Swiss pharmaceutical reimbursement and pricing: Ordinance Law Changes (KVV/KLV) as of January 2024: Today's Decision by the Swiss Federal Council (Bundesrat)

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Today, the Swiss Federal Council has decided to amend the KVV and the KLV as of **1 January 2024 (concrete operationalisation / dates of concrete implementation are yet to be defined)**. The relevant amendments are the following:

Reimbursement of pharmaceuticals in individual cases (commonly known under "Artikel 71") at present

For severe diseases, pharmaceuticals outside the SL ("SL" is the Swiss Federal Government's positive reimbursement list with prices for pharmaceuticals) may be individually reimbursed, when no other equivalent pharmaceutical is SL-listed.

Currently, there is no concrete mechanism for the evaluation process and the pricing mechanism of a pharmaceutical when reimbursed individually.

New

Insurers must apply the so called "OLUtool", a mechanism to define the benefit of an individually reimbursed pharmaceutical. Clinical experts must be involved for therapeutic areas difficult to assess. Insurers may define the benefit jointly. Benefits are categorized in classes: A to D.

Prices are set accordingly:

Benefit categories	New or patent protected pharmaceuticals	originals withouth patent protection, generics and biosimilars
	fixed price intervals	
A (very high benefit)	30%	10%
B (high benefit)	35%	15%
C (high expected benefit)	40% (after probation period of (mostly) 2 months)	20% (after probation period of (mostly) 2 months)
D (minimal or no benefit)	not reimbursed	not reimbursed
For pharmaceuticals and indications approved by Swissmedic, an additional discount of 10% is due after twelve months.		

Exceptions apply: There is no price deduction for pharmaceuticals with costs below CHF 730 / annum or CHF 2 / day; generics and biosimilars which are cheaper than originals / reference products minus the deduction according to the table here-above, do not undergo a price deduction.

Generic pricing at present

Generics and biosimilars are priced in Switzerland under reference to the original product / reference product.

New

Price deductions for generics of today 20 – 70% (according to volume) vs. the original product remain unchanged when generics are first introduced, with one exception: the minus 30% step is increased to minus 40% (which did not exist today). The deductions after the three-yearly price review of the original are increased from 10 – 35% to 15 – 40%.

Biosimilars are newly defined on ordinance law level. Their deduction vs. their reference products (according to volume) ranges from 20 – 35% when biosimilars are first introduced. The deductions after the three-yearly price review of the reference product are 10 – 20%.

Co-payment at present

In Switzerland, each patient must cover 10% of the treatment costs him-/herself (with a ceiling of total co-payment at CHF 700 / annum). For originals which are more expensive than their generics, an extraordinary co-payment of 20% applies.

New

The new co-payment for original products and reference products will be 40% (currently no higher co-payments for a reference product of a biosimilar), if their prices are not lowered to the generic price level, resp. the biosimilar price level.

SL-listing application at present

The SL-listing process starts when Swissmedic has rendered a positive pre-decision.

New

To accelerate SL-listing, a pharmaceutical company may file for market authorization at Swissmedic and for reimbursement and pricing at Federal Office of Public Health BAG at the same time. This only applies for certain pharmaceuticals which meet a high unmet medical need.

Distribution margin («Vertriebsanteil»)

This topic has long been discussed, but today the Federal Council has not decided on this matter as planned until very recently.

Link

You can find all amendments and comments by the Swiss Federal Government here (in German, French and Italian): Abgeschlossene Neuerungen und Revisionen (admin.ch)

Comments

Will the amendments improve access to treatments and lower costs as intended?

The matter has been highly controversial, and pros and cons have developed and changed over time.

In view of the major structural, operational, and economic issues in the Swiss healthcare system, this laborious reform is a small one. Nothing fundamental has been altered, except that the Federal Council is now forcing the reimbursement and pricing outside its positive list (SL) into a more unified process and a rigid pricing corset. The new inflexibility is intended to accelerate and standardize patient access, save costs, and bring new pharmaceuticals to the SL faster. It might work, but it could also fail. The greatest concern remains the access to treatments for individual patients. Improvement will only occur if insurers act benevolently. If not, the law still does not provide for adequate, reasonable, and fast countermeasures for individual patients against rationing decisions. It is interesting that the Swiss Government sets boundaries outside its positive list, without defining their material architecture, development, and control.

And whether higher co-payments for original / reference pharmaceuticals yield the intended higher penetration of cost-saving generics and biosimilars is unclear. It is also possible that the small Swiss market will be avoided, for the lack of a sustainable market share.

The faster access to essential new pharmaceuticals (start SL-listing process when filing for market authorisation) is a beneficiary step for severely ill patients.

Regarding the distribution margin: Currently, the higher the ex-factory price of a pharmaceutical, the higher its distribution margin in retail (pharmacies and self-dispensing physicians). Standardisation could prevent the economic incentive to prefer prescribing / dispensing an expensive pharmaceutical. The planned reform seems to have been unbalanced, because it had not been adopted today as planned until very recently.