EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication Division

Highlights – European Medicine Agency (EMA) and European Respiratory Society (ERS) bilateral meeting

30 October 2025, 13h00-15h00 CET

1. Introduction and tour de table

The Head of Public and Stakeholders Engagement welcomed the European Respiratory Society (ERS) delegates to this first formal bilateral meeting with the European Medicines Agency (EMA).

2. ERS key areas of work for 2025 and beyond

ERS is the largest global respiratory organisation, with over 35,000 members and a mission to promote lung health and reduce respiratory disease burden. ERS operates through advocacy, science, and education, aiming to influence EU policy, build coalitions, and raise awareness of respiratory conditions. Its priorities include producing unbiased education, supporting healthcare professionals worldwide, and funding high-quality research projects.

Key initiatives for 2025 and beyond focus on advancing respiratory science through guidelines, statements, and technical standards, as well as fostering clinical research collaborations (CRCs) and EU-funded projects. These projects address critical areas such as lung cancer screening, tuberculosis treatment, AI-driven oncology solutions, palliative care integration for COPD, and innovative therapies for drug-resistant pneumonia. ERS also emphasizes education via online learning, skills-based training, and comprehensive programs for respiratory physicians and allied health professionals.

ERS is organised in 14 assemblies, covering diverse domains from clinical care and intensive care to thoracic surgery, oncology, and paediatrics. Overall, ERS seeks to champion research, shape policy, and deliver impactful education to improve respiratory health globally.

ERS works closely with its patient organisation counterpart, the European Lung Foundation.

Two topics were addressed more specifically during the meeting, highlighting areas for which ERS could engage further with EMA:

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- Childhood respiratory health: ERS suggested to join efforts with EMA in raising awareness of the European Shortages Monitoring Platform (ESMP), strengthening confidence in respiratory syncitial virus (RSV) vaccine, and providing expert input in paediatric respiratory drug efficacy and safety aspects. EMA provided an update on the work of EMA's paediatric committee (PDCO), EMA's activities undertaken to mitigate shortages (e.g. recent shortage on salbutamol) and the possibility to engage on a more structured discussion with other organisations on the topic of vaccine confidence.
- Inhalation bioequivalence products, regulatory process and stakeholder participation: ERS offered support by providing clinical, physiological, and usability expertise to ensure that approved inhalation products perform effectively in real-world settings, in the interpretation of pharmacovigilance signals and design and interpretation of post-authorisation studies, to monitor real-world switching and usability outcomes and to feedback to EMA, contributing with potential corrective actions.

  EMA clarified that the review of the guideline on therapeutic equivalence for inhalation products has already been finalised. ERS was given the opportunity to comment during the public consultation periods and its final version is already published. With regards to the guideline on the demonstration of therapeutic equivalence for nasal products following the public consultation undertaken in 2024 on the Concept paper, work will continue into the drafting phase of the guideline and ERS will be involved in subsequent consultation phases.

3. EMA activities related with development support and medicines evaluation and guidelines

The meeting provided an opportunity to inform ERS about the PRIME scheme, scientific advice, qualification of novel methodologies and HTA interactions as well as existing regulatory science and academia support.

In addition, an overview of Emergency Task Force (ETF) on activities in preparedness and crisis was provided, highlighting some of the activities relevant to the ERS such as respiratory viruses' pandemic preparedness.

EMA also highlighted relevant activities included in the 3-year rolling work plan for the Rheumatology and Immunology Working Party (RIWP) 2025-2027.

4. Areas for further collaboration

In addition to the areas suggested above by ERS, the role of ERS in helping to identify experts for involvement in product-specific activities, including further interaction with their early career committee, as well as topic-specific involvement of ERS researchers in the European Platform for Regulatory Science Research, and the Emergency Task Force was emphasised. ERS input into EMA scientific guidelines will remain an important area of collaboration.

5. Summary of discussion/next steps

The meeting concluded with a shared sense of having had a constructive discussion, focusing on current and future opportunities for collaboration.

It was agreed to regularly review needs and opportunities fora bilateral meeting to continue the oversight of key strategic topics. This could be complemented with more specific and targeted discussions on specific topics.