Axel B Müller – Managing Director, Intergenerika, Switzerland

Why should Switzerland import a system that has patently been shown to be wrong-headed elsewhere and that will trigger drug shortages?

08.10.2020

Tags: Switzerland, Intergenerika, Generics, Association, Pricing

Intergenerika's Dr Axel B. Müller makes an impassioned case against the introduction of a reference pricing system in Switzerland, arguing that it would hurt not only the Swiss generics industry but, ultimately, patients. Dr Müller proposes an alternative way, leveraging the pre-existing system to generate healthcare savings, outlines the dynamics at play in the Swiss generics market today, and argues for the return of essential medicine manufacturing to Europe.

The Swiss Federal Council's potential introduction of reference pricing for medicines seems to be high on your agenda. Why would such a ruling be so damaging to the Swiss generics industry, as well as to the healthcare system overall?

We, as the generics industry, are not opposed to lowering prices. In fact, we want to support the overall healthcare system by reducing costs. The purpose of our industry is to bring affordable medicine to the people.

We oppose the proposed reference pricing for many reasons. In countries like Germany, where a reference pricing and rebate system was introduced, over 50 percent of generic companies have now disappeared from the market. Countries with this system have also consequently experienced severe drug shortages. Why should Switzerland import a system that has patently been shown to be wrong-headed elsewhere and that will trigger drug shortages? If prices are lowered dramatically

under a reference price system, our member companies will probably stop launching products in Switzerland as they will be unable to stay profitable, which will exacerbate the drug shortage issue. Also, if companies must significantly lower their prices they will have to cover the costs somewhere else – such as by lowering warehousing capacity – which will also trigger shortages.

The COVID-19 situation has shown up Europe's dependence on international supply but as Switzerland is a highly regulated market with a lot of entry barriers and low volume – we are a small country of only eight and a half million inhabitants –if we do not have reasonable prices, when it comes to making a decision as to which country gets what, we are very far down on the list. Only if we have commercially viable prices, are we an attractive partner that can obtain the medicines that our population needs.

Another issue is that if patients are forced to always take the cheapest generic, they will have to continuously switch medication at the pharmacy level. Research shows that if a patient has to constantly switch between medications in different packaging, although the active ingredient is the same, they will get confused and adherence will drop. In turn, this will lead to an increase in disease and hospitalisation, as well as an increase in overall costs.

A final problem is that, under a reference pricing system, if a patient wants a product they are familiar with but which has not had its price lowered, they will have to make a co-payment in the pharmacy. People in Switzerland already pay a lot of fees to the sick funds and charging them even more to get their usual medicine is highly unsocial. While this may lower the fees paid to the health insurance it represents a shift to greater private expenses.

What is the alternative to the reference pricing system that you are proposing?

We have worked very hard to show the Swiss government that a better system exists. A recent expert report proposed that before moving to a reference pricing system we should use levers within the existing system to reduce prices and make savings for the people.

Currently, doctors and self-dispensing pharmacists earn more if they give the patients originator or more expensive products; this is wrong. These doctors and pharmacists are incentivised to prescribe expensive originators rather than more cost-effective generics. Our proposal is that they should receive the same margin calculated on the generic price regardless of which product is prescribed.

Such a system would trigger a greater handover of generic products and pharmacists would stock more generics because the margins would be the same. Generic penetration could grow by between 10 and 20 percent and save hundreds of millions of Swiss francs. With the same margins, we would save another CHF 40 million and if we promote biosimilar penetration we could bring in another CHF 30 million.

Moreover, there is a price gap between originators and generics of 70 percent when a generic is launched. Why not increase that price gap to 75 percent voluntarily which would create another CHF 50 million in savings?

The last proposal is to change how frequently the Health Authority checks medicine prices. Currently, they check every three years, but we propose reducing that period to every year, which means lower prices and a potential saving of another CHF 50 million.

To sum up, these voluntary changes could lead to savings of over CHF 270 million every year without a change in law and no discussions in parliament. The Federal Council could make these changes next year by adapting existing regulations, which will be supported by the generic industry. While reference pricing has been touted as being eventually able to save the system CHF 400 million, our proposal would voluntarily bring in lasting CHF 270 million already next year.

How receptive are stakeholders to these proposed solutions?

The companies represented by Intergenerika – most of the Swiss generic industry – support this proposal. They know that a reference pricing system would be more harmful, both for Swiss patients and their own industry. They are accepting that this proposal may be a bitter pill to swallow but that it is better than reference pricing.

Originator companies do not like the proposal because higher generic penetration will lead to off-patent originals suffering, as will more regular pricing checks from the Health Authority. If I were in their shoes, I would not like it either! However, they need to either accept reference pricing which has downsides for everybody or offers something that we also do not like that affects our P&L but that is voluntary and a signal of solidarity and acceptance of the need to lower health insurance fees.

At the end of October 2020, the Swiss parliament will make a decision on whether to adopt reference pricing. A 25-expert National Council Health Commission is preparing the discussion and will make a proposal to parliament. Recently, this Commission voted against the reference pricing

system and supported our proposal, which is a good sign.

