Peter DrÃ¸idal â?? Country Manager Denmark & Nordic Head Market Access, Novartis

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Danish pharma industry veteran Peter DrÃ¸idal highlights how he steered the Danish Novartis affiliate through the COVID-19 pandemic period, the strategy in place to navigate an increasingly challenging market access landscape, and the lessons that can be leveraged from the value-based agreement that Novartis was able to strike with the Danish authorities for one of its gene therapy products.

Could you begin by introducing your responsibilities as Novartisâ?? country manager for Denmark, Nordic head for market access, and chairman of industry association Lif?

As country manager for Denmark, I represent Novartis externally and coordinate our efforts locally in the country. Novartis has a big matrix organization in the Nordics with certain departments â?? such as market access â?? working across borders. I bring the Danish perspective into the Nordic leadership team as well as running the Danish country leadership team, looking at the external environment and the dynamics in the Danish healthcare system.

I manage a market access team of 32 people working across the Nordics. There are very local access routes in the Nordic countries, creating the need to be close to the customers. Market access

is gaining in importance and becoming a critical function for life science companies everywhere, including the Nordics.

Finally, I currently serve as the chairman of Lif, having been on the association board for almost seven years in various roles. At Novartis, we try to really understand the healthcare system in detail and engage with stakeholders, making an association like Lif the perfect place to engage with industry peers In addition to my role as chairman, Novartis has key employees sitting on all the different Lif committees, from early research through to hospital and primary care. We believe that it is important to engage in the healthcare system, build relations, and shape the overall environment.

What are the key items on your agenda within Lif?

Right now, we pay a lot of attention to the Danish Life Science Strategy and the impact we hope it will get on the broad framework conditions for the entire industry, from the smallest biotech to the biggest pharma company, and covering both exports and attracting investments from abroad. The life science industry is gaining in importance for Denmark as a nation, now making up around 22 percent of Danish exports and a significant portion of national economic growth.

Improving patientsâ?? access to the right treatments at the right time is another high priority topic.

In 2017/18 you spent a year at Novartisâ?? affiliate in South Korea. Can you tell us about this experience and how you draw on it today?

I went out to Korea to work as Chief Operating Officer (COO), supporting the commercial setup there with some of the strategic launches that had already had success in Europe and the Nordics, including products in dermatology and heart failure. My role was to bring the learnings from Europe to Korea, as well as a sense of motivation.

It was great to be completely out of my comfort zone in a place where I was unfamiliar with the culture and market dynamics. This sense of unfamiliarity helped develop me as a leader; in such situations, it is vital to ask questions and work collaboratively with those who know the market, rather than relying on oneâ??s own experiences or assumptions. I learned that leadership is really about supporting people and removing the hurdles for them to excel.

All pharma executives have had their leadership put to the test by the COVID-19 pandemic; how have you managed your affiliate through this challenging period and what do you hope emerges from it?

During the pandemic, we have tried to keep the company culture alive through virtual tools. Even though our staff were working from home, we still wanted them to feel connected. Therefore, on top of all the business discussions, we held many virtual social events to keep the dialogue going.

Externally, we have been promoting Novartis as a partner able to support the Danish healthcare system. Probably the key learning from Denmarkâ??s handling of the COVID situation is the huge benefits that more intense public-private collaboration brings. This has been borne out in testing â?? during the heights of the pandemic, Denmark had one of the highest per capita test capacities in the world â?? but also in the speed with which PPE was distributed to HCPs and patients, as well as

clinical trials. Trials on COVID patients were approved and executed at record speed, underlining the importance of that collaboration.

During the pandemic, patients have not been meeting their doctors as regularly and surgeries have been deferred, especially in areas in which Novartis has a strong footprint like oncology. How has the business managed to continue to perform during this period?

