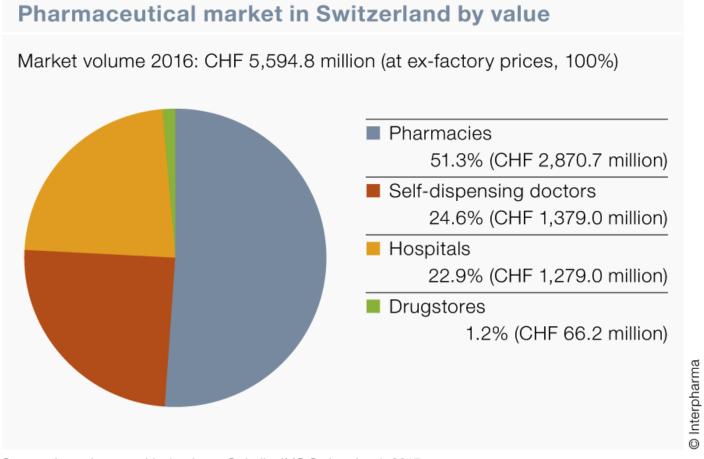
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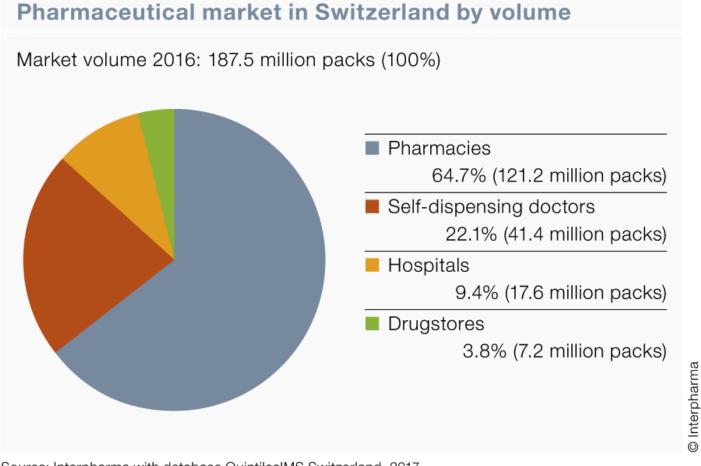
Pricing & Reimbursement Swiss perspective

BioLawEurope 4th Annual Meeting Rome, May 18, 2018 Stefan Kohler, Attorney at Law, VISCHER AG

