# RenÃ© P Buholzer â?? CEO, Interpharma, Switzerland (September 2020)

The challenge for the future of innovation in Switzerland and for Swiss pharma companies in general is to once again adapt to technological changes

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*Interpharma CEO Dr RenÃ© P Buholzer outlines the holistic strategy that needs to be put in place to maintain Switzerlandâ??s leading position in innovation, market access and reimbursement challenges for new medicines, and why an open, globalised Europe is key for security of supply.*

**Could you begin by introducing your background and what drew you to the pharmaceutical industry?**

I come from the world of banking, so working in economic policy and with multinational companies is nothing new to me! Banking used to be the leading private sector industry in Switzerland, but nowadays it is pharma, so I have experience in two of the countryâ??s most important industries.

The innovation part of pharma, developing new and ground-breaking treatments, is extremely exciting. On the other side, healthcare is highly regulated and part of a complex and complicated system. Pharma is, therefore, an interesting combination between a globalised, free market, innovation-driven industry on one side and a state with severe pressure in terms of costs and social security on the other. This intersection between economics and politics, at which I have spent my entire career, is especially crucial in Swiss pharma, given the industryâ??s relative weight in the countryâ??s overall economy.

**What is Interpharmaâ??s role within Switzerland and how does it differ from those of the other main pharma industry associations and lobby groups?**

We are the association of the research-based pharmaceutical industry. In terms of membership, we are a relatively small association with 23 member companies, but these companies represent 94 percent of the innovative market in Switzerland, 50 percent of the generic market, and over 90 percent of the biosimilars market. The association is organised as a classic industry body, focused on advocacy and trying to influence the framework conditions through dialogue.

Interpharma aims to be a driving force for an efficient, high-quality healthcare system that provides fast access to innovative therapies and the best possible care for patients. Our members contribute heavily to prosperity and health both in Switzerland and globally. Another key element of our mandate is to maintain Switzerlandâ??s position as the leading pharmaceutical hub in Europe.

**Switzerland and innovation are synonymous but is that still the reality on the ground? What challenges need to be overcome to maintain the countryâ??s leading position on innovation?**

We Swiss love to complain and find fault, regardless of how well we are doing in relation to other countries. Perhaps that is why we have been able to achieve so much success!

There has been tremendous growth in the Swiss pharma industry over the last ten years and it has been a great success story across a number of metrics, from employment to manufacturing, overall economic growth â?? pharma contributed to one-third of all Swiss growth in this period â?? and exports. 40 percent of all Swiss exports are now pharma-related.

We are a highly productive industry that pays relatively good wages as our employees have above-average qualification profiles. From many different angles, we are attractive and now, with COVID-19 meaning that individual countries are becoming interested in having their own research and production platforms, we are becoming even more so.

The challenge for the future of innovation in Switzerland and for Swiss pharma companies in general is to once again adapt to technological changes. The Swiss companies have been successful to become world leaders in adopting biotechnology. In the next year to come, the business models need to exploit the potential of health data at large scale.

**What are the major challenges for your members in the Swiss market today?**

Globally, the Swiss market is relatively small with a modest growth rate of 2.8 percent driven by an increase in volume and new products. The growth rate would be higher, but it is offset by increased price pressures, which represents our biggest challenge.

Market access for innovative specialty drugs is a particular pain point; last year only 24 percent of new products were given a price within 60 days as stipulated in the regulation, meaning that our members had a large backlog of products not being reimbursed. 11 of the 46 applications were admitted within 60 days, over half took longer than 120 days and there is a backlog of 136 new active substances not yet listed on the specialty list.

The technical and medical progress that has been made in drug development is really exciting, but the reimbursement procedures have not yet caught up.

**To what do you attribute these delays in the reimbursement process and what are your proposals to address this issue?**

The Federal Office of Public Health (FOPH) would tell you that the prices the industry is asking for are too high, but that is too simple of an answer. The products and active substances most affected are the new and complex ones that require advanced procedures not yet developed by the FOPH. Of course, there may be products missing long term data or for which the efficacy is questionable, but this insecurity is inherent in new therapeutic products and breakthrough ideas.

However, we must remember that these are products with a high medical need. That is why we are proposing to move more towards value-based healthcare, where these factors are incorporated into the drug pricing models. We would like to see price models for performance and outcome to properly address these insecurities.

Another key issue is ensuring that the FOPH and swissmedic work more closely together so that the technical elements of a new drug are well understood. Because these are complex questions, we need stronger early dialogue between the FOPH and the industry so that the day after swissmedic approves a drug, the reimbursement process can begin. The 60 days currently mandated in our legal system for this reimbursement discussion should be reduced to one day so that patients can benefit from new drugs as soon as a new therapy is approved by swissmedic.

In term of drug approvals, swissmedic is relatively fast and adaptive to new technology. It is the second fastest regulatory agency globally in giving scientific assessment. The delays tend to come in the labelling phase therefore we are in discussions to improve this. It is certainly not worth losing 200 days or more just because of labelling. That is the biggest gap between swissmedic and the worldâ??s other top regulatory agencies.

**What effects are these delays having on Swiss patientsâ?? ability to access innovative medicines?**

From a patient perspective, it is not sufficient if the regulatory agency is relatively quick but then the reimbursement process is not properly handled. For reimbursement we need more early dialogue, the right experts, and procedures that allow the FOPH to begin handing out scientific advice earlier in the process, thereby potentially decreasing insecurity. We are working towards minimising conflict and finding a compromise between our need to honour innovation and the concern that society should not pay high prices for drugs that may not deliver what they promise.

