

# **Centre of expertise for advanced therapy medicinal products (ATMPs)**

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# ATMPs as innovation?

Hair to skin





First Child to Receive Revolutionary CAR-T  
Therapy Celebrates 10 Years Cancer Free  
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Revolutionary biotechnological advances

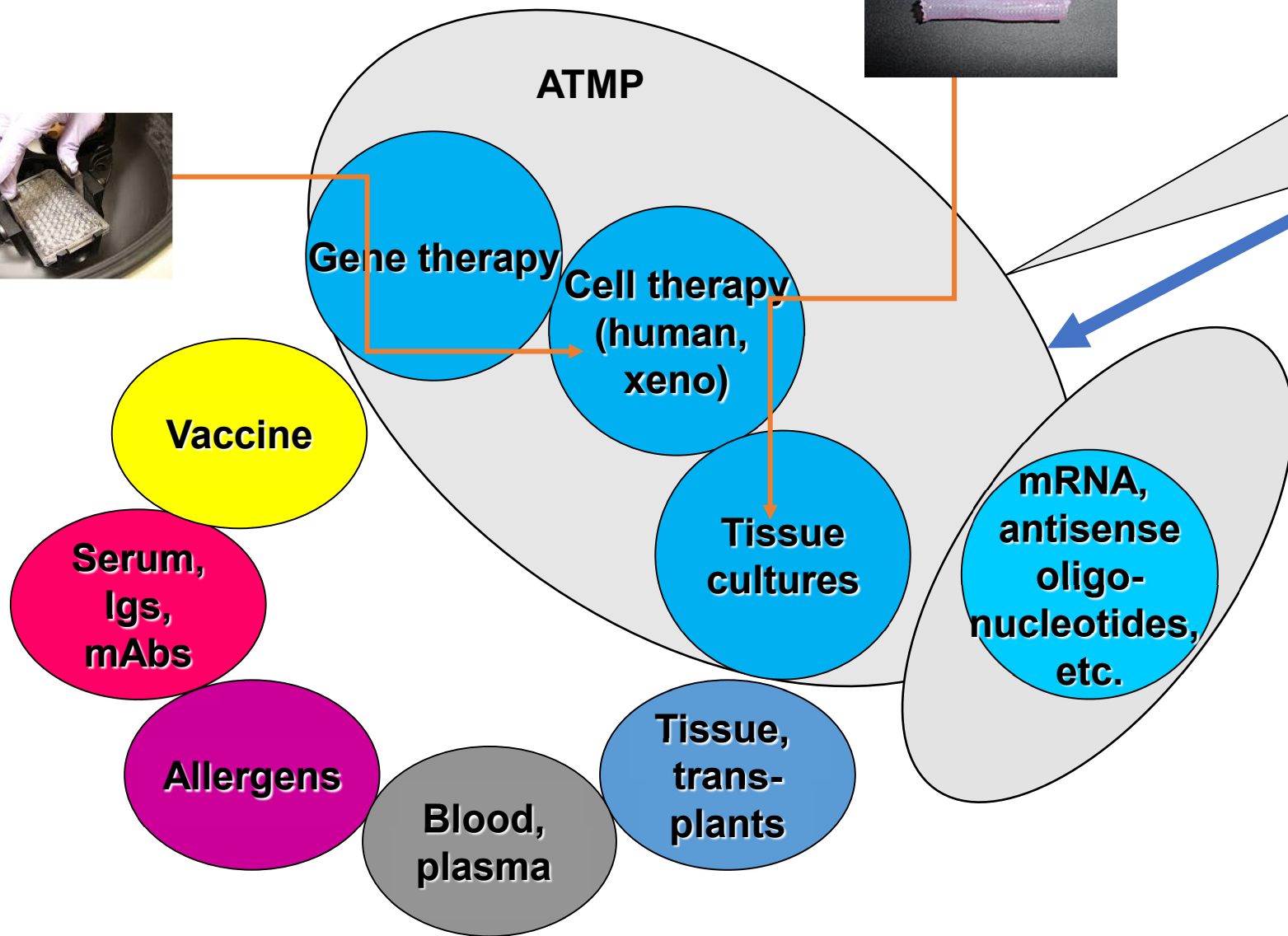


Rapid acceleration of research projects and  
therapy options



Advanced therapy medicinal products as beacons of hope

Oncologicals (CAR-T); genetic conditions such as haemophilia, metabolic, ophthalmological, musculo-skeletal, vascular, renal, skin or neurological diseases.

