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The Swiss healthcare law (KVG) outlines three key pillars: benefit, quality and security of supply, and cost affordability. All three are supposed to be considered equally, but the focus has increasingly shifted to cost alone

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Ernst Niemack, managing director of vips, the association representing pharmaceutical companies operating in Switzerland, comments on the government's latest cost containment measures such as mandatory rebates and new rules for biosimilars and generics, and the impact of these policies on innovative pharma. He also discusses the lag between registrations and reimbursement, addressing shortages and supply chain resiliance, and the challenges of digitalization in a country with 26 different local healthcare systems.

In a 2020 PharmaBoardroom interview, vips' President Marcel Plattner highlighted the negative impact of ongoing healthcare cost containment measures and criticized the idea of capping drug prices at the European average as "absurd." How have these trends evolved since then?

I can say that the situation has actually worsened since 2020, as we are now facing even more regulations. A few years ago, the primary concern was the cost containment measures, particularly the reference pricing system, which Parliament ultimately rejected. However, the mindset of minimizing costs has persisted. Since then, new regulations have emerged, including the revisions to the Health Insurance Benefits Ordinance (KLV) and the Health Insurance Ordinance (KVV), both of which were introduced by the administration. These changes have affected various business models, hitting primary care products particularly hard, while also impacting innovative drugs and the single-case reimbursement system outlined in KVV Article 71. This article covers products not

on the Specialty List (SL), where insurers may approve reimbursement in exceptional cases. However, the Federal Office of Public Health (FOPH) introduced mandatory rebates under this system, which have had a significant impact.

We conducted a survey with 75 member companies, and the results were alarming. A quarter of these companies indicated that they planned to delay the registration of at least one product in Switzerland, and some decided not to enter the Swiss market at all. Although industry intentions can differ from actual outcomes, this sentiment still reflects the gravity of the situation. Now that the new regulation has been in effect since January 1, 2024, we plan to conduct another upcoming survey to assess the real-world impact over the past months.

Mandatory rebates are just one issue. We also saw an increase in patient co-payments from 20 to 40 percent for drugs that are slightly more expensive than the lowest third, which has led to a push toward generics. Unfortunately, this has caused originator products to lose significant market share. The feedback from our members indicates that companies are likely to withdraw approximately 100 salespeople from this segment, as sales have dropped by about 30 percent compared to last year. In total, there have been around 40 to 50 regulatory changes, and these are the most significant factors negatively affecting the industry. This also includes new rules impacting biosimilars and generics, while some of the planned measures have been postponed to the next cost containment package.

You mentioned recent developments in the biosimilar space, with new incentives and rules driving growth in this segment. How do you view these changes, and what impact are they having on the industry?

The recent changes have certainly provided a boost for generics and biosimilars, but they have also introduced challenges, particularly in terms of supplier diversity. We are seeing a reduction in the number of suppliers, which puts supply security at risk. This risk is only expected to grow in the future. The price gap between originators and generics has become quite small, particularly for off-patent products, which further complicates the situation.

Then there is Article 71, which aims to ensure equitable access to treatments for all patients, regardless of their health insurance provider. While this is a positive development, it is being achieved at a lower level due to the mandatory rebates that some companies are unable to keep up with. Products are rated as A, B, or C, with mandatory discounts of between 30 to 40 percent and an additional 10 percent discount after 12 months.

For companies with a large portfolio, they may be able to balance these rebates across multiple products. However, for new biotech companies with only one product, these discounts are unsustainable. This is where we see a clear divide between big pharma, which can absorb these costs, and smaller biotech companies, which are struggling under the new rules.

Could you summarize the key objectives behind these new regulations and what the policymakers aim to achieve?

The primary goal of these changes is to reduce healthcare costs. In Switzerland, healthcare is quite fragmented with 26 different systems and each canton has its own responsibility for hospitals, healthcare professionals, and pharmacies. However, pharmaceutical pricing is regulated at a national level, making it easier for policymakers to lower drug prices rather than, for example, close a hospital, which would be politically unpopular and could lead to local politicians losing their positions.

We have already seen the implementation of the first cost containment package, followed by the KVV / KLV revision, and now there is ongoing discussion about a second cost containment package. The focus is increasingly on reducing the prices of innovative drugs and top-selling products. For example, if a product reaches a certain sales level, additional price cuts may be applied. These discussions are still ongoing.

There is also a price review process that occurs every three years, in place since 2012. Now, for more expensive products, policymakers are considering increasing the review frequency, while reducing the frequency for less costly products. Another proposal in the cost containment package is to allow reimbursement from day one, as well as to address the legal framework for pricing models, which are currently not fully regulated in Switzerland. While pricing models exist, there is no clear legal backing, and policymakers want to change that.

We are currently debating whether pricing should remain semi-confidential or be fully transparent, as is being discussed in Parliament. The small chamber, the Ständerat, has opted for semi-confidentiality, but the expert group in the big chamber is pushing for full transparency. If full transparency is implemented, it could discourage companies from launching their products in Switzerland, given the country’s small market size.

