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We must work together to sustain a healthy and competitive market, ensuring that the generic and biosimilar industries continue to provide affordable, high-quality treatments for patients worldwide

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Lucas Schalch of Intergenerika examines the challenges confronting Switzerland's generic and biosimilar sectors, such as high production costs and changing regulations. Schalch underscores the importance of maintaining a favourable economic environment for these industries.

What are the primary dynamics influencing the Swiss pharmaceutical market, especially regarding generics and biosimilars, in a country renowned for its innovative drug sector?

Switzerland's pharmaceutical market is distinct due to its strong emphasis on innovative drug development and its robust economic standing. Historically, this focus made it difficult for generics to establish a presence, as both patients and healthcare professionals were skeptical about their quality, and there was a strong relationship with the innovative pharmaceutical sector. Over time, however, there has been a notable shift. In response to escalating healthcare costs—a trend observed globally—Swiss health authorities have increasingly recognized the value of generics and biosimilars in controlling expenses. This acknowledgment has led to several strategic changes aimed at boosting their market share.

The rise in healthcare costs in Switzerland is driven by multiple factors, including an aging population, increased demand for services, and the high costs associated with new innovations. For

example, as seen in my own family, the growing reliance on healthcare services by elderly individuals contributes to higher costs. This complex landscape has prompted the Swiss authorities to implement measures to promote generics and biosimilars.

Recent reforms include adjusting distribution margins to eliminate financial disincentives for prescribing lower-cost drugs, a crucial step given that self-dispensing physicians—who account for about a third of Swiss healthcare professionals—previously benefited from prescribing more expensive medications. Additionally, the policy now allows pharmacists to switch from original drugs to generics and biosimilars more freely. While some countries, like Germany, face criticism over price pressures resulting from such switches, Switzerland has seen these changes as positive, with the market share of biosimilars growing rapidly as a result. Overall, while challenges remain, the Swiss market is evolving with increased support for generics and biosimilars, reflecting a shift towards more sustainable healthcare expenditure.

How have the priorities and mission of Intergenerika evolved, and what are the key challenges you are addressing today?

Intergenerika's primary focus is to maintain a sustainable and economically viable environment for generics and biosimilars. The Swiss market, known for its strong emphasis on innovation, has seen a significant push towards reducing drug prices to achieve greater savings. While this strategy has been effective in controlling costs, it has led to challenges, particularly in drug supply. The pressure to lower prices has compelled many manufacturers to relocate production to countries like India and China to sustain profitability. This shift has exposed vulnerabilities in the supply chain, which became evident during the pandemic when export restrictions disrupted access to critical drugs. Switzerland is currently grappling with severe supply issues, notably in areas such as antibiotics.

A key aspect of my role is to engage with policymakers and regulatory authorities to address these supply challenges. It is crucial to ensure that the pricing system does not undermine the availability of essential drugs. The current pricing model in Switzerland, which operates on a continuous downward trend, risks making drugs so inexpensive that it jeopardizes their supply. We need to advocate for a minimum price to prevent this unsustainable trend. The high regulatory standards in Switzerland, enforced by Swissmedic, alongside the complexities of the local market—including its small size and multilingual environment—further complicate pricing. Despite the perception that drugs produced abroad should be cheaper, the costs associated with local distribution, quality control, and compliance with regulations mean that prices cannot be aligned with those of other countries.

Price pressure for example is a significant challenge for Switzerland, particularly when it comes to securing essential medications. A specific case we're currently discussing involves a crucial antibiotic used in the pediatric segment. The medication is offered at such low prices that it has become increasingly difficult to obtain on the global market. One of our member companies requested a price increase over a year ago, but the Swiss authorities have been slow to act, focusing more on concerns about industry profits than on the urgent need to address the supply issue. We've reviewed the global price increases for this medication from 2020 to 2023, and they are substantial. One company has already halted imports because they would have to sell the drug at a loss under the current Swiss pricing. To prevent essential drugs from disappearing from the Swiss market, we need a transparent process that allows for price adjustments based on economic realities. While finding a solution may take time, it's crucial that we address this issue to ensure the continued availability of these important medications.

These supply challenges are not unique to Switzerland; other countries like France and Germany are also experiencing difficulties and are reevaluating their pricing strategies. Intergenerika's mission continues to focus on ensuring the steady supply of high-quality generics and biosimilars while advocating for a more balanced and sustainable approach to drug pricing.

Given Switzerland's small market size, how feasible is it to ensure self-sufficiency in the pharmaceutical supply chain, and what steps are necessary to address this challenge?

Ensuring self-sufficiency in Switzerland's pharmaceutical supply chain is indeed a complex challenge, particularly due to the country's small market size and relatively modest demand. There are two critical factors to consider. First, it is essential for Switzerland to maintain an economically attractive environment. In the global marketplace, where production capacity is fiercely contested, pharmaceutical manufacturers naturally prioritize markets that offer the greatest profitability. For Switzerland, with its smaller volume needs and specific requirements like specialized packaging, this means we must remain competitive to secure our share of drug supplies. If a producer can sell an entire production batch to a larger market at a favourable price, they are unlikely to accommodate Switzerland's smaller, more customized orders. Therefore, it is vital that we ensure our market conditions are appealing enough to be prioritized by global producers.

