8 May 2025
EMA/158016/2025
European Medicines Agency

Highlights- 2nd EMA- Alliance for Regenerative Medicine bilateral meeting

1. Welcome and Introductions

The chair and the EMA Executive Director welcomed the delegation from the Alliance for Regenerative Medicine (ARM) acknowledging the need to continue the collaboration and dialogue given the importance represented by Advanced Therapy Medicinal Products (ATMPs) for bringing innovative solutions to patients and healthcare systems.

The ARM welcomed dialogue and continued collaboration on cell and gene therapy space in order to overcome challenges and ensure global access to ATMPs. Multi-stakeholder engagement was emphasised.

2. Key priorities for the next 3-5 years and pipeline trends

The ARM presented its key priorities and pipeline for the coming years confirming Europe as an important innovation hub. To face the increasing global competition and ensure attractiveness, regulation should remain dynamic, competitive, predictable and supportive of innovation throughout the product lifecycle. The need to ensure a patient centric system was also flagged.

The EMA welcomed the overview of priorities and invited the ARM to provide additional insights on the data and pipeline estimates presented. Patients' centricity was also confirmed as fundamental, and the ARM was invited to participate to the upcoming public consultation on a draft Patient Experience Data (PED)Refection Paper.

3. EU-US Regulatory Convergence for ATMPs

An overview of the activities undertaken at international level with the US FDA and other authorities was provided flagging the importance of international convergence for bringing ATMPs to patients.

Given challenges in developing, commercialising and maintaining cell and gene therapies, efficiency and sustainability are key. Globally alignment and regulatory convergence can boost patience access by reducing the timelines and reduce duplications.

The summary of discussion of the regulatory Convergence Panel (Cell & Gene Meeting on the Mediterranean, 15-17 April 2025) were discussed highlighting the need to standardise regulatory

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terminology and concepts, strengthen reliance mechanisms and expand joint review process. Future learnings from current activities such as the CoGenT were considered important.

The EMA confirmed international collaboration as key pillar for its ATMP strategy. The ongoing initiatives aiming at increasing alignment and understanding with international authorities were outlined noting the longstanding and collaborative relationship with US FDA at multiple levels (bilateral, multilateral, and at individual) including scientific advice and ad hoc exchanges.

The Mutual Recognition Agreements (MRAs) already in place with several international authorities, some of which including ATMPs, were also noted.

The ARM was encouraged to use early engagement mechanisms in support to innovation such as the Quality Innovation Group (QIG) 1:1 meetings, Innovation Task Force (ITF) meetings, Academia support and Small, Medium Sized Enterprises briefing meetings.

4. ARM view on revised legislation

The ARM shared their views on the European Commission's legal proposal for the revision of the EU pharmaceutical legislation. The need to retain ATMP expertise, to ensure stakeholders engagement and ensure interlinks to other areas was stressed.

The EMA noted the views and suggestions presented. It was clarified that the EMA, not being part of the legislative process, was not in position to comment on any of the proposals made.

The division of working parties into five domains and the introduction of Operational Expert Groups (OEGs), Temporary drafting group (tDGs) an European Specialised Expert Groups (ESEP) was highlighted noting the importance of this restructuring in streamlining resources and retaining expertise.

5. Platform technologies for gene editing

ARM work in promoting discussion on platform technologies for gene editing were presented. This included discussion at the QIG listen and learn focus group in 2024. Pilot proposals to continue the dialogue and build learning were discussed.

The EMA welcomed ARM perspective and proposals on platform technologies and confirmed that, although the current legislation does not include a definition of "platform technologies", the concepts of "prior knowledge" allows companies to leverage available data.

Both parties agreed to keep an open dialogue and collaboration on this topic and the ARM was encouraged to participate any future initiatives (including EU founded projects) and events.

6. Conclusions and next steps

The bilateral meeting allowed both parties to exchange views on the opportunities and challenges represented by cell and gene ATMPs. The valuable collaboration with the ARM in this area was acknowledged and further dialogue on both strategic and scientific topics was welcomed. The ARM was encouraged to continue to participate to EMA initiatives and, as possible, to join the discussions of established groups and platforms such as the Industry Standing Group (ISG).