



Unpacking Drug Pricing & Reimbursement in Switzerland

A Guide for Innovative Medicines

The Swiss Reimbursement Landscape

- Central Authority: Federal Office of Public Health (BAG) manages the "Spezialitätenliste" (SL).
- Core Principle: Drugs must be Effective, Appropriate, & Economical (WZW criteria) for reimbursement by compulsory health insurance (OKP).



Step 1: Swissmedic Marketing Authorization (MA)

- First Hurdle: Mandatory regulatory approval by Swissmedic.
- Focus: Quality, safety, and efficacy assessment.
- Timeline: Standard MA can take over 500 days (including applicant response time). Fast-track for high medical need.



Step 2: BAG SL Inclusion & Pricing

- After MA, apply to BAG for SL listing.
- Focus: Reimbursement eligibility (WZW criteria).
- Timeline: Official target is 90 days, but typically 8-12 months for innovative drugs.



Innovative Drug Pricing: The WZW Pillars

- "Economical" (Wirtschaftlichkeit) is 50/50 based on:
 1. Foreign Price Comparison (APV):
Benchmarking against 9 reference European countries.
 2. Therapeutic Cross-Comparison (TQV):
Comparing benefits & costs to existing SL therapies for the same condition.



Capturing Value & Managing Access

- Innovation Bonus: Up to 20% premium for significant therapeutic progress (based on TQV).
- Managed Entry Agreements (MEAs): Confidential "Price Models" with non-public rebates to manage budget impact, especially for high-cost drugs.



Generic & Biosimilar Pricing

- Entry Trigger: Earliest SL listing is month after patent expiration and market exclusivity period
- Pricing: Mandatory percentage discount from original price, based on market volume:
 - Generics: 20-70% lower.
 - Biosimilars: 10-35% lower.



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

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