These topics form the core of the cost containment package 2. The Ständerat has already made its decision, and the big chamber will decide in December. In the meantime, we are working closely

with the Federal Office of Public Health (FOPH), health insurance companies, Interpharma, and vips to find a balance that reduces costs without excessively harming the pharmaceutical industry.

While IQVIA data shows that price reductions slowed Swiss pharma market growth by 2.7 percent in 2023, the market still grew by 4.9 percent. Does this indicate that cost containment measures can co-exist with market growth?

When you look at the overall market, there is indeed growth. We see these price cuts and annual price reviews, which had an average impact of about 2.7 percent. However, the real story comes from volume changes, as new products and innovations only contributed around 0.4 percent to the growth. The rest came from increased demand which can be attributed to several factors such as demographic shifts. With an aging population there is an increasing requirement for more treatments.

There may also be a lingering effect from the pandemic, where some therapies were postponed and are now being addressed. Additionally, the quality of new, innovative therapies is improving, offering higher benefits and better symptom management, which could contribute to increased usage. So, while the market growth is a positive sign for Switzerland, it is largely driven by factors beyond just innovation.

What are some of vips' key proposals for balancing the need for affordable medicines with the imperative to foster innovation in the pharmaceutical industry?

At the end of the day, we need to decide whether we want quick and comprehensive access to services, including new therapies and innovations, or if we are willing to settle for a more basic level of care through the standard insurance package. In Switzerland, the base insurance already covers a very extensive range of services. Now the political question is whether we continue providing this same level of service for everyone or move toward a system where people can choose between basic or more advanced packages.

We also have to be cautious because regulations often focus on specific services without considering the bigger picture. Sometimes, spending a bit more on one service can lead to savings elsewhere. For example, drugs are generally one of the most cost-effective treatments, even though some newer therapies, like gene treatments, are more expensive. However, investing in these treatments could prevent hospital stays, reduce doctor visits, or lower diagnostic and lab

costs. Take, for instance, a therapy that used to require a monthly infusion at a hospital but can now be taken as a pen at home. While the pen might be more expensive upfront, it saves costs in hospital resources over time. This broader perspective is often lacking in the current cost-focused approach.

Balancing affordability with innovation is critical. We recognize the responsibility to control costs, and there have been savings of around CHF 1.5 billion per year in the pharmaceutical sector over the past 12 years. However, these savings come largely from pricing cuts that affect industry margins. The pharmaceutical sector is a major economic driver in Switzerland, with CHF 9.5 billion invested in R&D and producing around 50 percent of the country's exports.

The real challenge is to strike a balance. The Swiss healthcare law (KVG) outlines three key pillars: benefit, quality and security of supply, and cost affordability. All three are supposed to be considered equally, but the focus has increasingly shifted to cost alone. This narrow focus risks undermining the broader contributions of the pharmaceutical industry to both healthcare and the Swiss economy.

What steps are the government and industry taking to address shortages and ensure the resilience of the country's supply chain?

As managing director of vips, I was part of the interdisciplinary working group led by the Federal Office for National Economic Supply (BWL) and the FOPH. This group has focused on finding solutions to strengthen supply chain security. A report was published in August, outlining several proposals, but it is important to recognize that when discussing supply security, we must consider different segments.

First, we have innovative products that are not entering the Swiss market due to poor reimbursement conditions. Second, there are products that are available but have new formulations, like transitioning from an infusion to a pill. However, if there is no reimbursement benefit for the new form, manufacturers may avoid bringing it to market due to higher production costs. This issue is often underestimated. The third segment involves primary care, where we are facing significant shortages in antibiotics, paediatric medicines, vaccines, and low-volume products.

These shortages are exacerbated by ongoing price cuts through the tri-annual pricing reviews, which allow little room for price increases. When prices reach unsustainable levels, companies

withdraw their products from the reimbursement list and eventually from the market altogether. This is a trend we are already witnessing. Six or seven years ago, the shortage list had around 200 products. Today, it has grown to approximately 1,000, and the situation is getting worse.

We have defined several measures, which are now subject to political debate. One proposal is to introduce mandatory stockpiling for high-risk products. However, there is ongoing debate about who should bear the cost. Currently, the pharmaceutical industry is responsible, but with pricing pressures, this may not be a sustainable approach.

Another important measure is revising the frequency of price reviews. Currently, prices are reviewed every three years, but under new regulations, the FOPH could extend this to nine years or potentially waive it altogether for certain products.

Additionally, BWL is developing a new platform with direct interfaces to pharmaceutical companies, which will provide real-time data on product shortages. This will enable more accurate forecasting of potential supply issues, including shortages that could arise within the next nine months. There is also discussion about reserving production lines to ensure continuous supply for critical medicines.

The timeline from drug approval to reimbursement in Switzerland has significantly increased, sometimes taking up to 300 days. How effective is the current reimbursement system and what reforms are needed to streamline this process?

According to the regulation, the reimbursement approval should be completed within 60 days. This is the legal requirement. A few years ago, we had similar delays with Swissmedic regarding product registrations, but now, Swissmedic has become more competitive with the EMA and FDA. There is still a submission gap, which is due to the resources of pharmaceutical companies. They cannot prioritize all markets at once. However, the registration process has been improving steadily.