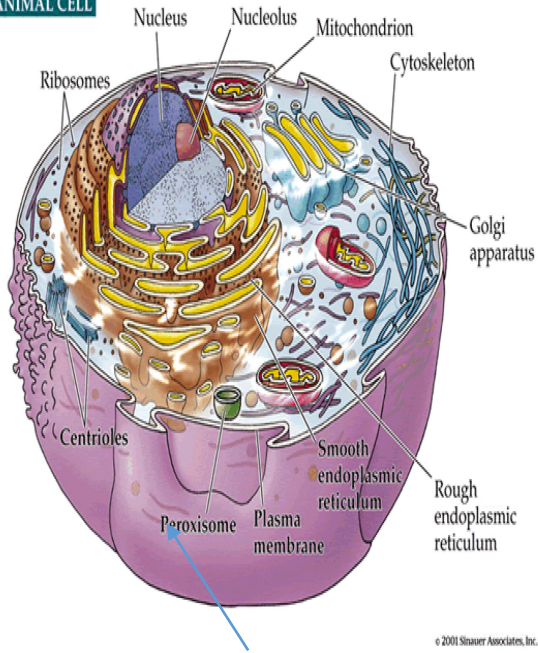


REGULATION (EC) No 1394/2007 OF  
THE EUROPEAN PARLIAMENT AND  
OF THE COUNCIL of 13 November  
2007

Transplantation Act,  
Therapeutic Products  
Act



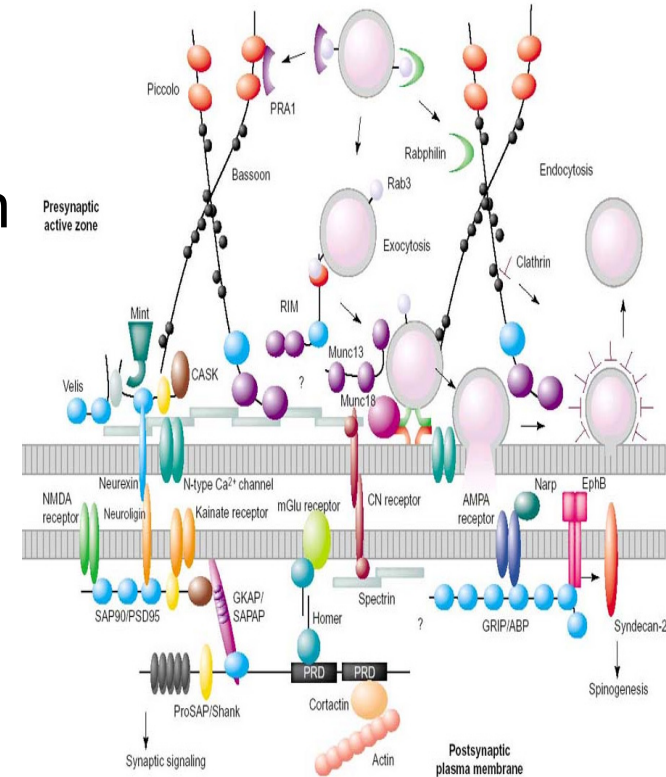
## AN ANIMAL CELL



Complex patient-specific products

Complex manufacturing and authorisation processes

Regulatory and scientific challenges



# **Swissmedic response to ATMP innovation**

## **Special division as a central point of contact for all ATMP topics**

- Experts with different areas of specialist knowledge, multidisciplinary committees
- Scientific and regulatory always “at the forefront”

