

Drug Reimbursement in Switzerland SN 1, Health Service Reimbursement

**19th Congress of the
European Association of Hospital Pharmacists
Barcelona, 26th to 28th March 2014**

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Conflict of interest

Nothing to disclose

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Health Insurance in Switzerland

- **Compulsory health insurance**
 - For all Swiss inhabitants
 - Same benefits for all
 - Free choice of insurer
 - No preconditions concerning age and state of health
 - Premiums are not related to the income of the insured person
- **Supplementary health insurance**
 - Voluntary
 - Governed by private insurance law

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Expenditure of Medicines in Switzerland in 2011

- Total health expenditures: 64.6 Bn SFr.
- Total drug costs = Total medicine consumption: 6.1 Bn SFr. (public price) or 4.9 Bn SFr. (exfactory price)
- Drug costs covered by compulsory health insurance: 5.5 Bn SFr. (public price) or 3.9 Bn SFr. (ex-factory price)
 - Drugs account for 20% of the total health expenditure in the compulsory health insurance (or 10% of the total health expenditure of 64.6 Bn SFr.)
- About 80% of the drug costs are covered by compulsory health insurance

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Approval and Reimbursement of Pharmaceuticals in Switzerland

Two step process:

- **Swissmedic:** Swiss market authorization institution and market surveillance.
- **Federal Office of Public Health (FOPH):** Reimbursement and Pricing. Swissmedic approval is pre-condition for granting reimbursement of new drugs

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List of Pharmaceutical Specialties (SL)

- List established in 1955
- Fixed prices
- Contains all the reimbursable pharmaceuticals with maximum prices to be reimbursed (ex-factory price and public price including distribution margin plus VAT 2.5%)
- Mainly for the outpatient sector (not in-patient sector, but many hospital drugs are on the list too)
- 85% of the listed drugs are prescription drugs, OTC pharmaceuticals can also be reimbursed
- Classic medicine and complementary medicine (homeopathy, anthroposophy, traditional medicine)

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List of pharmaceutical specialities (SL) II

- See: www.listofpharmaceuticalspecialities.ch
(in German, French and Italian)
- Ex-factory* and public prices are published
- Reimbursement of drugs can be restricted („limitations“ e.g. to certain patients, short time period)

* Without value added tax rates (VAT) and without distribution margin

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Reimbursement Procedures I

- Parallel to final Swissmedic approval process
- 3 kinds of procedures:
 1. **Fast track:** with EAK (Federal drug commission), takes 2 months (minimum) for therapeutic breakthroughs treating life-threatening diseases (only if Swissmedic granted fast track regulatory approval process)
 2. **Ordinary procedure:** with EAK, takes 5 months (minimum)
 3. **Simple procedure:** without EAK, takes 6 weeks (minimum, submission only after final Swissmedic approval), e.g. for generics, simple approvals of known substances

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Reimbursement Procedures II

- Manufacturer submits the application dossier to FOPH
- Application dossiers must contain a positive Swissmedic recommendation
- Federal drug commission (EAK) has an advisory role („sounding board“), the FOPH takes the formal decisions
- 6 meetings / year; about 20 dossiers per meeting

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Conditions for SL-Admission

- Pharmaceutical is approved by Swissmedic
- **Effective:** statistically significant is not always clinically relevant
- **Appropriate / suitable:** starter pack size, big pack size according to length of therapy, complete line for generics, pharmacologic profile
- **Cost-effective:** Foreign price comparison, therapeutic comparison with similar products
- Pharmaceutical has to be available in the market
- No advertising allowed to general public

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Criteria for Pricing of Originals

▪ Foreign price comparison

- Price comparison with countries that have similar economic and pharmaceutical structures
- Since 1.10.2009: comparison with Germany, Denmark, Netherlands, Great Britain, France, Austria
- Comparison on basis of ex-factory prices (FAP), because of different value added tax rates (VAT) and different distribution margins in Europe
- Prices higher than the foreign price comparison are usually not accepted

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Criteria for Pricing of Originals II

▪ Therapeutic price comparison

- Price comparison with comparable products already available and reimbursed in Switzerland (same or similar indication or mechanism of action)
- Costs comparison: treatment costs per day or total costs of therapy to adjust for differences in treatment duration
- Innovation bonus for therapeutic progress (better efficacy, less side effects)

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Practical Issues

- Therapeutic price comparison results in higher prices than foreign price comparison
- Therapeutic price comparison results in lower prices than foreign price comparison
- No therapeutic price comparison and no foreign price comparison available

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Generics

- Generics are obliged to enter the market at a discounted price to the **original** (after the patent expiry re-evaluation), depending on **turnover** of the original:
 - 60% price discount, if turnover > SFr. 25 mio.
 - 50% price discount, if turnover > SFr.16-25 mio.
 - 40% price discount, if turnover > SFr. 8-16 mio.
 - 20 % price discount, if turnover > SFr. 4-8 mio.
 - 10 % price discount, if turnover < SFr. 4 mio.
- No foreign price comparison for generics

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Cost Saving Measures

- **2012 start of regular price reviews every 3 years:**
 - 1/3 of all prices are being reviewed every year
 - Normally on the basis of foreign price comparison
 - Therapeutic price comparison only if there is no foreign price comparison (i.e. drugs not on the market in other countries)
 - Generics have to offer a discount of 20% to the new prices of the original

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General Issues

- Dependence of Swiss prices on pricing and reimbursement of other European countries
- Discounts offered in other countries (e.g. Germany, United Kingdom) – which is the actually reimbursed price?
- Evaluation of effectiveness and therapeutic progress, determination of the innovation bonus
- Missing transparency of the pricing process
- Differences between the costs of generics in Switzerland and in European countries

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Influence of Foreign Price Comparison

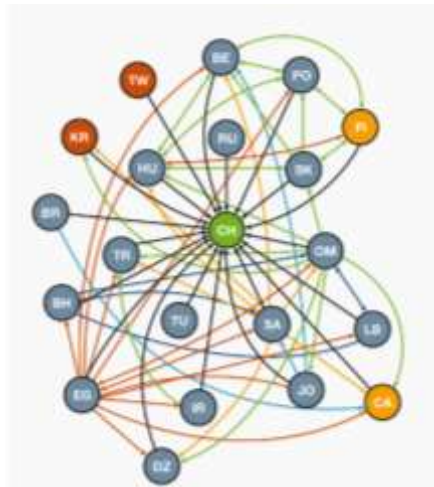
Figure 1 | Countries referencing Switzerland's pharmaceutical prices



Source: Study on behalf of Interpharma and Novartis "The international impact of Swiss drug regulation, CRA Charles River Associates, March 2013"

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Influence of Foreign Price comparison II



- Average of basket prices
- Other form of basket prices (e.g. median)
- Deepest basket prices

Source: Interpharma Switzerland

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Latest Changes

- **2009:**
 - Introduction of regular price reviews every 3 years, effective since 2012
 - Regular price reviews for line extensions (approval of new indications by Swissmedic)
 - Extraordinary price review of drugs listed in the SL in year 2009
 - Lower margins for pharmacists, doctors and wholesalers
- **2009-12:**
 - Stronger price regulation for generics

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Planned Changes

Discussions about changes of the pricing and reimbursement process of pharmaceuticals are ongoing

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