The European commission proposal for a new regulation on biotechnologies: why does it matter for Advanced Therapy Medicinal Products ?

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Background & Method

As part of the European Commission (EC) life sciences strategy for the European Union (EU), a proposal for a new European regulation aims at establishing a framework to strengthen the biotechnology and biomanufacturing sectors, and has been published on 16 December 2025. The proposal targets "health biotechnology" with a wide definition, including biotechnological applications relevant to animal and plant health, veterinary public health, and food safety, all contributing to the protection of human health. Does it matter for Advanced Therapy Medicinal Products (ATMP)?

Research has been conducted on the content of the new EC proposal on a so-called "EU Biotech Regulation" to identify rules that could directly impact on ATMP regulation, development, evaluation and commercialisation.

Results

Three sets of rules in the EC proposal for a new European Biotech Act will impact on the regulation of ATMP in the EU.

1. Proposed EC new rules for ATMP

Support Measures for Centres of Excellence for Advanced Therapies

Health Biotechnology Strategic Projects - HBSP (Art.3)

- Strengthen industrial capacity and value chains in health biotechnology,
- Scale-up or upgrade critical research and technology infrastructures,
- Accelerate innovation and technology deployment,
- Address talent and skills needs, OR
- Contribute to strengthen the EU's preparedness and response capacity to priority health threats)

▶ Recognised by Member State

High Impact HBSP (Art.4)

- Meet criteria of HBSP
- Demonstrate "a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications" (via scale, scope or cross-border relevance)
- Among targeted projects: centres of excellence for advanced therapies, including ATMP

▶ Recognised by the European Commission

Centres of excellence for advanced therapies (Art. 6): cumulative conditions

- Specialise in at least one advanced therapy, incl. ATMP
- Provide advanced infrastructures
- Integrate quality, regulatory science, & safety testing functions to support Union-wide development of advanced therapies
- establish structured cooperation (clinical centres, research organisations, industries, investors & regulators)
- provide multiple services enabling the transition from lab to commercial manufacturing

Enhanced cooperation

through Networks of health biotechnology clusters

- To be promoted and facilitated by EC and Member States

EC's support on projects implementation

in cooperation with Member States and a new European Health Biotechnology Steering group (composed of MS' representatives and the EC and advising them)

- Identification of funding opportunities at EU level & facilitation of liaison between project promoters and investors
- Mapping of EU Biotechnology ecosystem and Promotion of actions strengthening it
- Facilitation of access to relevant research & technological infrastructures (SME+)
- EU Health Biotechnology Support Network: network of national and regional antennas coordinated by EC to assist and support the developers of health biotechnology products

Priority status of (high impact) HBSP

- Considered of (overriding) public interest
- Most rapid way possible for permit-granting and licensing procedures
- Benefit from (EU/National) accelerated procedures
- Benefit from tacit approval for environmental assessment when no reply by NCA within established deadline
- Permit-granting process of 10 months for HBSP and 8 months for high impact HBSP
- Recognised urgency of any dispute resolution procedures, litigation, appeals and judicial remedies

Single point of contact at National level

- to facilitate and coordinate the permit-granting process
- to provide information on general administrative support
- to provide technical and financial support

New EU-level bodies to support the development of health biotechnology products

EU Health Biotechnology Support Network

Network of national and regional antennas coordinated by EC

▶ Support to developers/promoters of health biotechnology products/projects

Foresight Panel for Emerging Health Innovation

Scientific and regulatory experts from EC, EMA and NCA, Coordination Boards on SoHO, Medical Devices and HTA

▶ Regulatory, scientific and technical support to EC, EMA, relevant Union-level advisory bodies, NCA.

European Health Biotechnology Steering Group

MS' representatives and EC

▶ Advise to EC and MS to facilitate implementation of this Regulation

Supplementary Protection Certificate (SPC)

From 5 years → to **5 years + 12 months extension for ATMP and biotechnological medicines.**

Regulatory tools for novel health biotechnology products

1. A new Union-wide cross-framework regulatory status repository

With publicly available:

- Decisions, opinions, scientific recommendations on the regulatory status of health innovations (MD, SoHO, medicines).
- Summaries of CAT scientific recommendations on ATMP classification
- Discussion papers from Foresight Panel for Emerging Health Innovation

2. Assistance on regulatory procedural pathways

by EU Health Biotechnology Support Network, on

- Seeking guidance on regulatory status
- Applicable rules for authorisation of health biotechnology products
- Regulatory sandboxes

2. Amendments to the ATMP Regulation

- **Investigational ATMP based on GMOs :**
  - 2 exemptions
    - No Environmental Risk Assessment for CT **where there is no or negligible risks to human health and the environment** (BUT to be explained by sponsors as part of CTA)
    - No GMO requirements of the CT Regulation for manufacturing and import.
- **Possibility to amend the definition of a tissue engineered product by EC via delegated acts**

3. Amendments to the Clinical Trials Regulation

Acceleration of procedures:

- Shortened authorisation timelines from submission till decision:
  - Multinational CT: 106 → 75 days (incl. validation & ethical review)
  - Initial CT authorisations: 75 → 47 days if no request for information
  - Substantial modifications: 96 → 47 days; 64 → 33 days if no request for information
- Elimination of additional 50 days for assessing ATMP

Simplification of procedures, mainly:

- New category of 'minimal-intervention' CT
- Modified definition of 'low-intervention' CT
- Strengthened role of reporting Member State: lead on both scientific and ethical assessment
- Investigational medicinal product core dossier
- Public health emergencies: accelerated/simplified procedures for multinational CT
- Single assessment process for combined studies (medicines + MD or IVDMD) Mandatory use of EU harmonised templates (part II of CTA dossier)
- Clinical trial sandboxes
- AI systems and digitalisation in CT: uptake of the use
- Establishment of CT Coordination and Advisory Group
- Processing of personal data: harmonisation of CT Regulation with GDPR

Discussion/Conclusion

The proposed EC new rules for ATMP in the EU Biotech Act clearly prioritises Centres of Excellence for ATMP recognised as high impact HBSP with dedicated funding and supports. One can wonder if it would fully prevent other ATMP projects to be recognised as HBSP. In any case, these measures clearly provide for a targeting financial and material effort on the centres that are the most advanced in ATMP across the EU. Although it can be criticised as restricting the possibility for less advanced ATMP centres, it should be kept in mind that these new measures should be considered as a part only of the entire sets of supporting EU mechanisms for research (such as funding under Horizon Europe). It may also be seen as a more viable option for the EU action, in a context of limited human and financial resources at both National and EU levels.

The establishment of new EU-level bodies seems to be a clear answer to the administrative, regulatory and technical challenges that developers of health biotechnology products have to addressed while avoiding duplication of work among National and EU bodies and authorities. However, particular attention will need to be paid in clarifying the remit of each of these new bodies together and as regards as the existing ones, while an accessible mapping of all of them should be provided to stakeholders for understandability and navigability.

Finally, it should be kept in mind that the EU Biotech Act, through its amendments to the ATMP and CT regulations, should be an important legislative step in order to solve current issues in these fields as well as to maintain overall relevance of the EU legislation in the context of the forthcoming final adoption of the EU general pharmaceutical legislation reform.

Even though the EU Biotech Act is at the very beginning of the legislative process (EC proposal), it deserves to be followed and proposed changes are worth to be known by the gene and cell therapy community.