René P Buholzer – CEO, Interpharma, Switzerland

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Interpharma's Dr René P. Buholzer highlights the key lessons that Switzerland's innovative pharmaceutical industry has taken from the COVID-19 pandemic, the challenges inherent in the country's two upcoming cost containment packages, and progress made on the circuitous journey towards a more standardised national health data ecosystem.

What were the key challenges in 2020 for Interpharma and its members in the current context of this global health crisis?

2020 was an extraordinary year for all stakeholders. First, the shift to working from home was implemented extremely quickly – and worked quite well – but spending more than a year in this situation is challenging, especially for new General Managers coming in without being able to meet their teams in person.

Secondly, in December Switzerland began to vaccinate its population against COVID-19, which is good news and would have been unimaginable one year ago. This is a big victory for science and has led to a greater appreciation of the innovative pharmaceutical industry's work. However, it has also raised the public's expectations regarding our industry. Today it is clear to all that vaccination is the way out of the current crisis.

How would you characterise the approval and rollout of COVID-19 vaccines in Switzerland?

Swissmedic has been very strong on that end and approved the Pfizer/BioNTech vaccine faster than the EMA. However, we are still awaiting approval for the AstraZeneca vaccine, which is dependent on the receipt of new trial data. The J&J vaccine, some of the research for which was conducted in Berne, has been approved but the FOPH has chosen not to purchase it. Therefore, Switzerland currently has three approved vaccines from Pfizer/BioNTech, Moderna, and J&J, the first two of which have been purchased, and has pre-ordered those from AstraZeneca, Novavax, and Curevac.

Swiss companies are increasingly involved in global vaccine production collaborations, with Lonza now producing most of Moderna's vaccine supply for Europe and Novartis assisting with the manufacture of the Pfizer/BioNTech vaccine. Today, Switzerland is among the thirteen most important countries in the world for the production of vaccines.

Outside of vaccines, we are proud to have been able to maintain our part in the complex global supply chains. Moreover, the importance of countries having their own innovative pharma production hubs has been foregrounded; this trend looks set to increase in the coming years.

What are the key lessons that Interpharma has learned from COVID?

Prior to the crisis, we developed a Strategy 2030, which we reviewed around the three pillars of *patient-centricity, being a leader in R&D* and *developing a strong economic policy framework*. Via a bottom-up review with all our working bodies, we concluded that this strategy was still the right one during the crisis, although the circumstances had changed. Now the focus is on the lessons learned from the crisis and how to apply them moving forward.

For pillar one, the crisis showed that our healthcare system must be designed around people and patients. Switzerland is a wealthy country but the cost of the pandemic is estimated to be up to CHF 100 million per day. Therefore, a narrow view on costs is clearly wrong-headed. Looking only at the direct costs of vaccines and drugs or what is paid for by the insurance, does not cover the overall costs for society, which are huge. In Switzerland, we have spent almost CHF 60 billion to alleviate the economic impact of the pandemic, which does not account for psychological and other impacts. A holistic view is needed, which we knew before, but is now even more obvious. Siloed budgets lead to a fragmentation of care and often to inefficiencies in treatment.

Furthermore, we have had to work hard to retain patient trust, including trust in hospitals as we have seen people not going to hospitals out of fear of COVID-19. Therefore, the continuum of care for non-pandemic patients is a key issue. Delaying treatment for heart attacks or cancer has consequences both on patients' health and on costs.

The crisis has also led to greater focus on prevention and early care. We have to think about lifelong vaccination strategies and educate people even more on health literacy – particularly those at high-risk.

Another important issue under this first pillar is access. COVID-19 vaccines were bought collectively with tax money and are not reimbursed under normal procedures, where there is often a delay of several months. Such a delay would have been completely unacceptable for Covid-19 vaccines. Following the COVID-19 pandemic, we want to see Swissmedic's rolling fast-track procedure be applied to other products of high medical need. Patient access to medicines and vaccines on the day of Swissmedic approval must be possible outside of a crisis. At the same time, it must not delay access in other categories, as has been the case in 2020. People are not only dying of COVID-19, but also of cancer and other diseases for which a cure may be available but not yet on the market. The speed at which COVID-19 vaccines have been brought to market will not be matched, but it must be faster than it is today.