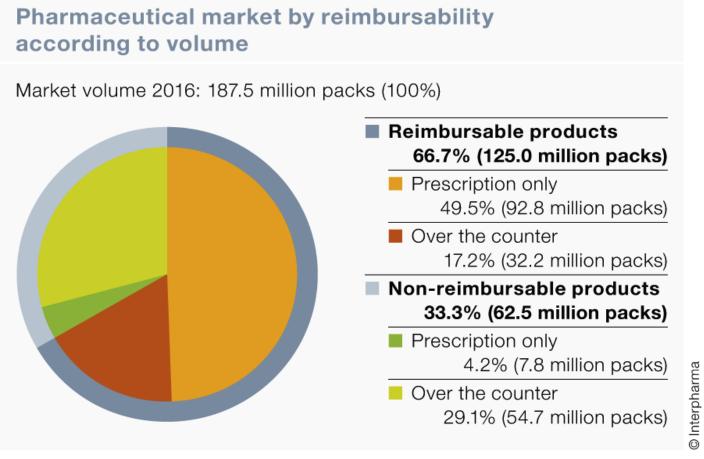
Pharmaceutical market in Switzerland



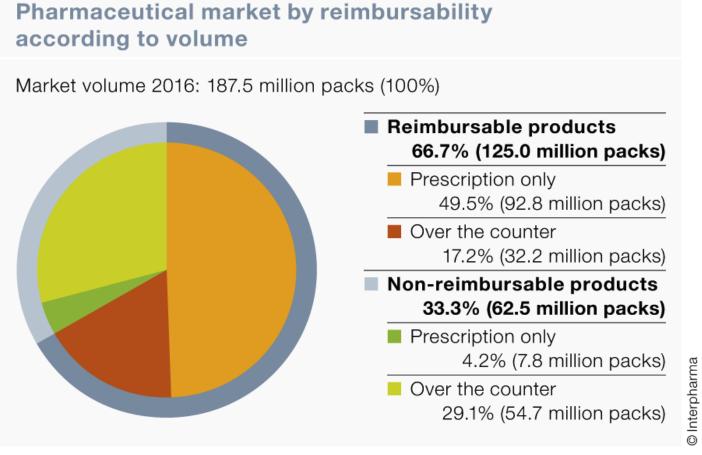
Pharmaceutical market in Switzerland



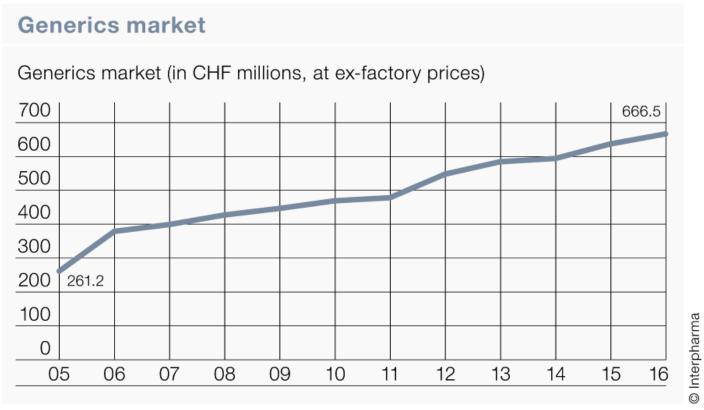
Pharmaceutical market by reimbursability



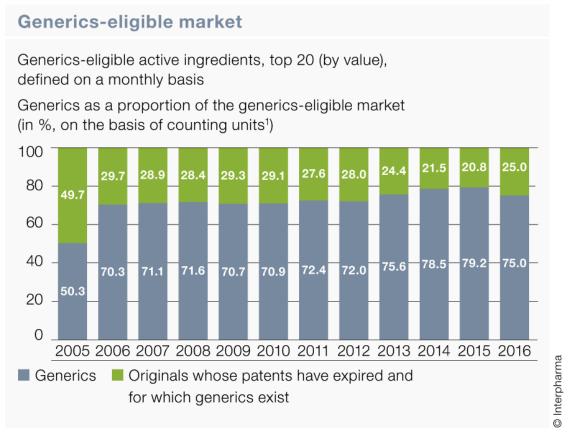
Pharmaceutical market by reimbursability



Generics

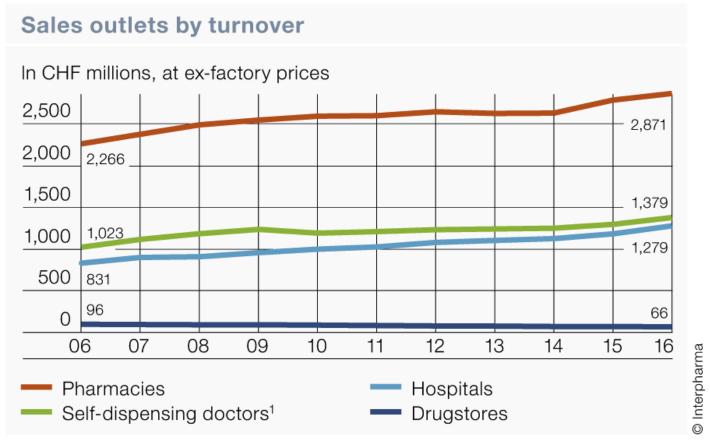


Generics

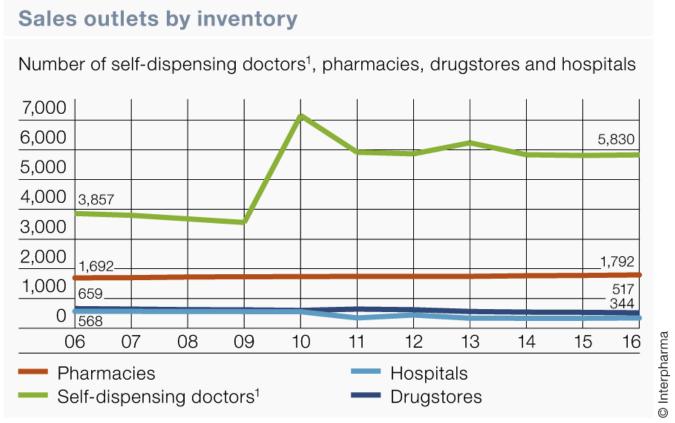


¹ Number of tablets, capsules, millilitres, etc. sold.

