

Katharina Gasser - Managing Director, Biogen Switzerland & Chair of the Executive Committee, Interpharma (October 2020)



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08.10.2020

Tags: [Switzerland](#), [Biogen](#), [Neuroscience](#), [CNS](#), [Strategy](#), [Access](#), [MS](#), [Rare Diseases](#), [Interpharma](#)

Biogen Switzerland's Dr Katharina Gasser outlines how the company's 100 percent commitment to neuroscience helps it to stand apart, why Switzerland will continue to play a vital role in Biogen's global clinical research footprint, and some of the country's market access and pricing challenges. Dr Gasser also highlights Biogen's burgeoning biosimilars portfolio and the importance of diversity in the workplace.

Katharina, you are one of the few pharma country managers with a background in Medical Affairs. Can you give us a brief overview of your career trajectory?

I am a trained physician and spent several years working in hospitals before moving into clinical research as an investigator, where my love for clinical trials was awakened. At that point I then decided to move into the pharmaceutical industry, working in both large and smaller companies active in several different fields and in a variety of roles, from medical affairs to commercial and back. This broad range of experience gave me a foundational knowledge of the entire value chain - from drug development to medical affairs, commercialisation, and market access - and helped me get to where I am today.

What were some of the challenges in moving from specific technical roles to general management?

When moving into a managing director role, you are faced with so many things at once that it can be overwhelming. As the external face of the organisation, you are expected to deal with both the broad political topics and sometimes you are required to go into details. It is important to prioritise, which has been a challenge.

Additionally, Biogen has been on a journey of transformation, from being a company focused on multiple sclerosis (MS) to a company delivering and developing molecules in many different disease areas within neuroscience as well as offering a biosimilars portfolio. Setting up the affiliate to ensure that we had the right skills, backgrounds, entrepreneurial mindsets, and curiosity within our team took time. However, the team we now have in place from top to bottom is well equipped to continue this journey, move into new disease areas, and broaden our horizons in neuroscience.

We are happy and proud to be pioneers in neuroscience, but our pioneering work also requires us to keep pace with an increasingly ambiguous and changing environment to ensure that patients have access to our breakthrough therapies. COVID-19 has hastened our digital transformation and forced us to rethink how we engage with stakeholders, what our go-to-market models look like, and how we meet physicians' needs. We have a fantastic opportunity to learn more, drive change, and be disruptive, bringing an innovative mindset to all our everyday interactions.

While several other companies have divested or scaled back their neuroscience investments, Biogen has doubled down on the field. What are the risks of taking on a role in this space and how do you portray the company's value proposition to stakeholders?

I worked in companies with much broader portfolios and being 100 percent neuroscience-focused may be perceived as risky but the passion of our development and clinical teams to bring neuroscience forward and create new treatments for patients with high unmet medical needs is truly inspiring. There are so many unknowns and research questions to be tackled when it comes to the brain and neuroscience. This is a challenge, but also fascinating.

The brilliance of Biogen's strategy is that it is highly scientific, interesting, and bold. We have had to deal with several setbacks over the past few years but also successes. Neuroscience is at the

beginning of a new decade which will hopefully bring new treatments for many underserved patients suffering from a neurological disease. The field is at a similar stage in its development to that of oncology in the 1990s, where not a lot of new innovation was coming through for patients, but which exploded thereafter.

Finding the right people is a challenge as we are not a big company and have limited resources. We have to play it smart and find people with the right mindset. For me, the most important thing I look for in our staff is that they think like entrepreneurs and treat Biogen as if it was their own company; driving it forward, carefully weighing up where investments go, executing all of their activities flawlessly, and bringing passion to everything they do. We need people that are bold enough to try new things and who do not give up when things get challenging and always stay curious.

How would you characterise the environment around neuroscience in Switzerland today?

Neuroscience in Switzerland is, in general, no different from other European markets or the US. What is different is the strong competition from the two major Swiss pharma companies that also have a neuroscience portfolio. Other companies working in Switzerland, such as Biogen, feel that they are on those companies' turf. Therefore, given this competition, the Biogen Switzerland team needs to deliver even better execution.

Switzerland also has a keen scientific community and engaged medical experts who are important in the clinical trials we conduct here. The participation of Swiss sites in trials across our pipeline is important for us as it proves that even though the Swiss domestic market is not enormous, Switzerland is still very important in our global research footprint.

