avenir debatte

When Are New Pharmaceuticals Too Expensive?

Ensuring Rapid and Affordable Access to High-priced Innovations

Major advances in the development of medicines are a blessing. But they don't come for free. How can we ensure that the healthcare system can afford such drugs? What can be done to enable innovative pharmaceuticals to be rapidly launched on the Swiss market? In a new study, Avenir Suisse analyzes the interplay of mechanisms in the pharma market between patients, the regulators, and the industry, proposing a new funding model that would increase the added value of such products for patients without pushing the entire system to its financial limits.

Thanks to advances in technology and medicine there have been significant improvements in the treatment and cure of many serious diseases. The flip side of this positive development is that the price of innovative drugs can sometimes be exorbitant: as the treatment of diseases becomes more and more specific, fewer people are treated with a specific drug, meaning that the development costs have to be passed on to a smaller number of patients.

In Switzerland, the price of these drugs is negotiated between the Federal Office of Public Health (FOPH) and the respective pharmaceutical manufacturer after the safety, efficacy, and quality of the drug have been verified by Swissmedic. Owing to the high prices, these negotiations can take several months. During this time, access to the innovations for patients is limited.

This problem basically exists for all newly approved drugs. In cases where there's only an incremental improvement to an already approved compound, it plays a secondary role: delayed access, while annoying, isn't life-threatening. The situation is different for innovative drugs for which no alternative therapies exist.

In this study, we therefore focus on access to such innovations and how they're funded. By the term "innovative medicines" we mean medicines that benefit from an accelerated approval procedure in Switzerland according to Article 7 of the Ordinance on Medicinal Products (VAM). Medicines that cumulatively fulfill the following three criteria are considered to be innovative:

- They are used to treat a serious, disabling or life-threatening disease.
- Approved treatment alternatives are insufficient or non-existent.
- Use of the medicine promises a high therapeutic benefit.

To ensure rapid access to new substances while keeping the burden on premium payers reasonable, we propose an approach based on three pillars:

A) Ensure rapid access to innovative medicines

A drug goes through a lengthy process before it is marketed in Switzerland. After a research and development phase lasting an average of twelve years, the drug must be approved. For this to happen, the manufacturer submits a marketing authorization application to the Swiss Agency for Therapeutic Products (Swissmedic), where the drug is tested for safety, efficacy, and quality. The manufacturer then applies to the FOPH for inclusion in the list of drugs and special therapies. Only drugs listed there are reimbursed by the health insurance companies.
The pricing mechanism between the authorities and the pharmaceutical companies must therefore be clear and fast, so that access to innovative drugs is not delayed or even made impossible. This requirement is particularly important for highly innovative medicines, as there are often no valid alternatives for the patients concerned.

Measure 1: *Costs reimbursed from the first day after approval by Swissmedic*:
Health insurers should cover innovative medicines at a provisional price from the first day of approval by Swissmedic. This price would be set "mechanically" using a formula to minimize prejudice to negotiations between the FOPH and the pharmaceutical company. The parties would then have 365 days to negotiate the final price. Pharmaceutical manufacturers would have to reimburse health insurers for the difference between the preliminary and final prices. If negotiations fail, the deadline would be extended by six months and the provisional price adjusted.

B) Define the "value" of a life and set the price of the drug accordingly

The question of whether a million francs for one dose of a life-saving drug is (too) expensive is not easy to answer. The price of a drug that eliminates the need for lengthy treatments should, on the one hand, reflect the value of these savings. On the other hand, the price should also be based on the financial "value" of the life or years of life saved. But what is this "value"? Diametrically opposed world views clash on this question. Even if it will be difficult and emotional, a political debate about this is inevitable in Switzerland. After all, it's simply not honest to declare life priceless on the one hand, while on the other complaining that the costs of healthcare are no longer sustainable. The study therefore proposes a new mechanism for setting drug prices that would allow the added value of the drug to be based on the financial "value" of a life.

