Vincent Gruntz â?? General Manager Oncology, Novartis Pharma Switzerland

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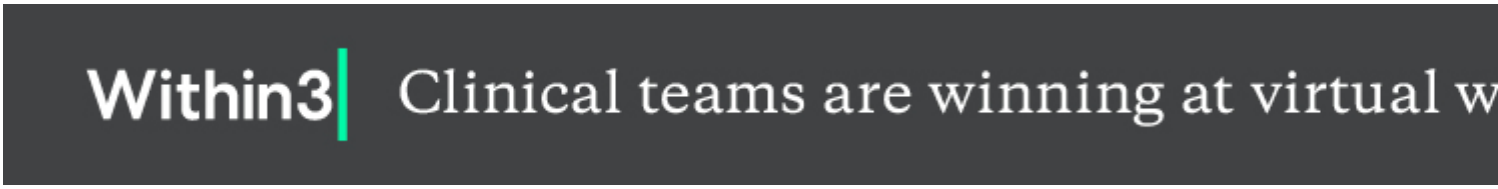
Vincent Gruntz looks at the market dynamics for oncology in Switzerland, where an increasingly cost-conscious approach is being taken to reimbursement and pricing, his experience of bringing CAR-T therapies to the country, and the challenges and opportunities of â??virtualâ?? product launches.

Can you begin by introducing your career trajectory up to taking on the general manager role for Novartis Oncology in its home market of Switzerland in 2019?

I am probably one of the few Basel natives working at Novartis, but today live in Bern with my wife and two young children. Having studied business and economics at the University of Basel, I started my career at the Swiss Federal Office of Public Health (FOPH) before moving to Novartis Switzerland, which at the time was based in Bern, in 2008, working in market access and public affairs.

I worked through several commercial and market access roles at Eli Lilly and then back at Novartis. Although at the time, I did not necessarily understand how important having a background in both of these fields was, I benefit a lot from both in my leadership role today. Before taking over Novartis Oncology Switzerland in autumn 2019, I was responsible for the Cardiovascular & Metabolism

business commercially in Europe, a position which included overseeing the launch of a new heart failure drug, a real success story.



What is the logic of having a dedicated general manager for Novartis Oncology in advanced markets like Switzerland?

More and more companies are today moving in this direction. Novartis was quick to notice that oncology is not only one of the biggest disease areas, but that it is also one of the fastest-growing. We built a completely independent and agile unit around oncology, which uniquely positions us to engage in long term and sustainable partnerships in this disease area; a real strategic advantage.

Having come from a role in the broader Novartis Pharma unit, what has surprised you in terms of how the Oncology division is organised and operates?

After more than one year at Novartis Oncology, I feel the focus that we can have on one disease area and one customer group allows us to be a sustainable and long-term partner. I also believe that having a unit built around oncology allows us to adjust our business model very quickly to the dynamics of oncology today, whether around market access or the â??beyond the pillâ?? requirements of our customers.

Even though innovative products remain our core value proposition, coming with innovation alone is insufficient in todayâ??s world. We must partner along the entire patient journey with additional services, diagnostic support, and evidence generation. The oncology unit has the agility and speed to respond to customer needs.

What are the market dynamics for oncology in Switzerland and how have they played into your mandate and objectives?

With the recent acquisitions in the field of radioligand therapies, Novartis Oncology is now uniquely positioned to deliver and develop innovation across all four technology platforms in the oncology space; that is radioligand therapies, targeted therapies, immuno-oncology therapies, and cell and gene therapies. To my knowledge, no other company can boast all four platforms in house. This gives us the unique opportunity to explore a combination of these platforms in the future and potentially realise our vision of one day curing cancer.

Looking at the specifics and trends of the Swiss market and their influence on strategy and objectives, firstly, market access is becoming more difficult. This is coupled with customers that must deal with increased budgetary complexity and who have less time to speak with the pharmaceutical industry. There is therefore a clear need to adjust our go-to-market model â?? including increased use of digital tools â?? to be future fit. Another key trend is the increasing importance of partnerships; going beyond delivering a product alone will be critical in the oncology space.

A final priority is adjusting our culture to the needs of our current and future employees. This means that â?? beyond all the strategies and products â?? believing that our employees can truly make a difference. We need to create an environment where they feel appreciated, motivated, empowered to come up with their own ideas, and willing to take ownership of them. This cultural shift started a couple of years ago with the rollout of the â??unbossedâ?? strategy and has influenced all our interactions; both internal and external.