Looking at the impact on the entire pharma market, we initially saw the authorities moving to stockpile medicines but over the full period, there has been no real impact in terms of volume. However, the impact has been felt very differently in different disease areas. Several treatments have been postponed in oncology, while in neurology, many physicians were allocated to COVID wards, leading to a lot of delays in treatments for migraine and multiple sclerosis (MS). Other areas, such as dermatology, have been almost completely untouched.

Some of your peers have described a tightening of the Danish market access landscape, with the Danish Medicines Council asking for a lot of data, taking longer to make decisions, and rejecting a lot of new medicines, especially in oncology. What is your take?

Companies with different portfolios are facing very different situations. In some areas, the Medicines Council has been fast and efficient, while in others they have been slow. However, from an overall market perspective and from listening to the concerns of the Lif members, market access *is* clearly becoming more difficult. The Medicines Council was established in 2017 to prioritise certain medicine approvals, so the market access process has become more challenging.

The Medicines Council is beginning to go beyond pure cost considerations and take a more holistic approach, considering the economic and societal value of medicine, which is really positive. However, there is still work to be done and the assessment criteria remain too narrow. The implementation of quality-adjusted life year (QALY) methodology is a good sign, but we have not yet seen an impact from it on speed to market. In general, the positive dynamic effects of investing in health are not fully appreciated and acknowledged throughout the political system.

Another issue facing the Medicines Council is manpower. Many employees have left, which has created significant delays in the assessment process over the last two quarters. It is questionable whether the Council is living up to its mandate from the Danish parliament in terms of deadlines. Here at Novartis, we have also seen delays, meaning that â?? at the end of the day â?? Danish patients are getting access to innovations later than expected. This needs to be changed.

How does the market access situation in Denmark compare to that in the other Nordic countries?

This also depends on portfolio. In Sweden, Norway, and Finland â?? as in Denmark â?? there are therapeutic areas where access is swift and others where it is slow. Compared to the other Nordic countries, Denmark is probably in the middle of the field in terms of market access speeds and is no longer the fastest country as it once was.

How much of a challenge does this access slowdown pose for you in convincing Novartis senior management to continue investing in Denmark?

It is certainly an issue, as it is for all countries. Management is always looking at how countries are embracing innovation and how fast they can get access to the market. In my view, we are still far away from Denmark becoming an international frontrunner with regards to easy and fast access, which is an ambition in the life science strategy.

In the Danish system we have both the Medicines Council as well as a tender organisation Amgros. This system â?? whereby we need to interact with these two separate stakeholders â?? exists in certain other European countries, such as Norway and the Netherlands, but not in most others. Tender-based systems have an effect both on speed to market and jumbo-groupings of products, leading to extreme competition.

Novartis is one of the few companies in Denmark that has been able to strike an outcome-based agreement for one of its products. What have been the key learnings from this long process?

The approval of a new gene therapy product came in March 2020. This was after more than a year of discussions and negotiations but I am delighted that we got there in the end. Amgros has even referred to the deal as a reference point for outcome-based agreements. At Novartis, we have a clear ambition to be at the forefront of the co-creation and implementation of new models, which benefits the company, the healthcare system, and â?? most importantly â?? the patients.

One of the critical elements behind our success in Denmark is a will to truly understand the concerns of payers, politicians, patients, and physicians and their view on getting our new gene therapy to market. Internally, we then held many discussions around how to mitigate these concerns before working with Amgros and the Medicines Council to co-create solutions. Engaging cross-functionally with all these stakeholders in a parallel process took a long time but, in the end, we gained their trust, and they could see that we genuinely wanted to share the risk of bringing the therapy to patients.

Healthcare systems have limited budgets and these highly priced therapies that only reach a small number of patients often become political issues. How have you worked to counter that?

It needs to be remembered that, despite the price, it is still a good investment. We have authored a report on the cost of blindness in Denmark which clearly demonstrates that innovative gene therapies could not only transform the lives of individual patients but is actually very helpful for society at large. The costs are much less than they would be if a young person became blind and needed support for their entire life. This plays into the discussion we have been having with politicians and payers, trying to shift their view from a narrow cost perspective to a broader picture of the drugâ??s societal value.