Second, addressing supply chain vulnerabilities requires robust international collaboration. Switzerland, given its size, cannot tackle these challenges in isolation. We must actively engage with other nations, particularly within the European community, to develop collective solutions. This might involve participating in joint initiatives or forming strategic alliances that ensure Switzerland's inclusion in global supply chains. However, this is complicated by Switzerland's non-membership in the European Union, which can limit our influence in these discussions. It is imperative that Swiss authorities and political leaders pursue active engagement in international negotiations to secure Switzerland's position. Without such collaboration, we risk encountering significant supply chain disruptions in the future.

Could you explain the recent reform in drug distribution margins and its impact on the pricing and availability of generics in Switzerland?

The recent reform of drug distribution margins, which took effect on July 1st, is the result of a 12-year negotiation process initiated by former Health Minister Alain Berset. The primary goal was to achieve savings by reducing distribution margins and lowering public drug prices. However, the compromise that was ultimately reached, has created significant challenges, particularly for generic drugs.

Under this new system, while some savings will be realized, there is a significant downside. Low-cost drugs, those with an ex-factory price below 15 Swiss francs, which make up 40-50% of generic drugs, have seen a dramatic increase in public prices. This is particularly concerning because it adds to the already substantial price pressure on generics. Alarming, it seems that the Swiss health authorities did not fully assess the impact of this reform. Our analysis shows that the price increase in the low-cost drug segment could lead to an additional 200 million Swiss francs in expenses, far exceeding the modest savings anticipated from the reform. The authorities had projected savings of around 60 million Swiss francs from this new model, but our calculations indicate that the actual savings are likely closer to 40 million at best. While the reform aimed to encourage the use of generics and biosimilars by correcting the previous system's bias toward more expensive drugs, the unintended consequence is that increased margins on low-cost drugs will eventually nullify these

savings—a fact that seems to have been overlooked.

We strongly opposed this reform and proposed an alternative model for drugs priced between 1 and 15 Swiss francs to minimize the negative impact, but our proposal was not adopted. Now that the reform is in effect, we are concerned that it will further exacerbate price pressures on low-cost drugs. This is an arbitrary price increase that benefits only the distribution network, with no added value for the industry, and it is a development we will continue to monitor closely.

The biosimilar market in Switzerland appears to be gaining traction. Could you elaborate on the current dynamics and opportunities within this sector?

The biosimilar market in Switzerland is indeed experiencing growth, but this transformation has been gradual. Historically, the Swiss healthcare system did not rely heavily on biosimilars for several reasons. There was minimal economic pressure to adopt them, and physicians maintained strong relationships with research-based companies. Additionally, concerns persisted about whether biosimilars truly matched the quality of the original products. This landscape is now shifting. For a long time, the pricing structure disincentivized the use of biosimilars, as the higher prices meant that healthcare professionals earned more by prescribing original drugs. Consequently, the biosimilar market struggled to gain traction.

However, recent developments have significantly altered the scenario. Several measures have been implemented to promote the adoption of biosimilars. The new distribution margin system we previously discussed is one such measure. Pharmacists are now allowed to switch patients from original drugs to biosimilars, similar to the process for generics. Additionally, the introduction of a 40% copayment as of January 1st has incentivized patients to choose more affordable alternatives, including biosimilars. In response, many manufacturers of original drugs have lowered their prices to avoid the higher copayment, which typically stands at 10%. Despite these adjustments, the cumulative effect of these changes has made biosimilars a more attractive and viable option in therapeutic choices.

Another crucial development has been the streamlining of reimbursement procedures. Previously, when a physician switched a patient from an original drug to a biosimilar, a new approval from the health insurance provider was required, adding unnecessary administrative complexity. Now, if the original drug has already been approved for reimbursement, the transition to a biosimilar can occur without any additional paperwork. This simplification is a significant relief for healthcare professionals, allowing them to focus more on patient care rather than administrative tasks. These changes, introduced over the past year, have revitalized the biosimilar market in Switzerland. We are now witnessing a positive shift towards biosimilars as a preferred therapeutic option, which bodes well for both the industry and patient access to affordable medications.

What are the next steps and priorities for further expanding the biosimilar market in Switzerland?

The primary focus is to sustain an economically viable environment that promotes biosimilar development. While the global biosimilar market has made significant strides, many reference drugs still lack biosimilar alternatives because they are not deemed financially attractive enough for development. The industry must work to create conditions that incentivize the development of biosimilars for all drugs as they come off patent. A study by IQVIA underscores that a substantial number of original products currently have no biosimilar development underway, largely due to

economic disincentives. To ensure wider access to affordable, high-quality treatments, it is essential to establish stronger incentives that make biosimilar development more appealing and feasible across a broader spectrum of drugs. By doing so, the market can expand to provide patients with a more comprehensive range of cost-effective therapeutic options in the years to come.

Any final message you'd like to share?

My message is straightforward: there is an urgent need to find global solutions that sustain a viable and healthy environment for the generic and biosimilar industries. These sectors are essential for the sustainability of healthcare systems worldwide. We must collectively address the pressures on these industries and develop innovative strategies to ensure patient access to affordable, high-quality treatments across the globe.

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