Our working culture is now better known than ever before, and I am increasingly being approached by external talent interested in coming to work for Novartis. We have a flexible approach to remote working, which will continue after the pandemic, and have done away with a ratings system for employees in favour of more meaningful discussions around performance. The trust that we place in our employees can also be seen in the fact that besides the usual maternity leave, we also grant fathers 18 weeks of parental leave â?? more than any other company in Switzerland. This culture and mindset set us up well for a successful future.

The right culture needs to be supported by the right solutions. To what extent is the fact that Novartis Oncology has all four technology development platforms in-house appreciated by external stakeholders?

The breadth of our pipeline at the cutting-edge of oncology innovation gives us a variety of touchpoints as well as a great deal of flexibility when talking with customers and payers about potential solutions. This being said, what really counts for patients is the impact that we can deliver with the product, regardless of which platform is used. However, we truly believe that having these four platforms in-house will allow us to come up with solutions that would not be possible using one platform alone.

What has changed from a market access and reimbursement perspective in Switzerland, where the FOPH seems to be embracing a much more cost-conscious model?

Firstly, the fact that we have our own regulatory authority represents a unique opportunity for Switzerland. Before reimbursement at the FOPH comes approval from Swissmedic, which has done tremendous work on innovative approval pathways. Swissmedic has also started to work with regulatory authorities in other jurisdictions on faster processes that allow Switzerland to often be among the first markets to receive new Novartis innovations.

The bottleneck lies in the reimbursement and pricing discussions with the FOPH, where the pragmatic reimbursement system in place â?? which was good in the past â?? is not future fit. This system is based on international reference pricing and comparisons of innovation with existing therapies in the market. In oncology, this can mean comparing old chemotherapies with new innovations like cell and gene therapies, which is simply not applicable or sustainable.

Unfortunately, while Switzerlandâ??s approval speed is very fast, a recent study from the University of Zurich shows that we are falling significantly behind with reimbursement and access. Some drugs, two or three years after approval, are still not reimbursed nationally. While some patients can gain access via the â??Article 71â?? mechanism that allows for case-by-case discussions with the insurer, with approx. 50 health insurances in Switzerland, access inequalities are being created. This runs counter to the stated aim of Swiss social healthcare insurance: equal access for all insured people in Switzerland.

On a positive note, Switzerland is still an environment where there is good stakeholder access and a culture of discussion and collaborative problem-solving. For us as a pharmaceutical company, we also feel a responsibility to come up with solutions and be open to risk-sharing and pay-for-performance agreements. Discussions around new legislation that would give the legal basis for a new pricing model are underway and we are very keen to engage in them. Our hope is that the FOPH does not look at this regulation as a pure cost-containment measure but tries to find a balance between managing costs and finding fair compensation for the additional value that an innovation brings to the market.

Is there a need for a separate, more elevated, HTA authority in Switzerland to help solve some of these problems?

There are different ways to achieve the same goal. In essence, we want patients to have access to new treatments as of day zero of approval, as in the US and in Germany. Additionally, the price of a new innovation should be linked to the additional benefit that it delivers to the market. It should not necessarily be linked to that therapyâ??s price in another country or the price of an older therapy. Transparency is also key, as is the possibility to plan. Too often we only know how the FOPH is assessing a product the moment we hand in the dossier. That is too late for us to adjust our studies and generate the kind of evidence that the FOPH wants to see. A platform for early dialogue, as seen in Germany and the UK, is needed in Switzerland.

If these principles are fulfilled, I believe that the pharmaceutical industry is ready to provide all the evidence that is required to do these HTA assessments and is even willing to engage in risk sharing and taking on part of the costs if the data provided is not yet mature enough.

What has your experience with bringing CAR-T therapies to Switzerland been? Are there any challenges particular to the Swiss context?

We are all still fascinated and touched by the impact that cell and gene therapies can have on patients, very often as a last resort. Once you have seen a patient â?? that without receiving a cell and gene therapy would have died within months â?? doing well, it has a huge impact on your perspective on the technology.

In Switzerland, we have a leading position in terms of research, production â?? especially with our new facility in the north of the country for our CAR-T therapy â?? as well as patient access, as Switzerland has one of the highest densities of centres certified to treat patients with CAR-T therapies worldwide.