One would assume being 100 percent neuroscience focused may be a competitive advantage for Biogen when it comes to talking to key opinion leaders (KOLs) and practitioners?

It absolutely is. Biogen has been a pioneer in the treatment of MS and spinal muscular atrophy (SMA) and, in both of these disease areas, was the first company to introduce molecules that change the course of the disease and therefore the life of patients. This has also led to the possibility of liaising with medical KOLs, bringing science to them, having a long-standing

exchange, and becoming a trusted partner. Any exchange comes down to trust and Biogen, as a company that came into neuroscience, decided to stay, and will continue to be there, has gained a lot of trust over the years.

The competition that exists in the Swiss neuroscience market is good for patients, who have a broader range of molecules to treat their disease. From a patient perspective, this situation should occur in all disease areas. Competition also pushes us to offer a more holistic range of solutions and services beyond the pill, such as our 'Cleo' app, which allows patients to get more information on their disease, track it, and interact with their healthcare practitioner (HCP).

Biogen has a rich pipeline in Phase I, II and III clinical trials, as well as drug repurposing. How have you championed Switzerland's role to actively be part of the company's clinical development plans?

Switzerland was already an important part of the company's research strategy, but I keep pushing for an even greater role. Although clinical development is not something strictly under my remit, we work closely with our colleagues in that department, and I remain outspoken to ensure that clinical trials stay here in Switzerland. With our international headquarters based here in Switzerland, as well as our international manufacturing site, we are keen to continue to have a strong clinical development presence.

Our medical affairs and clinical development teams communicate frequently about new disease areas and our medical science liaisons (MSLs) reach out to key medical experts to better understand the landscape. Often, this landscape is very specific and in rare and ultra-rare diseases there are not so many experts.

How has COVID-19 accelerated the uptake of digital tools, not only in traditional patient apps but towards more integrated solutions?

COVID-19 has shown us that new tools are needed in situations where patients cannot access their HCPs or clinics as easily. Telehealth will help physicians to better interact remotely with patients, but they also need the kinds of tools and information that we, as a biotech company, can provide. By better listening to and integrating the needs of patients - especially those suffering from rare diseases - we can provide new or adapted solutions to help their caregivers and physicians. Listening to patient associations and finding ways to partner with them so that the patient voice is

amplified in all our decision making and initiatives can help. However, this is a difficult task for which there is no silver bullet.

Scientific information is key for any HCP to take a well-grounded decision on how they want to treat their patients. With this in mind, Biogen's Neurodiem platform has already been rolled out in other countries in Europe and there are plans to do the same in Switzerland. Neurodiem is an unbranded neuroscientific information repository for physicians, which has been extremely well received.

Recent Swissmedic reform aims to accelerate approval timelines, but the market access process is frequently delayed, reimbursement is not clear, and discussions with the Federal Office of Public Health (FOPH) cause delays. What is your take on this and how does it impact how Biogen can operate in Switzerland?

What we fight for, together with Interpharma and other organisations, is for reimbursement to be given as soon as marketing authorization is granted. All patients that need innovative new treatments should be able to access them, but that is not the case in Switzerland today. There are significant delays in the reimbursement process and, at the end of 2019, there were 136 dossiers that had not yet led to a reimbursement. Since 2015, there has been an increase in those that are not being taken care of in the usual 60 days, which leads to delays for Swiss patients.

Through Interpharma we are in close dialogue with the FOPH and other stakeholders and work jointly on several initiatives as well as a new patient access scheme. A forthcoming change in leadership at the FOPH may have some impact in how quickly any updates are made, but the fact that market access is so slow here cannot be allowed to continue. Article 71a-d KVV - where on a case by case basis pharma companies can negotiate a treatment for individual patients with their health insurance provider - provides a possibility for earlier access, but this is not always fair to patients as it depends on the openness of individual health insurance providers to such a scheme.

Such a model has the potential to flip the entire Swiss healthcare system to something akin to that of the US - where companies are forced to be part of a "payment" system to alleviate patients' pockets and ensure their products reach the patients....

That is not what we want. Earlier dialogue with the FOPH about the molecules we have in late-stage development would not necessarily lead to marketing authorization but would lead to better understanding. The FOPH, like all stakeholders, needs to quickly get up to speed with new

treatments, therapies, and approaches.

