1 April 2026
EMA/73196/2026
Stakeholders and Communication Division

Highlights – European Medicine Agency (EMA) and European Alliance of Associations for Rheumatology (EULAR) bilateral meeting

18 March 2026, 14h00-16h00 CET

1. Introduction and tour de table

The Chief Medical Officer welcomed the EULAR delegation to the bilateral meeting, emphasising the intention to strengthen strategic discussions on regulatory science, clinical trials, scientific guidelines, and patient engagement. Both organisations acknowledged the importance of recurring structured dialogues to address shared priorities and long-term scientific and public health objectives.

2. EULAR overview and key activities relevant to EMA

EULAR representation extends to 41 countries across Europe, and it serves as an umbrella organisation bringing together rheumatologists and other healthcare professionals in rheumatology, patients, and national scientific societies. Its vision focuses on reducing the burden of rheumatic and musculoskeletal diseases (RMDs) through early diagnosis, prevention, treatment optimisation, and long-term disease control.

Its Advocacy Committee plays an important role in raising awareness about the scale and impact of RMDs – including their high prevalence, links with other non-communicable diseases, and significant effects on disability, the workforce and healthcare demand – as well as key policy areas where EULAR seeks progress, such as health, social policy and research. This also includes engagement with EMA across several regulatory initiatives, from contributions to guidelines (systemic sclerosis, psoriatic arthritis, idiopathic inflammatory myopathies) to involvement in critical-medicines discussions and participation in EMA trainings.

EULAR provided more detailed insights into the following areas of their work:

Research Infrastructure: The EULAR Research Centre supports RMD research across Europe. This includes clinical research networks, data registries, methodological support, and large-scale projects

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

such as ENTRI, a long-term initiative to develop a connected network of clinical trial sites. The strategic goals of ENTRI include improved trial readiness, harmonisation of site capabilities, mentorship for early investigators, and facilitation of investigator-initiated studies. The network aims to support both industry and academic research initiatives.

Quality of Care Committee: EULAR's structured methodology for producing clinical recommendations involves task forces, systematic literature reviews (SLRs), voting procedures, and development of quality indicators. The committee oversees more than 27 active recommendation projects.

Patient Engagement: The PARE Committee enables structured patient engagement across EULAR's decision-making bodies and activities. This includes a network of trained patient research partners shaping research design, conduct, and dissemination; contribution to governance and strategic decision-making; advocacy and awareness-raising activities; and capacity-building programmes that strengthen patient organisations and support sustained engagement of people with lived experience, including patients, carers and families.

3. EMA updates to EULAR

The meeting provided an opportunity to inform EULAR about the ACT EU Programme that aims to render the EU a more attractive place for clinical research. A key deliverable of the programme has been the EU-wide clinical trial map designed to improve visibility of recruiting sites for patients and healthcare professionals. The programme also addresses ongoing methodological work related to GCP modernisation, platform trials, improved scientific advice processes, and enhanced guidance for clinical trial design – particularly relevant for investigator networks such as ENTRI. Central to ACT EU is the Multi-stakeholder Platform (MSP) which brings together key clinical trials stakeholders. EULAR was informed of the upcoming revision of the MSP Advisory Group mandate and composition.

EMA summarised the activities of medicines evaluation and guidelines development in the field of RMDs. The therapeutic evolution and approvals in inflammatory arthritis, connective tissues disorders and vasculitides were presented. In addition, EMA is establishing a Scientific Advisory Group (SAG) for immune and inflammatory diseases to strengthen consistency in evaluation of new medicines and indications. This group will include rheumatology expertise and may invite additional experts as required. EMA's working party on immune and inflammatory diseases (IIWP) work plan 2025-2027 identifies the need for drafting new guidelines on drug development as well as the need for revision of existing guidelines, including those on systemic sclerosis and psoriatic arthritis.

EMA also shared progress on the reflection paper on Patient Experience Data (PED) following extensive public consultation. The initiative aims to integrate lived experience more systematically across regulatory decision-making and downstream HTA and clinical practice contexts.

4. Areas for further collaboration

The role of EULAR in helping to identify experts for involvement in product-specific activities was mentioned, as well as the opportunity to promote alignment with Regulatory Science Research Needs. EULAR researchers may consider joining the European Platform for Regulatory Science Research, which discusses cross-cutting research topics of potential interest . EULAR input into EMA scientific guidelines will remain an important area of collaboration.

EULAR and EMA identified strong overlap between ACT EU goals and ENTRI's mission. EULAR expressed interest in aligning methodological guidance and contributing insights from trial centres.

Both organisations acknowledged their strong alignment on patient engagement principles and discussed avenues to share training models, best practices, and cross-organisational representation.

5. Summary of discussion/next steps

EMA confirmed the primary point of contact for subsequent communication and coordination and EULAR invited EMA representatives to upcoming congresses, noting the potential for joint sessions on clinical trials, regulatory science, and guidelines.

Both organisations agreed to maintain an open channel for targeted discussions across their respective expert groups.