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What our members want is a good and stable relationship with their most important trading partners, top among which is the EU

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scienceindustries' Stephan Mumenthaler outlines the business-friendly regulation necessary to maintain Swiss life sciences' competitive edge, how the country's evolving relationship with the EU stands to impact the industry, and Switzerland's progress on the road to full digitalisation and Pharma 2.0

What is scienceindustries and what agenda is it trying to pursue?

scienceindustries is the business association of the chemical, pharmaceutical and life sciences industry here in Switzerland. As such, we represent a broad array of 250 members, mostly in terms of political advocacy and lobbying. We also provide services that facilitate business such as advice on exporting, guarantees, and some social insurance schemes. The majority of our work takes place at the federal level, but we also get involved with cantonal issues from time to time.

What items are at the top of your agenda in the short- and medium-term?

In general, our members need business-friendly regulation that helps to maintain the competitiveness of our industry. Switzerland is a direct democracy, meaning that big political issues are regularly put to a popular vote. The political system in Switzerland has so far proven its

worth, not least from an economic point of view, for the benefit of everyone. However, such a system is also a constant challenge. For example, the issue of bilateral agreements with the EU which affect the free movement of labour has been keeping us busy for the last few months and will come to a vote at the end of September 2020. Another example is the referendum about the Responsible Business Initiative RBI is scheduled for the end of November 2020. We stand behind the spirit of initiative. Paying attention to compliance with human rights in particular is commendable.

However, we are concerned about the implementation of the proposal. If approved, the RBI would introduce internationally unprecedented liability clauses in Switzerland for actions that companies have done abroad. A flood of legal cases – not infrequently initiated frivolously – would be expected. That's why scienceindustries is clearly against this initiative and supports the counterproposal of parliament which is aligned with international standards.

How might this bilateral agreement with the EU affect Swiss life sciences and what outcome would scienceindustries like to see?

It is a whole package of bilateral agreements that regulate the most important aspects of the relationship between Switzerland and the EU. One of these is the free movement of labour, which has made access to talent in both directions a lot easier. Many companies have important international operations, research centres, and production here in Switzerland, for which they need talent from all over the world and especially from the EU. These companies often have to send their employees, including Swiss nationals, to affiliates in other countries, both in Europe and beyond.

However, this bilateral agreement is also about the regulation of market access. It basically gives Switzerland full access to the European common market, not only in terms of zero tariffs but also in mutual recognition agreements, and all the norms that regulate trade.

The third part that is important to our industry is European research cooperation. Within the framework of the bilateral agreement, Switzerland has been able to access common European research programmes.

With the UK's exit from the EU now confirmed, a precedent is being set of an outside country entering into trade agreements with the EU. Is Brexit worsening the

possibilities of Switzerland being able to agree a beneficial trade agreement with the EU?

It has not yet had an impact. However, we are in the middle of negotiating a longer-term institutional framework agreement for our bilateral relationship and it is quite clear that the EU is very wary of giving Switzerland any advantages in this relationship that they would not want to give to the UK and vice versa. That makes negotiating quite difficult. Also, the EU's negotiating capacity is fully absorbed by the UK which does not leave a lot of time for other issues.

Is this tension and uncertainty hindering how Swiss companies are able to operate today?

It is not yet damaging to Swiss companies, but you can feel the insecurity rising. For example, there is a mutual recognition agreement in the medtech area that was scheduled to be renewed and modernised by Spring 2021 but, currently, it does not look like it will be finished in time. This coupled, with a new institutional agreement that is also not in place yet, does not hamper the current relationship but brings a little insecurity about the future relationship.

During this process, scienceindustries has presumably made strong recommendations to the government, what were they?

The main recommendations are really basic – what our members want is a good and stable relationship with their most important trading partners, top among which is the EU. We have made a lot of effort to explain this, not only to the Swiss government but – given our direct democracy and the fact that the Swiss population regularly has to vote on these topics – also to the population at large.

What are some of your longer-term concerns for the future of the Swiss pharma industry?

One of the big challenges for the future which cannot be underestimated is digitalisation. Switzerland, like every country in the world, has to think carefully about how it deals with data, creates access to data, and allows the free movement of data.

As Switzerland moves towards Pharma 2.0, where data will be more important than it already is, regulatory challenges will increase, as they will for the EU and US.

Where does Switzerland sit in relation to the US – whose fragmented healthcare system means that a lot of patient data is siloed – and the EU – where data is more harmonised thanks to its largely universal healthcare systems?

Switzerland is currently somewhere in-between the two. Compatibility in data exchange is one of the important aspects to deal with in our relationship with the EU, then afterwards with the rest of the world. A balance needs to be struck between the protection of individual property rights and data protection on one hand and making the data available for use in an efficient and timely manner on the other.

Although the Swiss people have been relatively pragmatic in terms of their approach to the handling of personal and healthcare data up to now, maintaining this balance is going to be a huge challenge moving forward. There is a certain ambiguity on an individual level – people will generally vote for strict data protection but then be willing to part with a lot of personal information on digital platforms if they see a potential benefit. The challenge for the industry will be to show that benefit exists in order for people to relinquish a certain level of data privacy and make the use of this data on an aggregate level possible

Where is Switzerland on the road towards Pharma 2.0 and digitalisation?

