# REDUCTION OF HEALTH COSTS

## Swiss government chooses the wrong medicine with reference price system for drugs

Since autumn 2018, the first package of cost-cutting measures in Switzerland's health care system is being reviewed. One of the measures is the so-called reference price system for pharmaceuticals whose patents have expired. Under the leadership of the industry association Intergenerika an alliance of doctors, pharmacists and patient organisations fiercely opposes the Federal Council's plans.

**Axel Müller,** Managing Director, Intergenerika

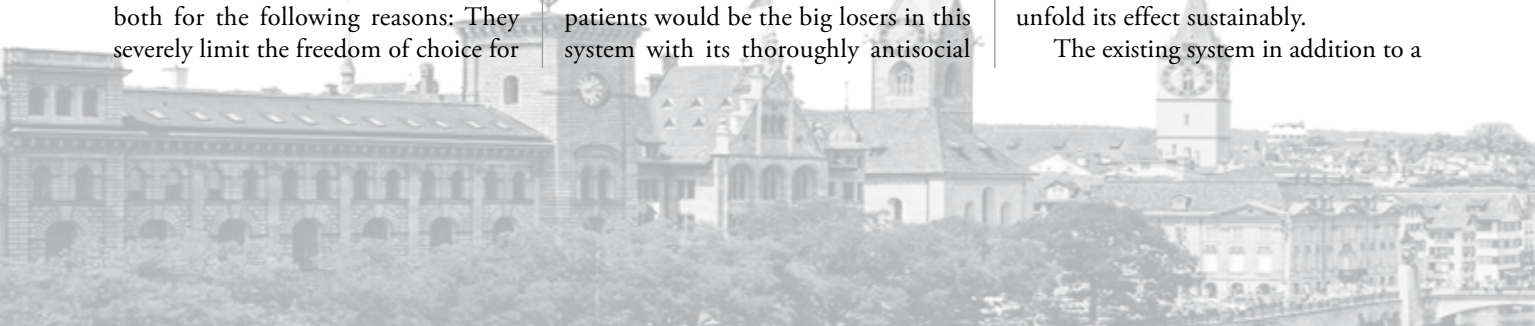
Since autumn 2018, the first package of cost-cutting measures in Switzerland's healthcare system is being reviewed. One of the measures is the so-called reference price system for pharmaceutical whose patents have expired. The Government Health Department has given two models to the consultation. We, i.e. Intergenerika in alliance with healthcare system's key players, reject both for the following reasons: They severely limit the freedom of choice for physicians, patients and service providers, a consequence that Swiss insured persons are unlikely to accept in view of the clear verdict in earlier referendums with similar aims. In addition, they only lead to marginal premium reductions, which are barely noticed by the insured. Sick people will also have to make additional payments that are not counted towards their franchise. In short: Above all, the patients would be the big losers in this system with its thoroughly antisocial consequences. Both models jeopardise the security of supply because falling prices lead to lower yields for manufacturers. These will in turn have to respond with reduced services and smaller warehouses, which will lead to increased delivery difficulties. With the models presented, low-cost generics and biosimilars will be increasingly withdrawn from the market after the renewed, disproportionately high price reduction. Delivery bottlenecks in primary care Swiss patients are becoming more frequent in the remaining products. This will weaken the generics industry as a whole and reduce the share of generic and biosimilars, a consequence that runs counter to the will of politicians and consumers. Both want to promote generic and biosimilars. Security of supply - despite alleged countermeasures - is also endangered because manufacturers must focus on fewer products in view of the sharp drop in prices and can no longer offer additional services. In addition, the choice of drugs will be smaller.

Last but not least: the intended changes in the Health Insurance Act leave many ques-tions open and lead to legal uncertainty. The corresponding regulations will lack demo-cratic legitimacy.

### Plea for Preservation of the Existing System

We completely reject both models and demand the preservation of the generic pricing system, which has only recently been adapted and significantly tightened. This system has already resulted in increased savings in the short time. The price reductions in 2017 alone led to savings of CHF 146.5 million in the patent expired area (generics CHF 60.1 million, originals CHF 86.4 million). It is precipitous in our view, if this effective system is already rejected shortly after its successful introduction, before it could unfold its effect sustainably.

