

# Interview: Walter P. Hölzle - President, vips, Switzerland

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*Walter P. Hölzle, president of vips, discusses the current priorities of the association, the importance of innovation, and the challenges of the current pricing system.*

**While growth is close to zero for many pharmaceutical markets in Europe, Swiss pharma spending increased 4.5 percent in 2015. What would you identify as the main drivers of this growth?**

Volumes were a big driver, up about 1.5 percent last year. Just like other countries across Europe, we have demographic changes and increasing chronic healthcare needs. In part this has been driven by products in the antiviral segment for the treatment of hepatitis C which have had a significant impact on overall spending, and by the introduction of an ever greater range of innovative products which are helping to change what were once life threatening diseases like HIV into chronic conditions. There is an increased cost to treating these ever growing numbers of patients living with chronic illnesses, but one that Swiss society is happy to pay to ensure a happy, healthy, and productive workforce.

As you can understand due to demographic change the cost burden in each country is changing; I don't like to say a burden, just a question of financing a system and maybe there are some reforms necessary, but still today in Switzerland people have fast access to innovative meds and we should try to maintain that.

It is also important to note that we have had a regulation freeze for the last three years, which has been mostly positive for the industry as many prices have remained constant. However, the next round of regulations will come in 2017, given the appreciation of the CHF we expect to see a downward adjustment of pharmaceutical prices on the order of 15 percent. That will be a major cut which will not be easily offset by cuts in spending.

### **How would you say the Swiss mentality towards pharmaceutical spending differs from other countries in Europe?**

One difference is certainly the relatively high price of generics in Switzerland. As a small market, we cannot compare our volumes and purchasing power to a country like Germany. Products must also be marketed in our three official languages, and thus packaged specifically for Switzerland, and we also do not use tendering in our healthcare system – as such there are structural costs which contribute to our high price of generics. Moreover, Switzerland as a quality driven market has very much prioritized patient and physician choice, and as such it is not considered acceptable to substitute an original product with a generic that doesn't exactly match its specifications; this means 20mg tablets for 20mg tablets, and no breakable larger tablets as seen in The Netherlands.

Collectively, this contributes towards our higher generics prices, which are 50 percent more expensive than in other countries; there is certainly some room for improvement, but certainly not on the magnitude of 50 percent.

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### **There are several associations for the pharma industry in Switzerland - what is the unique role of vips?**

First, vips is uniquely focused on the Swiss pharmaceutical market and environment, and as an association we represent the interest of our members to Switzerland's market regulators. Our members range in size from startups to global mid-sized companies who have a strong presence in Switzerland – 29 of our members have manufacturing operations in Switzerland.

As such, our main priorities are to advocate and encourage fast market access, which is supposed to be 60 days at most, in terms of marketing authorization and listing on the positive list for mandatory reimbursement. Because Switzerland has a mandatory solidarity financed health insurance model, there is a mandatory list for reimbursement which all insurance providers must cover – without being on this list, getting full or partial reimbursement requires many more administrative hurdles. Of course there are regulations which must be met, but it is important that

there are no artificial delays.

More than just speed of market access, it is important that the environment remains open to and supportive of innovation, and that the pharmaceutical industry's risky investments in innovation are fairly remunerated. The life science industry really is like no other in terms of both the time and funding that must be invested before you can really determine if the product being developed is likely to be successful.

As such, we want to ensure that the hurdles to market access and pricing levels are fair from an investment point of view, as there are still some issues regarding the financing of innovation which can be improved. Tax reform is a critical issue now given our industry's investment in intellectual property, and the strong competition for investment that Switzerland faces from other European countries.

**Switzerland is already recognized as one of the most innovative countries in the world: how does vips believe the environment for innovation can be improved?**

Although we do have a strong innovation environment, there are still some issues for the life science industry in particular. First, as a federalist and fractioned country, we do not have a centralized ethical commission and thus it takes significant time to get approvals for clinical trials – some improvement needs to be made in this area.