Unfortunately, the time gained in product registration has now been lost in the reimbursement process. On average, reimbursement approval takes over 310 days. For pharmaceutical companies, it is not just about completing one process, but the overall “time to market” that matters, and this has become a significant issue.

We are in constant discussions with the FOPH about this. For simpler products, especially in primary care, the process is relatively smooth and can be completed within 60 to 100 days. However, for more innovative therapies, the dossiers have become increasingly complex, making it

difficult for the FOPH staff to review. They often have the same pharmacists reviewing these complex cases, and when it comes to rare diseases, where there is limited data and early-stage evidence, it becomes even more challenging.

For new drugs entering markets where there has been no innovation for decades, the reference price in Switzerland ends up being unrealistically low, because the existing standard of care might have a cost of zero. This situation leads to a 50 percent reduction in the price compared to neighbouring countries, making the Swiss market unsustainable for companies.

Switzerland is also a reference country for about 20 other markets, including larger ones like Brazil, so a low Swiss price can have broader implications. As a result, more companies are trying to negotiate through pricing models, but it remains difficult. We have seen that it takes even longer to finalize pricing for non-oncology drugs, as the experience and negotiation processes in this area are less developed compared to oncology.

One proposal from the pharmaceutical industry is to offer temporary reimbursement from day one after registration, but the current rules are so restrictive that very few products can qualify for this benefit. The key point of contention in these discussions is the starting price. The pharmaceutical industry argues that the foreign country price should be the starting point, with the commitment to pay back any difference once a final price is agreed upon. However, health insurance companies are pushing for a starting price that is below the foreign country price, which is not acceptable for the industry. If this approach is implemented, it will effectively halt the system.

In Japan, years of cuts to drug spending have led to reduced access to innovative treatments and decreased investment from pharma and biotech companies and the Japanese government is now taking action to reverse that trend. Are you seeing similar warning signs in Switzerland?

Absolutely. As long as ideology drives the decision making, we will find ourselves going down the same path as Japan. With increasing cost containment measures, stricter co-payment rules, and other regulations that sometimes have no impact on health insurance prices, the environment will continue to worsen for the industry. For example, we only see small savings of a few hundred thousand Swiss francs from measures like price cuts on antibiotics. One of our members requested a price for a product with total sales impact of 150,000 Swiss francs per year, but the price was rejected and cut by 50 percent. This had no real impact on the system but is a huge burden for industry players.

The survey I mentioned earlier shows we will likely face the same issues as Japan in a few years and will need similar corrective actions in the future if we do not act today. Even Germany has also recognized issues with their tendering system for some therapies, which has led to a shortage of products for primary care, yet we are still managing the access of innovation in a similar manner here in Switzerland.

Currently, there is significant pressure on costs, and every autumn brings new announcements from health insurance companies about increasing rates. This creates problems for people with middle and low-class incomes. The solutions being proposed are not effective and the action points from politicians have had no real impact on health insurance costs. The current approach is not working so we must change course or be prepared to accept higher costs.

Switzerland has been slow to digitalize its healthcare system, lagging behind even some less economically developed European nations. How could a more aggressive adoption of digital health solutions help address some of the country's healthcare challenges?

A more aggressive adoption of digital health solutions could potentially save up to 20 percent in healthcare costs if we achieve full digitalization. However, this requires establishing consistent standards across all stakeholders. Currently, Switzerland has 26 different healthcare systems, and the cantons would need to improve their connectivity to exchange data effectively. Data protection regulations in Europe also complicate the use of big data and slow down the process.

During the pandemic, we saw significant progress in digitalization. Yet, projects like the electronic patient dossier, which have been in development for 12 or 13 years, are still not fully implemented. There is even an ongoing debate about whether to start the project over from scratch or improve the existing system. Transitioning from an opt-in to an opt-out system for data sharing could also be a crucial solution to ease the process by creating uniformity.

For example, Austria is a good case study of successful digitalization. During the pandemic, they linked health certificates needed for travel and public activities such as going to restaurants to their electronic patient database, leading to a significant increase in digital adoption from 0 percent to 70 percent. This shows the importance of creating standards, incentives, and the ability to connect and align stakeholders.

Although digital health is now a high priority for stakeholders, with the government allocating substantial funds to develop standards over the next 10 years, there is still much work to be done. The process is progressing, and discussions about the opt-in and opt-out system are on the political agenda, but there is still a lot of work ahead.

As managing director of vips, do you have any final thoughts or messages you would like to share regarding the future of Switzerland's pharmaceutical industry?

While we have discussed many challenges today, I want to emphasize that Switzerland remains a positive environment for the pharmaceutical industry. Our political system is very stable, and prices are in line with the European average—neither too high nor too low. Furthermore, we have a fantastic healthcare system overall which is easily accessed by patients.

For companies considering investment here, Switzerland offers a favourable environment. We have a strong talent pool and are known as a global pharma hub. Stability and a supportive environment are key strengths for Switzerland. Despite some specific challenges in the Swiss market, setting up a headquarters in Zug, or elsewhere in Switzerland, is still a very attractive and advantageous decision.

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