed on the complexity of supply chains, the need for reliable materials, appropriate transition timelines, and consideration of upstream sectors. Industry collectively called for stronger coordination across frameworks, science- and risk-based decision-making, improved legal certainty, realistic timelines, targeted derogations, and more structured dialogue between agencies, the EC, and stakeholders, as well as better leveraging of expertise across value chains to support simplification and harmonisation.

EMA and ECHA acknowledged the points raised, reaffirmed their intention to reflect the ongoing collaboration in an updated working arrangement, and emphasised the importance of stakeholder contributions, including data sharing, through consultations and participation to relevant fora. They also underscored their shared commitment to continued engagement in support of public and animal health and impact on the environment.

4. Open discussion: learning from experience and improving future operations

The last session focussed on an open discussion on how to improve the current interactions of both agencies with stakeholders, based on the following guiding questions:

- How can the implications for medicines be more effectively highlighted in the REACH/CLP (Classification, Labelling, and Packaging) process?
- How can industry stakeholders contribute to ECHA's scientific assessments?
- How can ECHA facilitate early monitoring of ingredients used by life science industry that undergo evaluation by ECHA, which would allow industry to respond adequately and in time?

In replying to the questions above, ECHA pointed to its introductory presentation and recommended that industry associations, via their members, engage early with chemicals authorities[1], as well as with medicines authorities, at the national level, noting that Member States are the final decision-makers in the implementation of chemical legislation alongside the European Commission. It was also highlighted that Member States authorities are usually in charge of preparing dossiers submitted to the ECHA committees and, in doing so, often organise national consultations to gather relevant evidence. Reference was also made to the Registers of Intentions and the Public Activities Coordination Tool (PACT)[2] available on the ECHA website, which provide advance notice of upcoming regulatory activities often more than one year earlier.

ECHA also offered clarification on the role of accredited observers in its scientific committees, noting that their participation is primarily to assist members by responding to questions, and on its legal mandate which is to provide evidence-based scientific opinions to the European Commission, while the latter can take wider socio-economic, as well as public health considerations into account.

EMA and industry participants emphasised the complexity of dealing with the differences between hazard-based and benefit-risk-based approaches, and the potential to generate confusion in the public in the absence of appropriate joint communication. The importance of ensuring environmental protection through feasible and implementable measures that do not compromise public and animal health was emphasised.

Industry participants stressed the need to account for sector-specific complexities, adopt a more proactive approach, and enhance alignment of data packages and scientific dossiers both across EU

[1] Contacts of the member states competent authorities and designated national authorities - ECHA
[2] PACT - Public Activities Coordination Tool - ECHA

agencies and at the international level. Challenges related to differing definitions, data requirements, and regulatory frameworks across sectors were also raised.

Both agencies continued to stress the importance of early and proactive engagement and of providing timely data to authorities as well as the need for industry stakeholders to request more transparency from their upstream suppliers.

Overall, the discussion provided an opportunity for open exchange on how to better reflect the implications for medicines of regulatory measures under REACH and CLP legislation, highlighting practical challenges through concrete examples. The dialogue underscored the importance of continuous collaboration, clearer communication, and earlier stakeholder involvement to ensure effective, science-based decision-making while minimising unintended impacts on the healthcare sector.

5. Conclusions and next steps

The discussion concluded with a shared recognition by EMA, ECHA, and the EC of the increasing complexity of the regulatory landscape and the need for continued collaboration. While acknowledging their distinct mandates, all parties reaffirmed a common commitment to protecting public, animal, and environmental health, and to reducing the environmental impact of healthcare products.

The meeting was seen as a valuable step in enhancing mutual understanding and identifying opportunities for closer alignment, with a clear intention to strengthen cooperation and engagement with stakeholders going forward to jointly deliver on their respective objectives.