Sales outlets by turnover and inventory



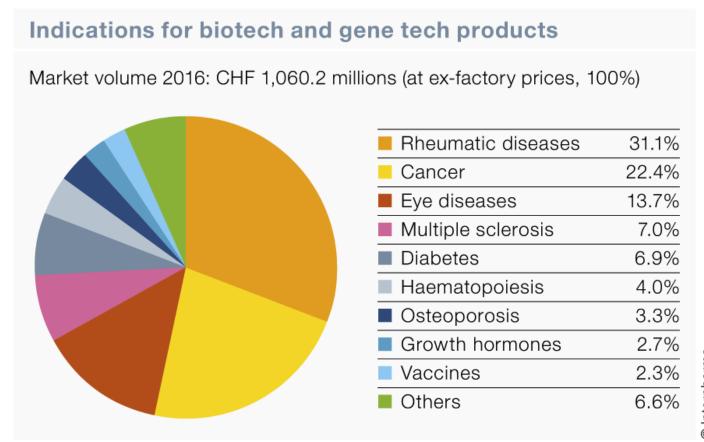
Sales outlets by turnover and inventory



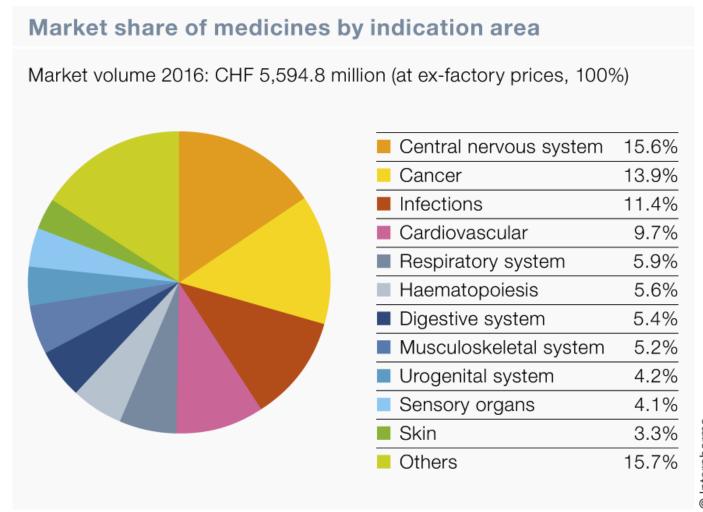
Source: Interpharma with database QuintilesIMS Switzerland; Cegedim Switzerland SA, Zurich branch; Medizinalberuferegister; pharmaSuisse, 2017.

Doctors with their own pharmacy are described as self-dispensing doctors.

Biotech and gene tech products



Market share of medicines by indication area



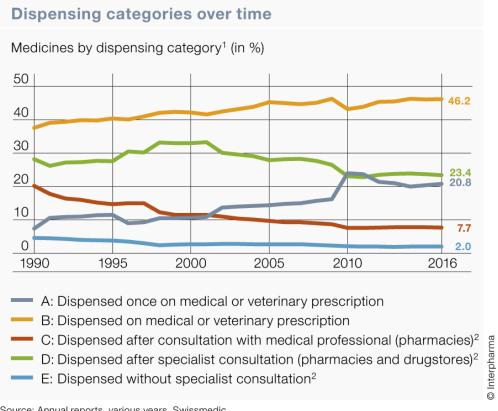
Approval of medicines/number of approved medicines

Number of approved medici	nes in Swi	tzerlan	d		
	2000	2014	2015	2016	
Human medicines ¹	7,224	7,662	7,593	7,683	8
Veterinary medicines	890	714	719	734) Interpharma
Total approved medicines	8,114	8,376	8,312	8,417	© Inte

Source: Annual reports, various years, Swissmedic.

¹ Human medicines, allergens, biotech medicines, homeopathic medicines, vaccines, herbal medicines, radiopharmaceuticals and other product categories.