## **“Innovation Office” – ATMPs as pilot project**

# All-in-one division



# Product groups of the ATMP Division

- ATMPs (tissue and cell therapies, gene therapy/GMO, oligonucleotides (all activities))
- Vaccines (mRNA, vectors (e.g. COVID, Ebola)) (all activities)
- Autologous transplants (notification, inspections)
- Inactivation procedures for blood, bacteriophages, microbiome, non-standardisable medicinal products (all activities)
- Devitalised products based on human tissue or cells (new devit. ordinance in effect from 2024)



# Innovation-promoting framework for ATMPs

Monitor scientific developments, adapt regulatory requirements

Revision of TPA, ATMPs as medicinal products

Active dialogue, support of research groups in universities

Scientific Advice Meetings

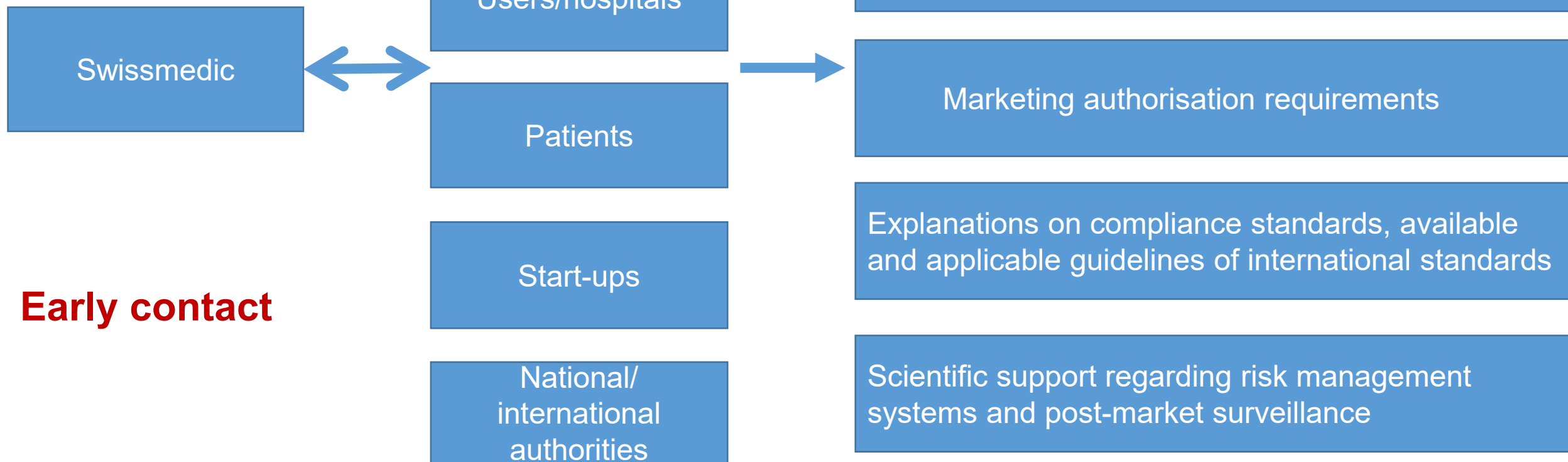
Collaborating with other authorities and consortia (e.g. ACCESS, ICMRA)

Expansion of expertise

Structure regulations in a flexible way, implement technical developments in real time

Risk-based assessment, fast-track procedures

**Open dialogue**



**Early contact**

# Tasks and objectives

- Better understanding of the needs of academics and researchers and of the learning process for both sides
- Transparency on regulatory decisions
- Establishment of Swissmedic as a highly modern, modernised and progressive regulatory authority

**Effective and safe innovative ATMPs are available in real time**

**Switzerland as an attractive location for research and implementation**