This comes back to our key concern of how we deal with more innovative payment models and agreements that consider quality-based outcomes.

For the second pillar related to R&D, we might see a higher level of collaboration between large companies, smaller biotechs, academia, think tanks and foundations. The COVID-19 pandemic has proven the value of such collaborations and they will be useful in tackling the threat of AMR.

Another key topic under the second pillar is the lack of digitalisation and poor data interoperability in Switzerland. We must leverage telemedicine and digitalisation, areas in which Switzerland currently is not strong. Also important is the harmonisation of processes between the different levels of state. Internally, we are working on a proposal for a holistic open health data ecosystem with strong data protection created in collaboration with non-industry partners.

Within our third pillar, economic framework conditions, a ban on animal testing in research is increasingly high on the political agenda. This ban is up for a vote at the end of 2021 or the beginning of 2022 and would effectively put a stop to all clinical trial activity in Switzerland. Such an extreme initiative stands a good chance of being defeated but we need to put a lot of effort into communicating the importance of animal testing. It is a part of the life sciences value chain from

which we all benefit but which is not widely talked about. Although we are making progress in terms of the Three ‘R’s – replacing, reduction, and refinement – of animal testing and digital technologies are playing a larger role, we are nowhere near a position, from a research point of view, to stop completely.

How has Interpharma engaged with the new Federal Office of Public Health (FOPH) leadership that arrived last October?

While the FOPH is still very much invested in crisis management, things are currently working relatively well. The bigger challenge is engaging with the newly installed Parliament, which has been in place for 1.5 years. Building relationships is tricky as parliament is currently closed for external visitors. Additionally, there has been a shift in the composition of the parliament with many new MPs, more of whom are left-leaning, younger, greener, and not necessarily very familiar with business. This combination of lockdowns and a new Parliament has meant that the ways in which laws are made, exchanges work, and how the Parliament works as a whole has completely changed.

The FOPH is bringing in two cost containment packages in 2021, what are your key concerns?

Costs have always been an issue and they are rising all over the world, including in Switzerland. As a wealthy country, we see the correlation between more wealth and more health spending. Obviously, we are committed to our high-quality healthcare system, but we are also very clear that this needs to be sustainably financed. Additionally, rapid and broad access to innovation must be available to patients.

The Swiss pharma industry contributes significantly to cost containment, more than any other actor in our country’s healthcare system. Switzerland’s Health Minister has stated several times that the pharma industry saves the system more than CHF one billion a year through the regular price reviews; something particularly impressive considering that pharma represents only 12 percent of total healthcare costs.

We support looking not only at costs but also at innovation. The issue lies on the access side. In 2020, only 11 percent of new innovative products were reimbursed within the legal 60-day period following Swissmedic approval. This is unacceptable for Interpharma and for patients.

The new cost containment packages are partly in the parliament, meaning that things are getting a little more complicated as the packages are being split into two.

Package One does not properly differentiate between generics and biosimilars. Biosimilars are very different to generics and we therefore believe that they should require a separate Swissmedic approval and different pricing rules. Biosimilars will come into the market more and more as patents expire, but this cannot come at the expense of safety. We accept that biosimilars reduce the cost from originals, but we are looking for a level playing field.

Package Two is more about moving from the idea of a budget to a target volume and lowest cost principle. We strongly oppose both ideas and want to ensure that broad access to innovation is secured. New payment and reimbursement models may be required to achieve this.

Furthermore, there also are ideas around introducing parallel imports to Switzerland, which have not really been seen before, other than for non-patent protected products. We strongly oppose this measure as it would allow Swissmedic to be circumvented and unapproved drugs to be brought into the country, raising questions of pharmacovigilance, safety and control. We struggle to make this point in the Parliament because many MPs see parallel imports as a significant cost reduction vehicle. In fact, parallel imports bring down prices slightly, but the biggest profit is with the parallel importers themselves, not the patients. We observe a narrow focus on cost at the expense of this measure’s broader implications.