We are also strongly suggesting that experts look into those dossiers and that the FOPH reaches out to these experts even more. Then we stick to timelines that will help everyone involved and build a good legal framework with clarity on how to manoeuvre and ensure earlier access. Interpharma and its member companies are open to discussing new price schemes and price models. There is not one way to approach this issue. However, this process needs to be sped up.

How has COVID-19 affected your operations in 2020 and what are your expectations for Biogen Switzerland in 2021?

2020 has been a challenging year across all industries. Most of Biogen's treatments, such as Spinraza for SMA, have to be applied in the hospital setting, meaning that if fewer patients are going to hospitals either because of reduced capacity or through fear of catching COVID-19, it will have an impact. Ensuring that all patients that are suffering can get their treatments on time has been, and will continue to be, a challenge on which we need to focus. 2020 will therefore not be a big growth year for Biogen Switzerland, however, our industry has not been as badly affected as many others.

Next year may also be challenging due to a sharp focus on healthcare budgets, a potential second wave of COVID-19, local lockdowns, and a reluctance or delay in investing in innovation. We must continue to work so that non-COVID-19 patients are not forgotten.

Might this be the moment for greater biosimilars adoption in Switzerland?

Biosimilars are a fantastic means to ease healthcare budgets and free up more money to be spent on innovative treatments. They are produced at a state-of-the-art level and differ greatly from generics in terms of the approval process and clinical studies. I am extremely happy that Biogen has moved into biosimilars, contributing approximately EUR 1.8 billion of healthcare savings in 2019 across Europe to fund other innovation.

Moving forward, as more biologics lose patent, wider biosimilar uptake will help more patients and companies like Biogen will move into new disease areas with new innovative treatments. It is a win-win-win for patients, those who work on innovation, and the payers.

Bringing biosimilars to the Swiss market was one of my initial remits. When I joined Biogen two years ago, we had no biosimilars on the market in Switzerland. With our global biosimilars lead Ian Henshaw I worked on an acceleration plan and, together with Samsung Bioepis, in a short amount of time we were able to build a very strong team and gain two biosimilar approvals. The first, in 2019 was Benepali (Etanercept), the first biosimilar of Enbrel, and the second, in July 2020, was IMRALDI, our adalimumab biosimilar referencing Humira.

What do you see as the importance of diversity in your leadership team at Biogen Switzerland?

I am a strong believer in diversity. Having people from different genders, places, and backgrounds and with different mindsets, work and life experiences leads to excellence in execution and performance.

Gender is a topic that has been close to my heart for many years as I have always worked in male-dominated environments, especially in leadership teams. Although pharma and biotech is probably more advanced than other sectors, I am a strong believer that we should work hard to foster an environment where more women can reach top-level roles and where there is no bias in terms of promotion and hiring.

I did not set out to create a female-dominated leadership team, but I was open to meeting a broader spectrum of candidates. We picked the candidates best suited for the positions, which happened to mean that 70 percent of our leadership team were women. Recently, Biogen Switzerland was voted the national leader in terms of the representation of women in leadership by DOIT-smart / Gender Diversity Consulting. This does not mean that we are any better than other companies but our diversity in terms of gender. We also have people with very different backgrounds and nationalities which makes working for Biogen a lot of fun and brings me a great amount of energy.

I am also a board member at Advance, a gender equality in business association with over 100 member companies in Switzerland, where we drive gender equality, which still has a way to go in our country. The University of St Gallen's annual Gender Intelligence Report, which looks at women in leadership across a very diverse set of companies, found that 18 percent of top management were women compared to 49 percent in non-management. This means that potentially 30 percent of talent gets lost on the way up.

Advance has been working on that and, at a CEO breakfast I attended a few weeks ago, 30 business leaders across many different sectors committed to ensuring that there is a gender balance from the bottom up and drawing more heavily on female talent to make their companies more successful. Without setting quotas, gender diversity has to be implemented on every level – something Biogen has long been committed to.

Where do you hope to take Biogen Switzerland?

Biogen is, and will remain, committed to unmet medical need in neuroscience. We will not rest until we can bring innovative treatments for neuroscience to patients. This has been in our DNA since our foundation – two of the company founders were Nobel Prize winners 40 years ago.

Our state-of-the-art Swiss manufacturing site will provide good manufacturing capacity for innovation and help us to remain at the forefront of innovative treatments. We will continue to fight for a good, healthy environment where we can drive research, innovation and attract talent to Switzerland, foster an attractive way of working, and find ways to bring innovation to patients as early as possible after marketing authorisation.

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