Measure 2: *Define the medical added value of a drug compared with the standard of care using additional QALYs*:
Currently, there is no concrete and transparent way of measuring the added value of a drug in Switzerland. The Swiss price is based on a simple formula that reflects the price of comparable drugs in Switzerland and abroad. If Switzerland wants to be among the first countries to offer an innovative drug, it needs an independent definition. In parallel with the current formula, we propose an alternative in which the price of innovative medicines can be assessed on the basis of additional quality-adjusted life years (QALYs) compared with a standard of care. QALYs are a measure of a person's state of health, with the utility in terms of the quantity of life adjusted for quality of life. One quality-adjusted life year (1 QALY) is equivalent to one healthy year of life.

Measure 3: *Define the Swiss franc value of a QALY*:
In order to introduce the QALY as a measure of value added by an innovative drug, its value in francs must first be defined and calculated. Various methods are conceivable to determine the value of a QALY, but the value should ultimately reflect the amount society is willing to pay for an additional healthy year of life.

Measure 4: *The pharmaceutical industry and society should be allowed to benefit from the value of a drug*:
Once the added value of a drug has been determined in francs, the question arises as to who should benefit from this value and to what extent. A pragmatic division of the value might be to give half of the determined additional benefit to society and the other half – in the form of reimbursement of the drug – to the pharmaceutical companies.

C) Ensure sustainable premium funding with a dynamic cost impact model

If Switzerland wants to remain an attractive place for marketing innovative but expensive drugs, it needs a new funding model that takes into account the added value of such products for patients as well as the financial impact on the overall system.
In principle, there are two ways to limit costs from the outset: lowering the price or reducing the volume. Both options could result in patients not receiving the latest medicines. To prevent this, a more sensible approach would be to adjust cumulative sales – and thus total costs to health insurers – ex post, rather than curbing the price or volume ex ante. To this end, we propose a dynamic cost impact model that takes into account, on the one hand, the life cycle of the drug and, on the other, the development of sales.

Measure 5: *Introduce sales-based pricing models:*
This mechanism for sales-based cost regulation consists of three phases:

1) If the cumulative sales of a new drug in Switzerland are below CHF 25 million, the price is based solely on the added value for a single patient (see above).
2) If, on the other hand, sales exceed this threshold, a new pricing mechanism comes into play. In this phase, sales above the threshold are reduced retroactively at the end of the year, for example by 20-25%. This can be justified by the fact that by this time the research and development costs have already been largely amortized. In order not to affect the published retail price in Switzerland, which in some cases serves as a reference abroad, the price on the list of drugs and special therapies remains unchanged.
3) If the annual sales in Switzerland exceed another sales threshold, for example CHF 100 million, the reimbursement rate could be further increased, for example to 30-35%. At this point it can be assumed that the pharmaceutical companies are achieving large economies of scale.

The proposed sales thresholds and reimbursement rates are to be understood as plausible orders of magnitude. It's advisable not to set the thresholds too low or the reimbursement rates too high at the beginning. If the costs entailed in new, innovative drugs prove too high, the revenue thresholds and reimbursement rates can be adjusted later. If, however, the financial incentives for pharmaceutical companies are too restrictive, Switzerland could cease to be attractive for the rollout of innovative drugs, which would be to the detriment of patients.
The positive effects of the proposed model are manifold: The automatic sales-based price adjustment mechanisms will curb the cost impact of innovative products on health insurance premiums. For the pharmaceutical industry, this model means that research and development costs could be amortized quickly and the Swiss retail price would remain high. For the Federal Office of Public Health (FOPH), the proposed approach has the advantage of being clear and transparent. In the long term, it could replace the confidential pricing models negotiated between the FOPH and pharmaceutical companies. Last but not least, from the patients' perspective, such a pricing mechanism prevents access to particularly innovative technologies from being restricted for reasons of price.

Drugs as part of a value-based healthcare system

There are complex mechanisms involved in the approval of innovative medicines. If new, innovative drugs are to continue to be introduced rapidly in Switzerland, international competitiveness must be maintained. At the same time, the collective and solidarity-based financing of the health care system obliges us to achieve a maximum outcome with the resources deployed.
To ensure that our system continues to be among the most efficient, a value-based healthcare approach should be pursued in the future. The proposals in this publication apply such an approach to access and the funding of medicines.

Naturally, however, drugs are only one part of the healthcare system. The care provided by physicians and nurses, the role of relatives, etc., are just as important as medications per se. A treatment can only be carried out effectively if the diagnosis and the resulting indication have been correctly determined. Optimizing the entire patient pathway is the goal to strive for.

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