How can patient groups in Switzerland play a larger role in presenting the unmet needs of patients in specific disease areas – and the need for access to innovations – to parliamentarians and legislators?

Unfortunately, patient groups are relatively weak in Switzerland. The strongest groups are focused on consumer rights, which are not particularly helpful on this front. Stronger patient groups would be beneficial and we need Swissmedic to speak up on this issue. Additionally, compared to the EU, Switzerland has an extremely good track record with very few medicine scandals, perhaps leading to a complacency and lack of activism.

How has Interpharma pivoted to interact more robustly with citizens and be an agent of change?

Interacting with the public is not new because Switzerland has always had a direct democracy. However, we are now starting to think about more basic campaigns, leveraging the attention that COVID-19 has put on this industry to explain our business model and put a face to pharma. Switzerland is proud of its pharmaceutical industry but there remains a public trust issue which needs to be rectified.

The country's economic performance is still outstanding, particularly compared to the rest of Europe, but we are losing some ground to the Asian economies, which is obviously a concern. Within Europe, we are following the Pharmaceutical Strategy and the EU's reaction to the crisis closely as the Union looks to boost its 'open strategic autonomy'.

The crisis has taught us that, given our industry's global character, there is a need for open borders for goods and persons. Although we managed reasonably well, stronger and more reliable international arrangements are needed to prevent border closures, allow a free flow of goods, and ensure that research collaborations can continue in the event of any future crisis. Better crisis management plans are also needed domestically.

Switzerland lacks a unified health data ecosystem. What is Interpharma's position related to this matter?

We have to make substantial progress now. On this front inter-stakeholder collaboration is crucial. There is a need for more collaborative systems all along the patient journey. Private industry has an important role and cannot be sidelined in this process; the challenges ahead can only be met with dialogue and collaboration:

The state has a pivotal role to play in infrastructure building, while private players – from pharma to insurance companies and start-ups – will get involved creating thematic or illness-specific ecosystems. To bring together industry knowhow and facilitate change, we have founded the multi-stakeholder platform santeneXt in collaboration with Swica, one of Switzerland's leading health insurers and newly welcomed Galenica to the team.

Flagship projects like this can help people understand the need to invest in the digital infrastructure and put pressure on politicians. We'vre a momentum as Switzerland's digital shortcomings have been laid bare.

How has the establishment of electronic patient records in Switzerland progressed?

Electronic patient records should have been here a long time ago. Most cantons still have not implemented them. Moreover, it remains unclear how far these records will go. The question is whether this really is the foundation for a national platform, which is what we need. National level projects are always challenging in Switzerland, as evinced by the recent shutdown of the portal that could have formed the basis for a vaccination passport due to potential security concerns. I hope that there will be enough political pressure now to really move forward. However, we must do this in a collaborative spirit and include expertise from the private sector.

Additionally, I feel that we have still not managed to adequately explain to the Swiss public the division of labour between the private actors who run these systems and the state. This has led to the public voting against the implementation of electronic identification services. Hopefully, the crisis foregrounds the need to forge ahead on digitalisation, otherwise, Switzerland risks being left behind.

Switzerland’s healthcare & life science industry seems at an inflexion point where taking the right decisions will have an impact on its innovative capacity and on patients.

On digitalisation, we are already a laggard. The Bertelsmann Foundation’s index on digital health shows that we are in a bad position compared to other European countries. Countries like Denmark with more centralised systems as well as the Baltic nations that have a more greenfield approach perform well, but so does Canada – another federalised state. Health data is essential for public health, but also for medical progress, research, and better patient treatments. Therefore, we must not only focus on the immediate costs as data and digitalisation can be used to reduce costs, improve the patient journey and facilitate research and innovation to improve the quality of the healthcare system.

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