Approval of medicines/number of approved medicines

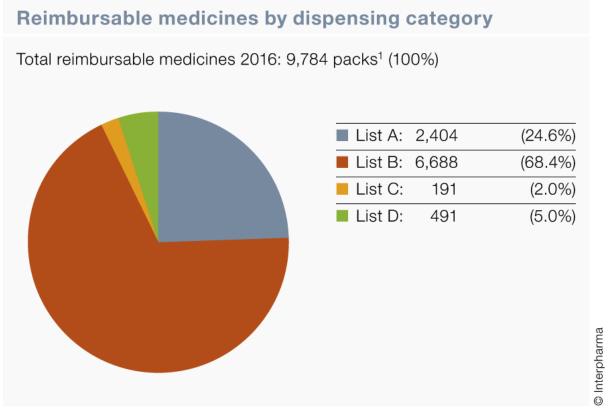


Source: Annual reports, various years, Swissmedic.

¹ Certain products are assigned to more than one dispensing category and have therefore been counted more than once (pack size or dose).

² Over the counter.

Medicines in the Specialties List (SL)



Source: Federal Office of Public Health, 2016, as at 1.12.2016.

¹ 10 packs (0.1%) could not be assigned to a list. These comprised pens, diskhalers and baby food.

Medicines in the Specialties List (SL)

Medicines in the Specialties L	ist (SL)				
	1995	2014	2015	2016	rma
Number of products	2,255	2,898	2,922	2,948	Interpharr
Number of packs	5,383	9,725	9,649	9,784	© Inte

Source: Federal Office of Public Health, 2016, as at 1.12.2016.

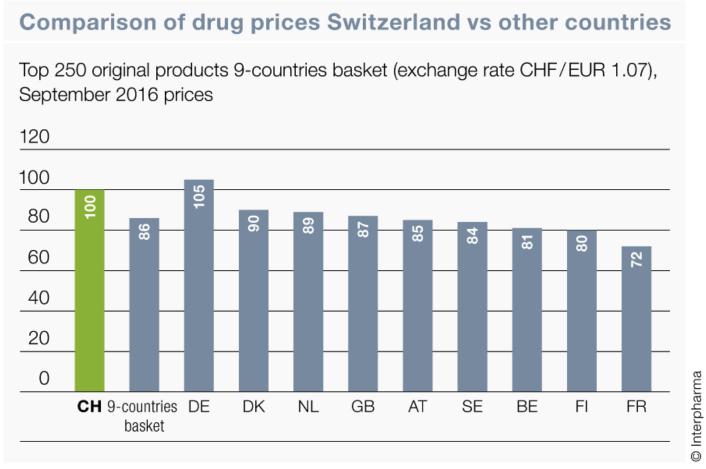
Composition of the price of a medicine

Pharmaceutical be	nefits according to LAM	al		
	Value-added tax (2.5	Value-added tax (2.5%)		
Retail price (according to Specialties List, SL) ¹	Sales and	Production costs (logistics, infra- structure, personnel		
	distribution costs	Capital costs		
	Ex-factory price	Sales tax		
		Foreign price comparison (AT, BE, DE, DK, FI, FR, GB, NL, SE) based on ex-factory prices		
		Therapeutic cross-comparison		

Source: Federal Office of Public Health.

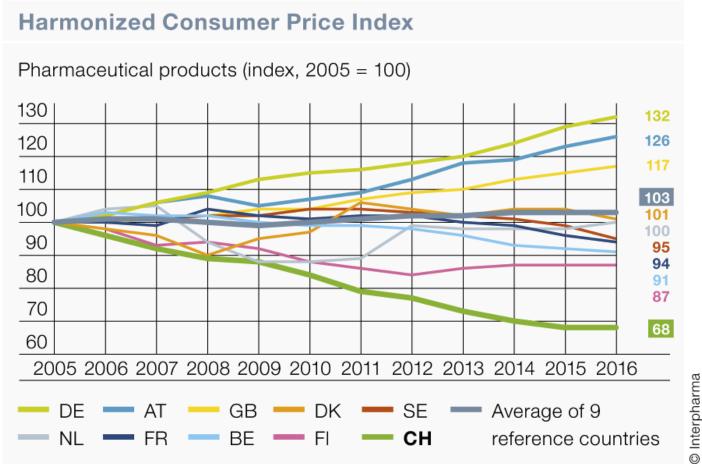
¹ The relation between retail price and ex-factory price can be found at www.spezialitaetenliste.ch

Prices of medicines: foreign-price comparison



Source: Joint foreign-price comparison by santésuisse and Interpharma, April 2017.

