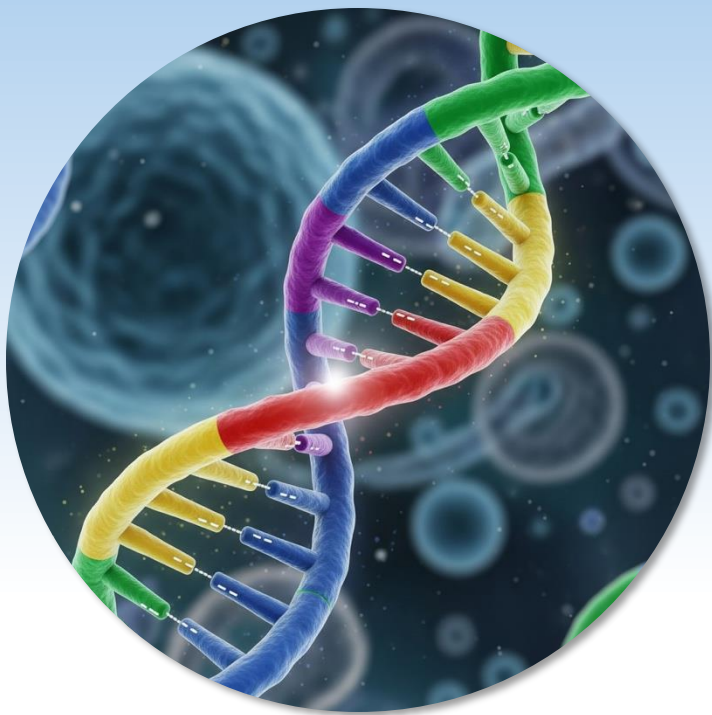




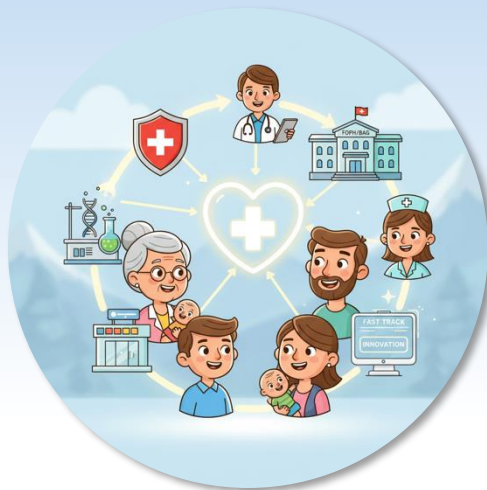
Switzerland's Strategic Edge: A Clear Path to P&R for Your ATMP

The Promise and the Pricing Paradox



- **The Promise:** ATMPs often offer a one-time, curative treatment for rare diseases.
- **The Challenge:** They come with high upfront costs and limited long-term data at launch.
- **The Problem:** Health systems must balance the high financial risk with the urgent medical need of patients.

Switzerland's Strategic Response



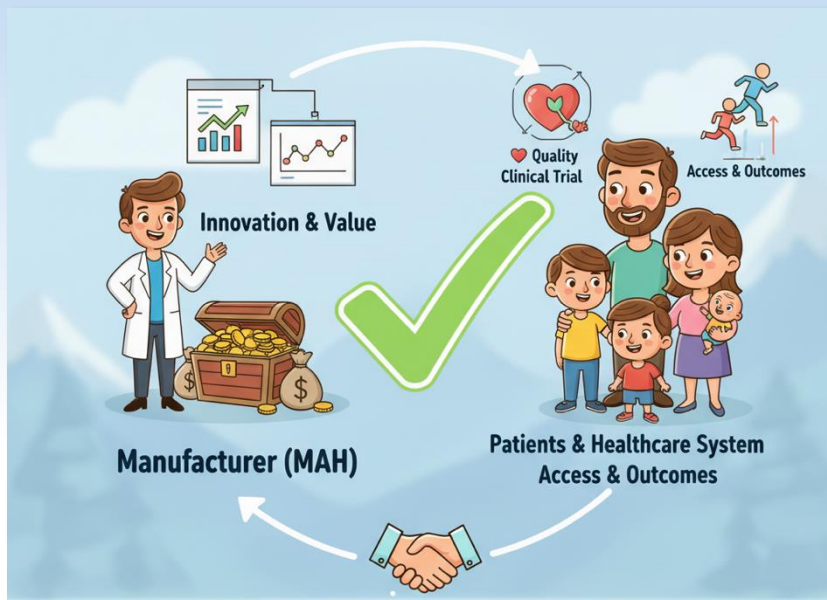
- **Patient-Centric Approach:** Switzerland prioritizes patient needs, especially for conditions with a high unmet medical need.
- **Specialized Divisions:** To streamline market access for ATMPs, Swissmedic established a dedicated ATMP Division and an Innovation Office in 2022.
- **Accelerated Pathway:** These units serve as a single point of contact for developers, providing the clarity and speed needed to bring therapies to patients faster.

Pre-Launch Dialogue: Your Strategic Advantage



- **Scientific Advice:** Begin with Scientific Advice from Swissmedic to define data requirements and align your reimbursement strategy.
- **Early FOPH Engagement:** Initiate an early dialogue with the Federal Office of Public Health (FOPH/BAG) to prepare for innovative pricing models and Managed Entry Agreements (MEAs).

Innovative P&R Models: From Risk to Shared Value



- **Innovative Agreements: Payment-for-Performance (P4P)** models link reimbursement directly to a therapy's long-term clinical outcome.
- **Win-Win Solution:** This approach mitigates financial risk for the healthcare system while securing coverage for patients.
- **Contingent on Data:** Reimbursement is contingent upon real-world data collection, proving the therapy's lasting value.

The Role of Real-World Evidence



- **Contingent Access:** Patient access to ATMPs is often conditional on a commitment to long-term data collection.
- **Established Infrastructure:** Switzerland has a proactive data management approach and rare disease registries, such as the **Swiss Rare Disease Registry (SRDR)**.
- **Cornerstone of the System:** These registries enable the long-term monitoring of patient outcomes to validate a therapy's value and secure continued reimbursement.

A Swift Path for Breakthrough Therapies



- ✓ **Accelerated Pathways:** Switzerland offers fast-track options for ATMPs that address a high unmet medical need.
- ✓ **Early Access Program:** Patients can gain access to therapies for severe, life-threatening diseases with no other options available.
- ✓ **Fast Track MA & P&R:** Once approved, these therapies can immediately become available on the Swiss market, ensuring rapid patient access.
- ✓ **Patient Commitment:** These mechanisms underscore the Swiss healthcare system's commitment to prioritizing patients.

Your Partner in Swiss Market Access

- Navigating this highly specialized and evolving landscape requires a partner with deep expertise. Need a guide to shape your strategy for Swiss market access for your ATMP product?

Contact us: www.sur-access.com

