Pierre Morneau â?? General Manager, Takeda Switzerland

> The environment is shifting at a more rapid speed than ever before. Past paradigms are obsolete

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Pierrre Morneau of Takeda Switzerland explains the therapeutic areas at the core of the company, equitable access, the Swiss framework for rare diseases, and the major challenges he is dealing with today.

Having worked across Europe and the US, what were your first impressions of Switzerland?

I have been really impressed by the level of education across Switzerland. There are many PhDs here who are very engaged and have high levels of motivation; it is an excellent place to recruit high-quality talent.

The Swiss healthcare system and its quality are overall on a very high level.

What therapeutic areas are at the core of Takeda in Switzerland?

Our focus is on gastroenterology (GI), oncology, neuroscience, and through the acquisition of Shire, we are a global leader in Rare Diseases. Rare Diseases will remain one of our core focus areas in future: we have approx. 20 compounds with an orphan designation in our pipeline.

How have you had to adapt and channel your resources to serve this diverse portfolio?

We need to adapt to individual models within therapeutic areas. It is impossible to manage GI, which requires many resources and a broad spectrum, in the same way as Rare Diseases, for which there may only be a few patients across Switzerland. Different business models are needed within the organisation to cope with the needs of patients and customers.

Equitable access is very important, and we are investing many resources in getting treatments to patients. Switzerland still has a pricing and reimbursement system geared to giving access to drugs that have gone through large-scale randomised trials, like our mature GI portfolio. This is not the case in Rare Diseases where only limited data exist. Thankfully the Article 71 system allows for early access for individual patients to some rare disease treatments. However, Article 71 also has the potential for inequality built into it as cases are decided on a case-by-case basis and the health insurance that the individual holds determines whether or not to grant access to the treatment.

How does the Swiss framework for Rare Diseases need to change?

In the US, once a product received FDA approval, it can be accessed immediately. In Germany, the situation is similar, where access is granted following EMA approval, while France also guarantees early, universal access via its ATU system for innovative drugs. The pricing negotiations in all three countries are then discussed, but the patients do not face access delays during this period.

However, although Article 71 does grant some access, it is not universal and creates discrepancies and inequalities as the decision lies in the hands of the health insurance companies.

Who will be the agents of change to create a more equal access system for Rare Disease treatments in Switzerland?

Along with other members of Interpharma, we are calling for a system that draws from those abroad like France and Germany: once Swissmedic approval is granted for innovative drugs, they should be accessible in the market and the final price should be negotiated thereafter. Intensive discussion with the authorities are ongoing around who manages the prices during this time, how long it will take, and what happens if no agreement is reached.

On a broader level, we are trying to bring about a performance-driven drug reimbursement system and share the risks of bringing innovation to market with the authorities and payers.

How much of a risk to equitable access and European values is this system, where power rests in the hands of the health insurance companies?

It is *the* big risk in the system. The fewer drugs that the government approves, the more that access decisions will rest in the health insurance companies, and the more unequal access will be.

Although use of the Article 71 system increases dramatically every year as more targeted therapies are introduced, the Swiss authorities have not yet made a commensurate shift in the way they assess drugs. The question remains: how can we ensure expedited access to a drug that will

perhaps serve only 15 patients in Switzerland?

How well-developed is the data infrastructure and patient registers for rare diseases in Switzerland?

There is no centralised system here as seen in other countries where scientific societies collect data from several hospitals. Additionally, the Swiss population is very cautious about data privacy, which contributes to complexity in data collection. One of Switzerlandâ??s biggest challenges today is getting the data necessary for AI and data science without a strong national database. Some initiatives to address this situation have been proposed, but at the moment Switzerland remains a fragmented country, at least in terms of data.

How can companies like Takeda help create a more robust data infrastructure for Rare Disease patients?

The authorities also recognise the need for such an infrastructure; every time a positive reimbursement decision is given for a drug that treats a small patient population, they want to create a registry to capture the ongoing data. This ensures that if there is a lack of mature data at the time of listing, more can be generated and the true performance and effects of the drug on the market can continue to be assessed. Takeda is actively collaborating with scientific societies and patient advocacy groups to build these kinds of big databases.

How does this access issue for Rare Disease treatments in Switzerland impact your plans for the next five years? Does it require a change of focus?

We are staying on course and want to bring all of Takedaâ??s indications to listing and reimbursement, meaning that all of our indications are covered by the obligatory health insurance: every patient should have access.

The level of complexity to put one small indication or drug on the market is huge, so together with Interpharma we are trying to improve the situation for Rare Disease treatments. Furthermore, we are collaborating in the Rare Disease Action Forum to improve that the value of these drugs is recognized for these small and vulnerable patient populations.

Looking at the other parts of Takedaâ??s portfolio, oncology is a very competitive market in Switzerland as home to both Roche and Novartis. How have you had to adjust?

We need to refocus on the portfolio we want to have and invest in very early new concepts. Now Takeda has shifted towards rare oncologic diseases, establishing many new partnerships at early levels within universities across the world on innovative new concepts Our approach is based on both internal development and external partnerships; acting as a hub, anchoring and building capabilities both inside and outside of the company. We also need to refocus on the â??Dâ?? in â??R&Dâ?? â?? development. For example, recently, we signed an agreement to develop a CAR-NK treatment, the first in this category, and have invested in companies working on the early stages of CRISPR-Cas9. This is perhaps where the strength of the modern pharma company lies.

Switzerland, with its excellent engineering schools and many small health start-ups is a good breeding ground for innovation and has a lot of potential as a collaborative partner for Takeda.

How do you explain the discrepancy between Switzerlandâ??s high level of medical innovation and the fact that these innovations take so long to reach patients? For example, Swissmedic only approved the first CAR-T therapy in Switzerland in 2019.

There has been a paradigm shift in medical development that has not been matched by administrative procedures. Institutions know how to deal with common tasks but breakthroughs like CAR-T, where the line between product categories is blurred, need a different approach. The same is true for Rare Diseases; drugs that have gone through big randomised two-arm Phase III trials can be reimbursed straightforwardly, but there is no mechanism for Rare Disease drugs that have only passed through a single arm 19-patient trial.

It takes time to adjust. That is also why discussions need to start much earlier; our dialogue with the authorities for CAR-NK is starting *now*, despite this product potentially not reaching the market for many years. In this way, we can start to adjust, predict what questions might be asked, and co-build a model for the future.

What kind of competencies do companies need to have to engage in this complex science at an early stage?

The key word is â??agileâ??. The environment is shifting at a more rapid speed than ever before. Past paradigms are obsolete, like an innovative drug enjoying ten years without competition in the market, as rapid innovation is creating more competition at an earlier stage.

Leadership teams need to constantly adapt to the situation, look at the way they are working, and engage with other parts of the business and also external partners. They need to examine the market response and understand this new, demanding market requires constant progress and innovation.

What would you like to achieve during your tenure as GM at Takeda Switzerland?

We have 100 people here, covering many functions, business areas and managing a lot of complexity. My core focus is to bring agility to the team and help them achieve sustainable success. We need to be adaptable and continue to attract people; the organisation will be successful if the people have a strong sense of purpose and are always engaged to make the difference for the patients.

What are the challenges in maintaining that spirit of agility at what is now one of the worldâ??s top 10 pharma companies?

Takeda is changing constantly. This makes it a very dynamic and attractive pharma company to work for. We have been able to make this transformation while staying true to the companyâ??s 239-year-old values, which will not change and will continue to bring stability for the next 239 years.

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