Prices of medicines: foreign-price comparison



Source: Eurostat, 2017.

Pricing for Reimbursement | Basics

step 1: market authorization

- legal basis: Therapeutic Products Act
- competent authority: Swiss Agency for Therapeutic Products («swissmedic»)
- requirements: (i) high quality, (ii) safety, (iii) efficacy

step 2: pricing and reimbursement

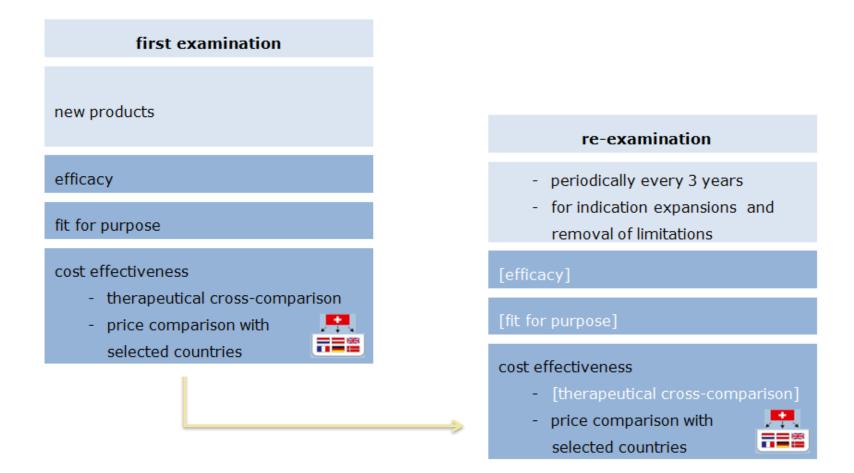
- legal basis: Health Insurance Act
- competent authority: Federal Office of Public Health («FOPH»)
- requirements: (i) market authorization; (ii) efficacy, (iii) fitness for purpose, (iv) cost effectiveness

Pricing for Reimbursement | Requirements

scope of FOPH's review:			
market authorization	given?		
efficacy	does product indicate capacity for beneficial effect?		
fitness for purpose	acceptable risk of adverse effects / improper use?		
cost effectiveness	best price for best healing power?		

 if all requirements are met, FOPH includes product in the «list of pharmaceutical specialities» which allows reibursement by health insurances

Pricing for Reimbursement | Examination



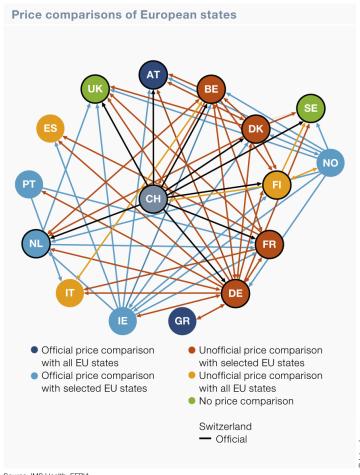
Basic Principles

- In the three-year price reviews, prices can only be reduced, but not increased
- Applications for price increases are possible
- Since March 2017, equal weight has been given to international reference pricing and therapeutic reference pricing both for the initial inclusion in the SL and also for all price reviews

Foreign Countries Comparison

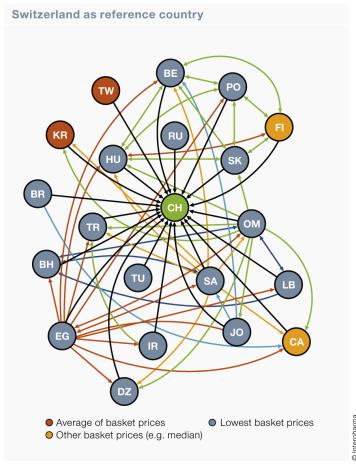
- Basket of countries made up of
 - Austria
 - Denmark
 - France
 - Germany
 - Great Britain
 - the Netherlands
 - Belgium
 - Finland
 - Sweden.

Price comparisons of European states



Source: IMS Health; EFPIA.

Switzerland as reference country



Source: The international impact of Swiss drug regulation, Charles River Associates, study on behalf of Interpharma and Novartis, March 2013, Interpharma, 2015.

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