My hope is that parliament will decide against the reference pricing and asks us to put our proposals on the table. However, even if our motion is passed by the parliament's large chamber, it will also have to pass through the small chamber, which creates some further complications.

Last time we spoke, back in 2016, you lamented that the Swiss generics market lagged behind those of Germany, UK, France and the Netherlands in terms of market share and penetration. However, the Swiss generics market grew by 3.2 percent in 2019, faster than the overall reimbursed market. What market dynamics are at play?

The generic market is outgrowing the overall pharma market in terms of volume and sales. That is the good news. Doctors and health insurance providers better understand and accept that generics have the same efficacy and safety level as originators. However, generics make up 20 percent of the market by value and 37 percent by volume, based on defined daily dosage, a number which is increasing slowly but steadily. Once the parliament agrees that the incentives for doctors and pharmacists need to be changed, then we expect generic penetration to dramatically increase.

There are also issues in terms of packaging. The originators are playing hardball on this, which is understandable, and arguing to Swissmedic that generics need to match all the pack types offered on the original product. Even if only 50- or 100-tablet packs are sold, if the originator also sells 10- and 30-tablet packs, then so do the generics firms, meaning that our firms have to manufacture medicines in package formulations that are not profitable.

A final issue is that generics firms have to submit a substantial amount of paperwork to SwissMedic, even if their products have been successfully introduced to the market by the EMA or other health authorities, which creates extra costs.

Only 299 generic APIs are currently approved in Switzerland, far less than some other countries because some products are so small in terms of market volume that the price of the originator has come down so far that it is not worth launching generic equivalents. Generics have a 20 percent market share by value, but another 20 percent is taken up by off-patent originator products with no generic competition. There is therefore still a lot of potential for generics penetration, but that other 20 percent is not currently a worthwhile segment.

Biosimilars have begun (albeit at a somewhat delayed rate compared to European peers) to be approved on the Swiss market in the last couple of years. What is the state of the Swiss market for biosimilars and what cost savings are they able to offer?

Last year, the overall biologic market grew by 10 percent in value and 77 percent in volume, to now make up 24 percent of total value despite only representing two percent of total volume.

There are currently 12 APIs for which a biosimilar is possible, but the biosimilar market size is small at CHF 48 million of a CHF 1.6 billion total market. However, the biosimilar market is growing rapidly, shooting up by 80 percent in value and 60 percent in volume last year.

At Intergenerika we are increasingly focusing on biosimilars but facing the challenge that companies that have both biologic products and biosimilars are reluctant to be associated with the generics industry.

Therefore, we launched Biosimilar.ch, a new sub-association under the roof of Intergenerika focused on biosimilars and their promotion in Switzerland. Biosimilar.ch provides an educational platform for doctors to understand the concept of biosimilars and advocate for reasonable pricing. We hope that with this new initiative, companies with mixed biologic/biosimilar portfolios will be more willing to come on board.

COVID-19 has highlighted Europe’s dependence on Asia for essential medicines and ingredients, as well as the potential for bottlenecks and shortages. What is your proposal for bringing essential medicine production back to high-cost European countries like Switzerland and is this part of a viable solution for shoring up medical supply chains?

I am a strong advocate for that, although my colleagues from the originator associations do not necessarily agree! My demand is not for innovative Big Pharma players to start producing paracetamol – that would be foolish. They should continue to manufacture their high-price, unmet need, innovative products. Also, the shortages we have faced were not of innovative products but pure generics and cheap antibiotics, making this purely an issue for generics.

20 years ago, because prices were reducing dramatically every year, manufacturers were forced to look for new suppliers which they found in India and China. We were all happy to get APIs at a minimum cost and keep our profit margins stable. However, COVID-19 has made us realise that in a crisis, countries will look after their own people first and deal with export markets second. We are

faced with a dramatic situation where, despite being a rich nation with a history in pharmaceutical science, we are not able to produce the simplest paracetamol or antibiotic.

If we try to repatriate the production of essential medicines, costs will increase. But for the sake of our health we should be willing to cough up a higher price. If an antibiotic that formerly cost five Francs now costs ten, but it treats my lung infection and allows me to survive, I am happy to pay!

It is not realistic for a small country like Switzerland to try and produce all of the essential generics it needs. However, we should coordinate with our neighbours in Germany, France, Austria and elsewhere in Europe to do so. These countries have already made movements in this direction, but we are yet to see Switzerland send similar signals.

Switzerland has an established chemical industry which could work with other European countries to produce certain APIs and guarantee a minimum of volume every year. I hope that this initiative to bring essential medicine back to Europe, with Germany as its motor and supported by France and Austria, will be successful. There should be agreement on a European level of the list of 25 or so essential medicines – antibiotics, painkillers, blood lowering agents, and antivirals – that need to be produced and the support that companies need to be able to produce them. This could be commercial incentives such as tax relief, a guarantee of purchase, or exclusion from annual pricing reductions.

This has nothing to do with China- or India-bashing but rather increasing the portfolio of potential suppliers for essential medicines in cases with only one or two global manufacturing sites. That situation is too dangerous and unacceptable. Moreover, securing the supply of essential medicines important for safeguarding against future crises. COVID-19 is a big problem now, but others will come soon.

See more interviews