



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Highlights 1st EMA- ISCT (International Society for Cell and Gene Therapy) bilateral meeting

Chaired by Caroline Pothet, Head of advanced therapies and haemato-oncology

1. Welcome and introductions

The chair welcomed the ISCT delegation highlighting the importance of the sector represented and inviting further exchanges on specific topics within the relevant established platforms and groups.

2. Clinical trial regulation for advanced therapy medicinal products (ATMPs)

ISCT emphasised the importance of maintaining a predictable and internationally competitive environment for first-in-human and early-phase advanced therapy medicinal product (ATMP) clinical trials. Key areas identified for improvement included greater consistency in scientific expectations, more harmonised interpretation of guidance across Member States, and enhanced access to coordinated scientific advice, building on the strong expertise already available in the EU.

EMA outlined relevant activities under [Accelerating Clinical Trials in the EU \(ACT EU\) initiative](#), including consolidated advice mechanisms involving the Scientific Advice Working Party and the Clinical Trials Coordination Group, the pre-clinical-trial-application advice route, and work supporting future implementation of the proposed Biotech Act. ISCT members were encouraged to make full use of these established mechanisms and to consider participation in the [ACT EU Multi-stakeholder Platform Advisory Group](#), which brings stakeholder and regulatory perspectives together to identify challenges and support improvements to the clinical-trials ecosystem. EMA also highlighted the recent findings (published in [Clinical trials on medicinal products in the EU/EEA, 2013–2025: a cross-sectional analysis of CTIS and EudraCT data](#)) indicating a slight increase in the proportion of ATMP clinical trials in the EU/EEA, from 3.2% in 2013–2019 to 4.0% in 2022–2025.

EMA described ongoing efforts to promote a consistent understanding and application of ATMP guidance, including targeted training for assessors and the use of question-and-answer formats in rapidly evolving areas (reference was made to the Q&A on genome editing products that is currently



being drafted). The importance of regularly reviewing existing guidance and retiring outdated documents was also acknowledged, particularly in the context of implementing the New Pharmaceutical Legislation.

3. Other technical topics

3.1. Monographs for cell and gene therapies

ISCT welcomed the contribution of European Pharmacopoeia texts to greater standardisation of cell-based preparations and discussed how future texts could support clearer product characterisation, manufacturing controls, quality-control release and stability approaches.

EMA clarified that European Pharmacopoeia texts are developed through the European Directorate for the Quality of Medicines & HealthCare (EDQM). EMA and EU network experts contribute scientific and regulatory experience through relevant quality forums, while final decisions remain with the EDQM.

ISCT was invited to share proposals on cell-therapy areas where additional monographs could be useful. The discussion noted that priorities should be informed by regulatory and manufacturing experience and by products that are sufficiently mature to support meaningful standards.

3.2. Boundaries of "Minimal Manipulation"

ISCT asked clarifications on when substances of human origin (SoHO) and good manufacturing practice (GMP) requirements apply when it comes to minimal and substantial manipulation. EMA confirmed applicability of GMP requirements from the point at which manufacture of the active substance or finished medicinal product (for an ATMP) begins. Donation, procurement and testing of tissues and cells may remain under SoHO or tissue-and-cell framework, as applicable. For patient-derived materials, collection and initial testing may therefore take place under tissue-and-cell requirements, while subsequent processing intended to manufacture an ATMP must meet GMP requirements. Borderline cases also require consideration of the cells' intended use and the nature of the processing.

EMA informed ISCT of the availability of the paper [Development of non-substantially manipulated cell-based ATMPs1: flexibility introduced via the application of the risk-based approach on non-substantially manipulated cell-based ATMPs](#) and will reflect on how existing guidance (e.g. on minimally manipulated ATMPs and the interface between classification and GMP requirements) could be made easier to find.

4. Conclusions and next steps

The discussion confirmed shared interest in making European ATMP development more predictable while maintaining robust scientific and quality standards. It also identified practical routes for continued engagement through ACT EU, EMA scientific and quality forums, and future Committee for Advanced Therapies (CAT) stakeholder discussions.