As Novartis moves forward with more cell and gene therapies, Denmarkâ??s strong data footprint will surely play a role in proving efficacy years into the future. How are you utilising this data today and how do you hope to be able to utilise it in the future?

Denmark has a unique health data infrastructure with national registers and electronic medical journals for each patient. This data footprint is a true asset for Denmark in its bid to establish itself as a leading life science nation, but we still do not leverage it well enough. There are several hurdles in the system and a myriad of approaches across the countryâ??s five healthcare regions to working with private companies on health data on aggregate level. There is an ambition to create a single point of entry, but this has not yet been realised, and there are still concerns among many politicians around private use of health data. Finding the right solutions in terms of data privacy is important, and this is addressed as a key action point within the recent Danish Life Sciences Strategy so I am confident that progress will be made, although I am concerned about the speed at which it will do so.

Novartis currently has 11 ongoing real-world evidence (RWE) studies in Denmark currently, focused on demonstrating the efficacy of innovations locally. While we come with global data, local payers and physicians want local data to assess drugsâ?? efficacy in a local real-world setting. It is natural that many of the cell and gene therapies developed in small clinical trials are then assessed in a local context post-approval.

Additionally, we are utilising epidemiological data. Within cardiovascular, this could be assessing the real status of heart failure in Denmark compared to other countries and using that in our market access process. This helps make the submissions as country-specific and relevant for the payers as possible.

Political and public concerns about private companies accessing the personal data of citizens are completely natural. How far away is Denmark from having the infrastructure in place to allay these concerns?

Things are moving in a very positive direction, although we are still not at the end of this journey. The trade associations, physician associations, patient organisations and various other stakeholders have worked hard to explain the importance of leveraging data for the benefit of Denmark as a nation and for the quality of treatment we receive now and in the future. Thus, there is broad support to find solutions on greater use of aggregate healthcare data.

Given the relatively modest size of the Danish market, how significant is the countryâ??s data treasure trove to being able to attract investment from Novartis?

We are a small country but being able to quickly generate RWE evidence on how our innovations work in real life can certainly be leveraged. The same goes for clinical trials; getting approvals and patient inclusion in high-quality clinical trials quickly and efficiently also makes the country more attractive. In other words, we are punching above our weight and we have already been able to attract some big trials to Denmark.

The Trial Nation initiative has also been very positive in this regard. It is a public-private partnership, that offers a single, national entry point for global companies, patient organisations and clinical researchers wishing to conduct clinical trials in Denmark,. Novartis has been part of the Trial Nation steering committee since its inception, working with different stakeholders, and have found it to be highly efficient.

What are the short- and medium-term goals you would like to achieve with Novartis Denmark?

Firstly, I hope to work closely with the Danish Government on reducing cardiovascular death. We have several products for cardiovascular diseases and heart failure, and I would like to replicate the agreement between Novartis and the UK NHS on population health in this field. In the medium-term, I would like to see a breakthrough in the way that politicians and payers work with the industry on population health, seeing medicines as an investment rather than just a cost, and collaborating with the industry as real partners.

On an industry level, post-COVID I hope to see implementation and execution of the 38 initiatives contained within the Life Sciences Strategy. This stands to have a truly positive impact on clinical trials and on collaboration between academia and industry.

What kind of culture are you looking to build within your teams?

Culture is incredibly important and, as the old saying goes, eats strategy for breakfast. Novartis globally has adopted an â??unbossedâ?? culture, a concept which actually comes from the Danish authors Lars Kolind and Jacob BÃ¸tterâ??s 2012 book, *Unboss*. Unbossed is almost by our very nature how we are here in Denmark.

At Novartis Denmark we have a very flat organisation focused on allowing people the freedom to grow and have an extremely open â??speak upâ?? culture. The organisation is not about me as country manager but rather what we can do together as a team.

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