The existing system in addition to a



defined price difference to the original preparation and dynamic differentiated deductible has proven itself. It is accepted and appreciated by the participants for the following reasons:

- It guarantees patients freedom of choice and gives them reassurance that they will receive a consistent medication without constant change
- Uninterrupted medication increases adherence and success, reducing costly hospitalisations
- It increases the security of supply of drugs in various dosage forms and pack sizes, even in niche indications
- It allows a predictable and socially acceptable burden for the patient with deductible and franchise without additional payment in the pharmacy
- There is planning and legal certainty for manufacturers and their distributed medicines
- It allows for competition among manufacturers and leads to regular significant savings in patent expired areas.

With the two proposed reference price models, these benefits will not only disappear, the universal service in Switzerland with low-cost generics will also be damaged.

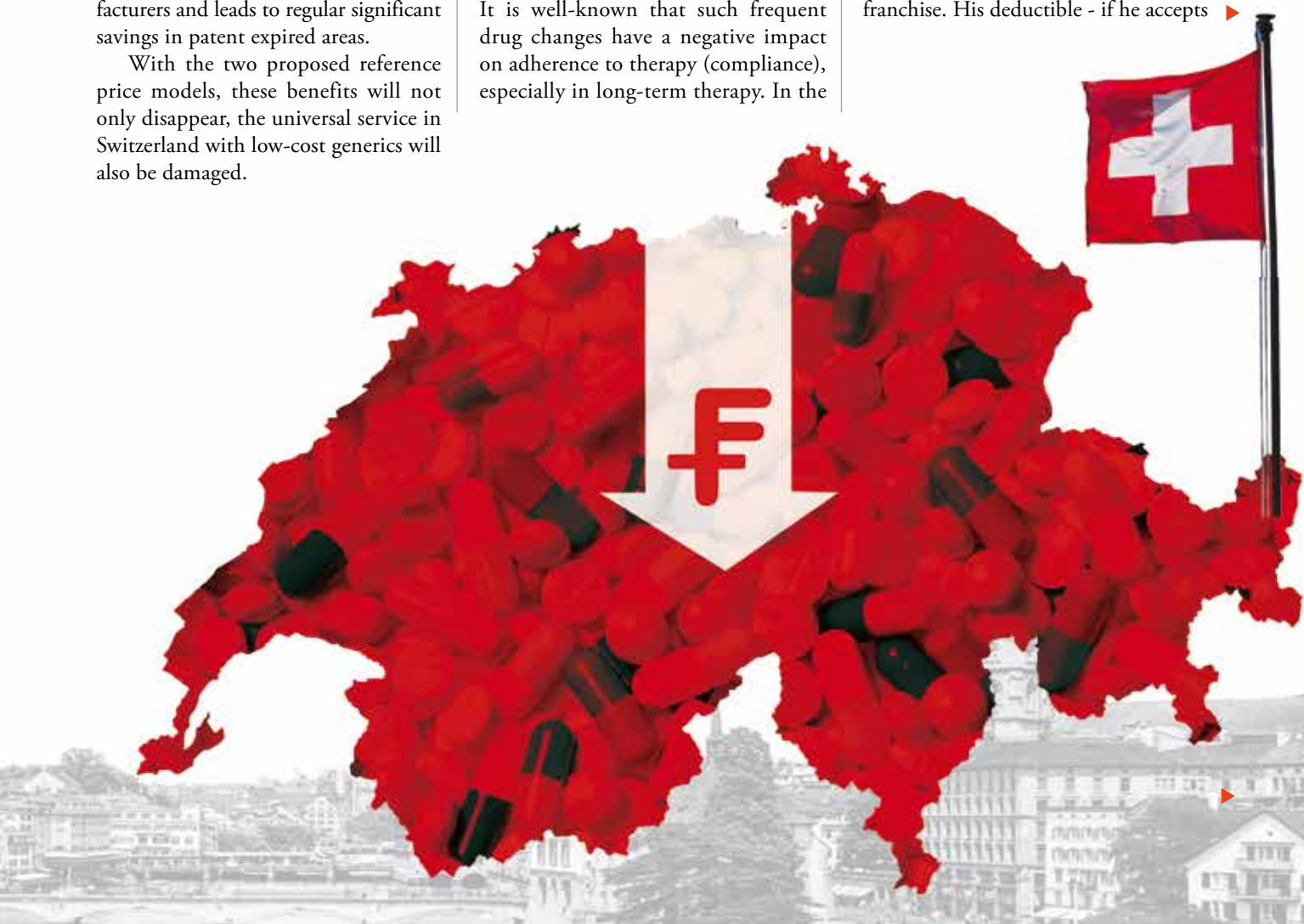
**Opinion on the Models**

The criticisms of the two models are identical with the exception of a few points. The models do not lead to the promotion of generics and biosimilars as intended by the Federal Council, but will destroy or at least greatly reduce the Swiss generics and biosimilars market in the medium term.