However, the CAR-T therapy story has shone a light on the challenges that exist in Switzerland. Swissmedic gave fast approval but having submitted the reimbursement application for the CAR-T therapy as a drug, we were then made aware during the process that it needed to be applied for as a medical service. This requires a very different route. Therefore, we had to find a solution, together with all the health insurance companies and the individual hospitals, which was extremely time consuming and difficult.

Finally, we were able to find the reimbursement solution for 100 percent of the Swiss population in 2020, of which we are very proud. However, it was clear to see that the Swiss reimbursement system was not ready for CAR-T therapies. Although there was a lot of public debate about the price, I would say that our CAR-T therapy has a very good cost-effectiveness ratio. I am convinced

that given the value that it generates as a one-time application, it is clearly cost-effective.

It will be difficult for a single company to move the dial on cell and gene therapies. Are you advocating for greater collaboration with other actors in this area to mould a more conducive ecosystem?

Given the competition laws in Switzerland, there is a very limited possibility or willingness to align with our competitors commercially. However, given that we are based in Novartisâ?? home country, we want to be in the leading position when it comes to solution generation. We are not sitting around waiting for others to come up with a solution but instead taking the lead. Through our trade association, Interpharma, we are creating a more sustainable environment for all upcoming innovative therapies.

With more competitors entering the market, I expect cell and gene to become a much more competitive environment in Switzerland in the coming years. We hope that with our Swiss manufacturing site, our leadership position on access and reimbursement, and our beyond the pill services now well-established, Novartis will continue to differentiate itself as the partner of choice in Switzerland

How strong are patient groups in Switzerland in relation to Europe and the US and what role do they play?

At Novartis Oncology, we believe that the patient voice â?? through patient associations and groups or via patients directly â?? should be much more embedded in both the regulatory and access and reimbursement processes. However, this is currently not happening enough. The history of patient advocacy groups in Switzerland is different to that of, for example, the UK but there are well-organised and large groups like Krebsliga. It is important that we continue all together to make sure that in the future, patients can access innovation faster in Switzerland.

Recently, a lot of effort has been put into the Article 71 health insurance process that often gives patients the possibility to access our innovation where there is not yet national reimbursement. There, we have been working a lot with different stakeholder groups including the patient advocacy groups, especially to introduce more expertise into the health insurance assessment. Today, a request from an oncologist to get a therapy funded by health insurance is often assessed by GPs without the right expertise. With the complexity of the oncology environment, it is very important that these complex requests are answered by neutral but well-educated expert boards.

Can you talk us through the challenges of launching Piqray virtually in the middle of a pandemic? To what extent was the â??unbossedâ?? Novartis culture a benefit during this period?

Firstly, this was our first fully virtual launch, and it has been a real success story. This experience has taught us new ways to engage with our customers and will have a strong influence on our go-to market model in the future.

Secondly, I would say that the unbossed culture was our only route to success during this period. At the core of unbossed is trust in, and accountability of, our employees. This allows them to take

responsibility and ownership of their ideas. My job as a general manager is not to micromanage every minute of my employeesâ?? days. The talent at Novartis is truly incredible and putting limitations around such people is just wasted potential. Once you give them space and trust, they will thrive.

We are still constantly experimenting with new ways of organizing ourselves. For example, in one unit, we have been cancelling all our meetings and replacing them with new virtual platforms. On these platforms, employees can share their ideas and read other peopleâ??s ideas when they have a spare moment. Experimenting with totally new ways of working and engagement helps to create excitement and a sense of belonging.

Although there are limitations in some areas and we are looking forward to seeing each other again, many of the things we experienced through this virtual launch will remain post-pandemic.

What then are the disadvantages of virtual lunches?

When I see people virtually, I do not get a good sense of what is happening before and after the moment they appear on the screen. As human beings, a lot of communication happens between meetings and therefore connection and trust, both within our teams and externally, can be built more quickly face to face. We are lucky in that we have very established relationships with most of our customers, but if we did not have these relationships and were launching in totally new area things would be more challenging.

What message would you like our audience to take away about Novartis Oncology in its home market of Switzerland, where there are very high expectations?

Primarily, we want to be the partner of choice, partnering beyond our innovative oncology products. Secondly, we also want to be the employer of choice. Triggering the right mindset shift among our employees and providing them with a culture where they are empowered to come up with, and follow up on, their own ideas will allow us to achieve our goals. I want to lead a team of entrepreneurs, developing themselves and taking on responsibility.

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