FEDERCHIMICA ASSOBIOTEC

Round Table discussion
Translating Innovation into access for ATMPs
15th November 2024, Rome

Opportunities and Challenges in Access and Sustainability of Advanced Therapies (ATMP) to Support Innovation and Equitable Access for the Benefit of Patients

Regulatory Data Protection and Market Exclusivity
possible extensions linked to the Unmet Medical Needs criteria, to the orphan drug designation, to the existence of comparative clinical studies supporting the initial application for a marketing authorization or to the presence of a significant part of the R&D activities

Early Access
A regulatory framework is encouraged for early access to ATMP medicines, with a particular focus on severe diseases and unmet medical needs. This regulation would allow access to drugs prior to official approval, similar to the French "Accès Précoce" model.

Reimbursement Approval and Funding Models
ATMP therapies require complex assessments for reimbursement, with early dialogue between manufacturers and AIFA and the use of real-world data to reduce clinical and financial uncertainty. A new regulatory framework is proposed to economically support these therapies, including payments models and a central fund for treatments with a significant impact on quality of life.

Criteria for Identifying ATMP Delivery Centers
Identifying ATMP delivery centers requires a structured clinical governance model, with Hub centers for administration and Spoke centers for follow-up. Additionally, coordination between authorities and institutions is needed to define the criteria and investments required to ensure uniform access to therapies.

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