**Impact on the Patient and Premium Payer**

In terms of treatment, patients and premium payers will suffer losses. The freedom of choice of patients is limited. Depending on the choice of drug, they risk having to make a co-payment because insurers only have to reimburse certain drugs at the reference price. Long-term patients will be confronted with frequent drug changes if drug prices are reviewed and adjusted on a short-term basis insurers will only reimburse the cheapest It is well-known that such frequent drug changes have a negative impact on adherence to therapy (compliance), especially in long-term therapy. In the long term, this will result in higher costs for the Compulsory Health Insurance, because the diseas-es worsen in the absence of compliance or inadequate treatment. The choice of added-value medicines (special galenics, different dose strengths and pack sizes, divisible tab-lets, etc.) will be smaller, as manufacturers will have fewer resources at the proposed discounts. Also, because of uncertainty as to whether their product will ever be remunerated by health insurance, there will no longer be any incentive to develop such special, valued forms by patients. These will include those patients who may need to be treated with a drug that is not optimal for them.

The potential financial savings are also barely noticed by the patient. On the contrary, they even have a negative effect on the patient in the form of additional payments in the pharmacy. In addition, co-payments are not counted towards his franchise. His deductible - if he accepts



a generic at a reference price level - will be imperceptibly a few centimes cheaper than is the case in today's system. If the doctor prescribes a certain, more expensive drug for medical reasons, the patient has to make additional payments.

According to calculations by market research firms, these add up to CHF 41.7 million per annum. The same applies if, due to supply bottlenecks with generics, only the original is available. If all savings in the patent expired area of approximately CHF 423 million were completely passed on by the health insurance companies to approximately 8 million insured persons, this would lead to a one-time reduction in the monthly patient premium of approximatelyfour to five francs. This saving is smaller than the annual premium increase, that is, the effect would not be noticed by the patient. In addition, a representative study carried out by Gfs Zurich in 2017 showed that three out of four patients would not be willing to switch to a model offering only the cheapest generic, even if the premium would decrease by five Swiss francs per month.

As a result, healthy insured persons would be marginally relieved of the health insur-ance premiums, but patients would have to pay more, in addition to their franchise and deductible, they would already have high 'out-of-pocket' payments compared to other countries. In these countries, Switzerland is in the lead compared to others. They ac-count for 28 percent of total health expenditure, compared with only 20 percent in the OECD.

The models also mean that the prices between patented original preparations and ge-neric drugs are aligned to a large extent. Thus, the price advantage of generics in com-parison to the current model is largely eliminated, and patients have no incentive to use more generics. In addition, the principle of the differentiated deductible, which in today's system ensures fair price competition and companies, is eliminated in the refer-ence price model.

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At the same time, the patient's deductible difference between the original and the generic decreases compared to today's system. That's why the patient will be in the future have fewer incentives than today to replace an original with a generic one. The negative consequences for the generics market and security of supply are shown below.

### Impact on The Market

The newer generics are already at the planned, so-called "maximum price" (Foreign Price Comparison minus defined price gap). Further price reductions, depending on the number of suppliers, would therefore come about primarily as a result of the price reduction to be set by the Federal Council on this maximum price. The size of this price difference is not defined in the law, but can be determined by the Federal Council in the ordinance. This means that the Federal Council can determine the amount of the dis-count freely. Since the regulations on the Health Insurance Act are only so-called en-forcement orders, such a competence goes too far. This would have to be specified in the higher-level law. Otherwise, the democratic legitimacy for the amount of such deduction is missing. Without binding information on the price intervals, which can be changed arbitrarily by the Federal Council according to time and amount, the manufacturers are not able to plan ahead and reliably budget. For older, very cheap generics, a price reduction on the "reference price" defined under new rules would lead to price levels, which in many cases would no longer allow further marketing for economic reasons. As a result, especially these low-priced generics in the universal service would disappear from the market, resulting in higher costs of the Compulsory Health Insurance and thus runs counter to the objectives of the Health Insurance Act. We expect drastic consequences:

- Manufacturers will reduce their stocks. This will lead to increased supply bottlenecks and a reduction in security of supply, followed by an increase in the number of neces-sary drug changes in the patient
- Generics with additional benefits such as confusion-proof packaging, special galenics, additional dose levels, etc. will disappear from the market, as the more expensive manufacturing and development costs can no longer be met
- Manufacturers will try to focus on high-volume packs and less frequently take pre-scribed packs off the market. This, in turn, has implications for the security of supply and patient choice
- Declining revenues and earnings as a result of price reductions will lead to a reduction in generic drugs and, as a consequence, elimination of smaller generics companies. Over time, it is likely to form a monopoly or duopoly in Switzerland
- The idea that the reference pricing system will lead to more competition in the market is inappropriate. In addition, security of supply is jeopardised if the market is dependent on a few companies. A loss of production at one supplier has a much greater impact in such cases because no other supplier can fill the gap

• By aligning the prices of generic and patented original products, generic products be-come less attractive to patients and healthcare providers compared to today's systems. Generic penetration of the market will decrease in comparison to today, and there will be a decrease in generic generics. This in turn has far-reaching consequences for manufacturers
• Quantity reduction will increase manufacturing costs. Switzerland already has very small quantities by international standards, which aggravates the problem of more ex-pensive production
• By simultaneously reducing the prices, the contribution margins and, as a result, the investment opportunities for generic companies will decrease in percentage and abso-lute terms. This, in turn, affects supply and supply security.

**Aggravating Supply Shortages**

We fear that the new models will increasingly lead to supply bottlenecks.
• It is envisaged that the reference pricing system will only be effective if at least three medicinal products with the same composition of active ingredients are listed in the Specialties List (SL)
• But nowhere is it defined what kind of vendor it must be. It is also unknown if the rule also applies if, for example, there are two big providers and one very small provider or even just one big and two small ones. The security of supply in such a constellation is by no means guaranteed, even if the number of providers meets the legal requirements
• Companies could refrain from marketing their products if there are already three suppliers in the market, as they would have to start with lower prices
• It is envisaged that the Federal Council can take measures if security of supply is jeo-pardised. This is hardly effective in practice to implement, because often not even the manufacturer knows when a supply bottleneck occurs
• It is acknowledged that security of supply in the Swiss generics market is currently high, especially when compared to other countries.

This high level of security has two main reasons:
• The comparatively higher prices in Switzerland automatically direct international drug flows first to ''stock-out' situations in Switzerland, and any inventories are also preferred to Switzerland. This mechanism would be compromised.
• Due to the high service expectations of the customers, the ability to deliver is an im-portant competitive factor. Generic companies in Switzerland therefore keep above-average stocks in order to compensate for external supply fluctuations as much as possible. For economic reasons, such warehouses will no longer be possible in the future, which will lead to increased supply bottlenecks. Due to these circumstances, the reference price system will inevitably lead to increased supply bottlenecks as the balanced system that exists today will no longer be possible. The countermeasures can not in any way capture or neutralise the expected consequences of the new system. On the contrary, supply insecurity will worsen because of the mechanisms outlined. With the new model, the prices of patented originals would probably be between 20 per cent and 70 per cent, and for imported products 10-35 per cent below the EU average (nine reference countries), since Foreign Price comparison's reference price is the benchmark and to a certain tee comes. For the pharmaceutical country Switzerland, with the highest wage level in Europe, this is an absurd situation.

The consequences are foreseeable: Some original manufacturers will take their originals from the market, since their sales no longer pay off due to the fixed costs with the massively reduced yield. Others will reduce the price to the highest price and thus be close to the price level of the generics or the reference price. This increases the pressure on generics and their prescription would collapse. Many patients and doctors would prefer the original if it is as expensive as a generic. With a greatly reduced prescription, many generics no longer pay off for the manufacturers, with the result that they are taken off the market. The market would then be largely dependent on the original preparations. As shown above, with declining revenues, the original manufacturers will examine which medicines can still be marketed profitably and which are to be withdrawn from the market. However, the market will hardly contain any generic drugs because they had to be taken off the market for economic reasons. The result is that while the proposed reference price system will result in a short-term price reduction, in the longer term it threatens the security of supply and the selection of medicines to a considerable and probably irreversible extent. ■

AUTHOR BIO

With over 30 years of experience in leading companies in general management, development, regulatory, manufacturing and marketing, **Axel Müller** knows the pharmaceutical and generic industries in all aspects across the entire value chain. The study of pharmacy and PhD in pharmacology were followed by specialised training at international educational institutions such as Columbia University, New York.