Second, the lead time for getting new indications approved for an existing substance is too long. Unlike the FDA and EMA, Swissmedic treat applications for new indications the same as they treat new chemical entities, which is inefficient and illogical as the compounds in question have already been proven as safe!

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Finally, we do believe that the value of the innovation the life science industry brings to patients is still not fully recognized in the pricing – however, we have a new regulation that will come into place next years and as we have fairly wide support in government for our proposals, we are confident that it will incorporate the recommendations made by vips alongside the other associations.

We have encouraged Swissmedic to try to stick to the 60-day time limit for marketing authorizations, which we understand is very difficult to achieve. However, approvals have slowed down slightly over the last few years, and we need to see an improvement. This is particularly important as Switzerland is the home market for so many innovative companies, and I am a firm

believer that every company needs a strong home market. Moreover, even though Switzerland is a small market it is very important as it's a quality driven market and Swiss KOLs are often internationally recognized as well; therefore, it's important that everything in Switzerland is kept at the top end of the innovative spectrum.

**What were the association's key points of concern regarding the new pricing regulation?**

We have concerns about the current use of reference pricing and have advocated for some changes. This is an important point because every country has very different financing systems and social insurance models, and thus it is problematic to compare prices across very different systems; it is particularly improper to compare prices in a country like the UK, where there is centralized purchasing and rationing, to Switzerland which is highly fragmented and has no rationing.

As such, while we accept that reference pricing is perhaps unavoidable it is important that it not be the only component of Swiss prices. At present, the price is calculated as a weighted average of the reference price and estimated "value" of the product, with the weights being two thirds and one third respectively. We expect that the new system will feature a 50-50 weighting.

For this "value" estimate, the new regulation we have a chance to make the valuation process more predictable and assessable. At present, the Federal Office of Public Health makes what I call "HTA Light" assessment, where they look at the therapeutic cross comparisons for a new products and then trying to define the additional benefit. We have proposed that a new systemic approach be used.

Finally, we have significant concerns about our industry's current exposure to currency fluctuations, particularly given the risks related to the Brexit and ongoing financial challenges in Greece. If the Euro were to appreciate against the CHF to CHF 1.20-1.30 per Euro as we have seen in the past, then our current prices would be on the same level as Greece overnight! At present we can only decrease the prices when the CHF strengthens, while increasing requires a full assessment to be completed again. Thus, we believe the new regulation must provide a mechanism to address currency fluctuations symmetrically such that we can address the direct impact of the exchange rate on pricing, for both increases and decreases in the value of the CHF versus the Euro.

**Do you have a final message to our readers, executives across the global pharmaceutical industry, regarding how the industry can continue to bring valuable**

## **innovation to patients?**

We must continue to foster innovation and education as before, but at this point in time it is critical that we are very open to new ways of doing things, driven by digital solutions, which can speed up research and bring results to patients faster – and help to improve the efficiency of healthcare spending. Given changing demographic structures and growing number of patients living with chronic diseases, many societies are currently working to find new ways of sustainably financing healthcare expenditures, and this is putting pressure on the prices of innovative medications. Thus, it is essential that the life science industry find ways to develop new treatments more efficiently, which in concrete terms will mean decreasing the time from discovery to market entry from eight to ten years to four to six years.

This is a challenge we must address together with regulators and government, but I firmly believe that between our growing knowledge of human genetics and the capabilities for analysis offered by bioinformatics companies, we now have the ability to develop information more quickly which will allow for the faster development of new drugs while still ensuring a high level of safety for patients.

E-Health and telemedicine solutions also offer great potential to engage and support patients to improve adherence to prescribed therapies, reducing the wasteful or ineffective use of medications. Moreover, healthcare IT solutions including electronic patient records can potentially enable significant savings by reducing the duplication of diagnostic or treatment efforts – and better data collection and analysis can potentially drive significant optimizations in patient care.

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