According to various comparisons, Switzerland is not doing too badly in regulatory terms regarding digitization in the healthcare sector. However, problems arise in the effective implementation of specific projects. On the one hand, this is due to the federal structure of Switzerland with its 26 health systems. Moreover, a lack of technical standards with regard to the electronic patient record also plays a role. The large number of actors in the health care system from the cantons to hospitals, doctors, pharmacies and health insurers does not make the project any easier. In addition, an obligation to introduce such a dossier was approached too late and there is still a lot of persuading the patients to be done. All these factors pose a challenge in terms of data collection and data compatibility and means that there is a lot of work still to be done.

In recent years, Switzerland has fallen slightly in the global innovation, competitiveness, and intellectual property (IP) protection rankings. How do you see Switzerland's global position today?

We can still be very satisfied as a country. scienceindustries has just commissioned its own competitiveness study with one of the leading Swiss economic thinktanks, creating, for the first time, a global industry competitiveness index. The results are quite remarkable – Switzerland comes in second, only behind the US, and before Ireland. Switzerland is especially strong in innovation and new technology. The signs are still good, but we do not want to rest on our laurels, which is why we are continuing to work to improve framework conditions. If you stand still, you fall back.

What adjustments on either market dynamics, regulatory frameworks for R&D, or the incentivisation of investment will be needed in the next five years?

It depends on which level we are talking about. On the overall level, research cooperation with the EU will be a crucial component. At a pharma industry level, accelerated market access for drugs – which is related to research – will be key. Switzerland already has a very extensive network of free trade agreements (FTAs) but we still must work to extend and modernise it, in particular in terms of IP protection. For example, we are currently trying to finalise an FTA with the South American trading bloc MercoSur, the member countries of which are notoriously difficult to navigate in terms of IP.

Swissmedic lags slightly behind the European Medicines Agency (EMA) and the US FDA in terms of the number of days taken to approve innovation, do you see this as a serious issue?

We are in extensive dialogue with Swissmedic and, from a scienceindustries perspective, they have made a lot of progress. Although there is still a way to go to achieve the final goal of positioning Swissmedic as a first-wave-agency, we are confident in seeing further progress here. The more virulent problem is getting an adequate price for the therapies from the Federal Office of Public Health (FOPH) in a reasonable timeframe. These dialogues take much longer than they previously did and represent a significant headache for our members.

Switzerland is one of the world's richest countries in terms of income per capita. In such a market, is the battle over pricing justified and understandable in Switzerland?

Both the industry and the pricing body want to get as good a deal as possible – that is human and perfectly understandable. Health costs are a challenge in all wealthy economies and industry must be constructive in finding solutions. The Swiss pharma industry has contributed significantly with more than a billion francs savings in the last few years, which has to be acknowledged. What we miss in Switzerland is real value-based pricing. The FOPH needs to remember that the products under discussion are often lifesaving medications, these in therapeutic areas where we had no cure at all, so far. They often make treatments much more effective and leads not only to higher quality of life for patients but also relieve the general public, for example by reducing or even preventing lost work. There is an urgent need for introducing new pricing models which take the full value of innovative therapies into consideration to maintain access for patients in Switzerland.

Switzerland is known as home to Big Pharma giants such as Roche and Novartis, but how would you characterise the environment for start-up biotechs here?

There are some good examples of biotech success stories in Switzerland such as Actelion, which was originally a spin-off from Roche and became a big attractive company in its own right before being acquired by J&J for a significant amount. Another example is Moderna which is leading on COVID-19 vaccines and investing in Switzerland with the recent announcement of additional jobs at his European Hub in Basel. We have a very vibrant ecosystem with high levels of competitiveness and good prospects for biotechs.

How can Switzerland compete with giant markets like the US and, increasingly, China?

This is certainly a challenge, but the domestic market is only one of many parameters. An attractive home market is important, but innovation, openness, smart regulations, functioning infrastructures and reliable legal security are just as important for a small economy. That is why we are just as committed to all these concerns as we are to a small but attractive home market.

How do you hope for Switzerland to maintain its competitive edge?

Competitiveness is like a puzzle; many pieces have to fit together to be successful. To name but a few of the most important pieces:

- Protection of Intellectual Property in general, especially patents and related rights
- Conclude further free trade agreements, but only with sufficient protection of intellectual property rights
- Advancing the digitization (esp. in the healthcare system) not least by securing a modern and internationally compatible data protection regulation
- Maintain optimal conditions for the production of innovative goods in Switzerland
- Safeguard a highly qualified and internationally competitive university research and foster an active exchange with the industrial research to drive innovation in general
- Accelerate market access for drugs which also attracts more research activities
- The industry is committed to high international standards, but calls for uniform implementation, as in the example of the Responsible Business Initiative mentioned in the beginning.

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