

Early Access to Medicines in Switzerland CH



- Getting innovative drugs to patients with severe diseases is a challenge.
- Switzerland's early access system is a complex landscape balancing patient needs and cost.
- Here's what you need to know about navigating the paid vs. unpaid pathways.

Conditions for Early Access

Early access is strictly for cases of significant unmet medical need. This means the drug is for a disease that is:

1. **Severe:** It's life-threatening or causes severe, chronic health impairments.
2. **No Alternatives:** There is no authorized treatment available in Switzerland, or existing options are unsatisfactory.
3. **Therapeutic Benefit:** If an alternative does exist, the new medicine must offer a major therapeutic advantage or a meaningful reduction in disease morbidity or mortality.



The Paid Pathways: Reimbursement is the Goal

The reimbursement system has two key paid pathways for manufacturers and patients:

1. **Individual Reimbursement (Art. 71 KVV):** A doctor can apply for reimbursement for a specific patient's unapproved or "off-label" drug. A pragmatic HTA model with fixed discounts is applied based on benefit.
2. **Strategic Access (Art. 69a KVV):** Manufacturers can submit their reimbursement dossier to the BAG *before* Swissmedic's final approval to accelerate the process.



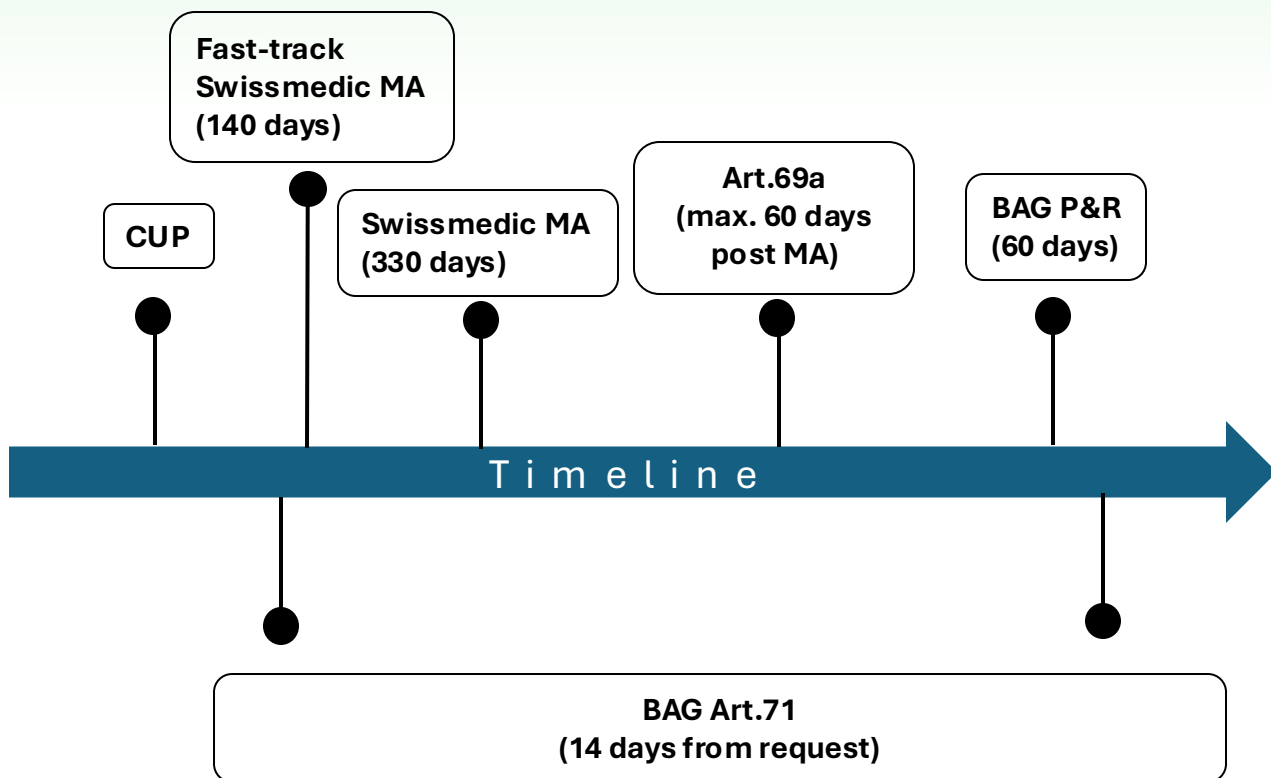
The Unpaid Pathway: Compassionate Use (CUP)

Another route for early access is through Compassionate Use Programs, a **regulatory pathway** managed by Swissmedic.

- **The Drug is Free:** The pharmaceutical company provides the unapproved medicine free of charge to a group of patients.
- **Regulatory Oversight:** The program requires approval from Swissmedic before it can begin (temporary authorization).
- **What's Covered?** For medicines that are still undergoing clinical trials or have entered the marketing authorization process.



Timeline for Early Access & Approval



Partner with Sur Access

Need a partner for Swiss Market Access?

- **Expert Guidance:** Navigate complex Swiss regulations.
- **Strategic Insights:** Optimize pricing & reimbursement.
- **Seamless Entry:** Accelerate patient access.

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