The situation, worsening since 2016, is that at the end of the day the patients cannot access these drugs, apart from through the exemption rule which comes with a lot of bureaucracy on the insurance doctor and pharma side. This is unproductive and often unequal, with access depending on which canton a patient lives in or which company they are insured by. That is not the promise we gave in law to the Swiss population â?? the basic insurance should ensure that patients get the same kind of treatments, regardless of their wealth, location, or insurance company.

**Switzerland is one of the most advanced countries in Europe in terms of value-based contracts. How is this developing?**

In the European context, Switzerland is often cited as being very advanced for this type of price modelling, and we are now going even further down this route. We are curious to look around to learn what is happening in the US and other parts of Europe and to adapt this to a Swiss context. A new law proposal now in consultation would provide a legal basis for this type of price model and, while the government may perceive it as a vehicle to get lower prices, we see it as a model mitigating the insecurities and concerns that exist around new therapies.

**Does the impending change of leadership at the FOPH represent a change of direction? What impact do you expect this to have?**

It is a change of the FOPHâ??s director, but not a change of the Minister of Health (MoH). Of course, a director has some leeway to push certain agenda items forward and we hope for a more dynamic and visionary approach to shaping the environment than we have seen before, but it depends how much scope she is given by the MoH. It takes two to tango so it is premature to judge in which direction things will move, but we want to see a rapid pace of change and a greater adaptation to digitalisation, an area in which we are lacking. We have excellent infrastructure, some of the best technical universities in Europe, and a lot of IT know-how e.g. with Googleâ??s Europe hub, but our health system is not yet adapted to this.

This is part of building a stronger data ecosystem within Swiss public health. We are making some progress in terms of integrating data into pricing models and in work being done at the University Hospital of Basel collecting patient data to help create a patient-centric healthcare system. These efforts would benefit hugely from a better and more connected digital infrastructure.

Given the federal system in Switzerland whereby we basically have 26 healthcare systems rather than one, there are no homogenised electronic health records, many healthcare competencies lie in the cantons, and there are many silos. There is a pressing need for a more nationwide system on health data

Industry and academics are united in the opinion that we will never be able to compete with China and the US in terms of numbers of patients, but we still have a chance if we move quickly given our quality of data and quality of physicians. High-quality data has a lot of added value for research, the development of new drugs, and also the treatment of patients.

**Europe fares well compared to the US in terms of the homogenisation of its data, but Switzerland risks being left behind in this and in overall competitiveness, as other countries catch up. What is the message of Strategy 2030 and the wake-up call that Interpharma is trying to convey?**

We are in excellent shape overall as an industry with a great track record over the past ten years, but we should not take this for granted. Now, we are at a turning point where cards might be newly distributed as medicine becomes as much a data science as a clinical science.

To ensure that Switzerlandâ??s pharma industry retains its leading position, a holistic strategy needs to be put in place. Our proposal is built on three equally important pillars. The first is putting the patient at the centre. In our healthcare system, as in many others, patients are not as central as is

often claimed. This is about swissmedic authorising medicines as quickly as possible, making rapid and broad access to innovation at the FOPH and ensuring we get innovation rewarded.

The second pillar is about being a leader in R&D. R&D has been integral in modern Swiss history, given our lack of natural resources, so this is about an effective and strong IP system and a high-quality health data ecosystem.

The third pillar is the broader economic policy frameworks, making Switzerland attractive to companies which are in fierce competition on a global level. Here, we are talking about the recruitment of top talent, which relates to the relationship between Switzerland and the EU and immigration policy â?? a hot topic at the moment. This third pillar is also about maintaining an attractive financial environment and ensuring that companies have access to export markets, especially given the rise in protectionism amid the COVID-19 crisis. The last part is political stability and legal certainty. Historically, this has been a strength, but we have lost some ground in recent years.

**Most innovation done today and financed by Big Pharma was initiated by smaller biotechs, not something that Switzerland has at times doing less well in terms of translational science or financial mechanism via early listings or aggressive VC investmentâ?¦.**

Switzerland has no tradition in strategic industrial policy. This might be seen as a challenge but maybe also the reason why we are so successful. The Swiss philosophy is to set the framework right and let the market dynamics unfold in an environment regulated by principles rather than detailed decrees. The Government doesnâ??t attempt to know the right direction in which to go. This proved to be a successful approach for industrial development in the past but has certain downsides when a framework for cross-sectoral data-ecosystem should be founded.

Secondly, clusters are essential. We have top-notch universities, an excellent SME-dominated medtech industry, many European headquarters of pharma companies in the Zug area and at the Lac LÃ©manique and Basel is home to two of the biggest pharma companies worldwide; so there is a strong cluster. Our weakness is not so much innovation itself but bringing that innovation to market. There are some initiatives on the way to improve that, but this kind of entrepreneurial mindset and spirit is something Switzerland could improve.

**What other issues are at the top of your agenda?**

Security of supply. The Swiss industry believes in open markets and borders and the need to focus on improving framework and conditions overall, not falling into the trap of subsidising certain industries. Despite COVID-19, we have not seen shortages of supply. There have been some issues in terms of supply bottlenecks for products needed in ICUs, but overall Switzerland is doing well in a European context.

Nowadays, there is a danger of closing too many frontiers and destroying global supply chains which have overall been very functional given the extreme jump in demand back in March on which we were still able to deliver. We have to keep that in mind and understand that the market for patented products is different from that for generics, as well as from antibiotics and vaccines. These elements need differentiated solutions.

I hope that Switzerland and Europe do not fall into this trap of closing borders. That is key for our industry and for Switzerland, which has always been economically one of the most open and global

countries, which we have strongly profited from. That is why we have the talent pool and why we are home to so many international companies. In this era in which de-globalisation is growing in popularity, we have to remind ourselves of this.

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