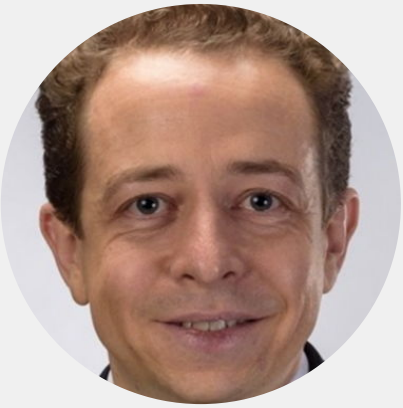
Mario Klesse – Country Director, Janssen Norway



We will only see the massive advantages of individualised medicine in Norway when we really change the system

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Janssen Norway's Mario Klesse shares his first impressions of the Norwegian pharma market, his strategic priorities for the affiliate, how Janssen is defining and meeting unmet patient needs, key access challenges, and the importance of bringing more clinical trials to Norway.

In February this year, you took on your first country manager position, having previously held a variety of roles at Janssen, most recently as business unit director haemato-oncology for Austria and Switzerland. What have been your first impressions of Norway, Norwegian healthcare, and the Norwegian pharma market?

I have had a warm welcome in Norway; people here are very welcoming, and it is a wonderful country. As a German, it has been relatively easy for me to adapt because Norway is highly developed and very well organised. This has been evidenced through the country's measured and structured reaction to the COVID-19 pandemic.

In terms of healthcare, Norway's deeply rooted principle of equality is apparent, and the country boasts a very developed system with top-class healthcare facilities, transportation, and infrastructure to serve what is a geographically large area.

However, compared to some other developed European nations, Norway's pharma market is rather constrained. I previously held European and global roles in market access – working in Austria, Germany, and Belgium – and Norway clearly lags behind those countries in terms of fast and broad

access to innovation. One of our top priorities is to work together with the authorities to create better market access and pricing schemes so that innovative products are more readily accessible to patients who need them.

Given the fact that Norway was put under lockdown not long into your tenure as country director, how has this process of reaching out to external stakeholders and building a team internally gone?

Starting this journey in a pandemic was a very special situation! When taking on a new role, the most important thing is to connect, listen, and understand both the needs of both internal and external stakeholders.

Luckily, I had six weeks at the beginning to be on the ground in Norway and had – at least internally – plenty of time to connect with our 35-person team here. I have been really impressed by the team and how quickly everyone adjusted to the situation. After lockdown was imposed, we began working remotely, with the team in Norway and myself from Austria where my family was still based. At that time, it was of critical importance that we stayed in continuous communication with each other and created platforms for internal informal exchange.

For external stakeholders, I had my first meetings in the first six weeks before the situation became more challenging as everyone switched their focus to the continuity of their own organisations. The healthcare system was working on pandemic preparedness and ensuring they had the capacity to cope, leaving little time for anything else.

At Janssen, we also needed to respond quickly to the pandemic in terms of securing the supply of medicines and being able to answer any questions from medical practitioners about the use of our medicines. As well as patients, we also took action to ensure the safety of our employees and, of course, since February Janssen has been working on a vaccine for COVID-19. We have also put efforts into supporting communities. The global J&J foundation has been supporting frontline workers around the world, and locally we have made donations to Norwegian Red Cross and its COVID-19 aid.

What skillset has been needed to move from an operational role to that of country director?

I had already had some exposure to external affairs through previous roles in Germany, and in Austria and Switzerland I was a member of the management board. However, the topics you work on are enriched dramatically when you become the face of the company in a country and are also responsible for the safety and wellbeing of all employees. Especially in a pandemic situation that is an extra responsibility which I take very seriously.

It is exciting because in a GM role you can shape strategy and set the strategic priorities. I greatly enjoy working with the team here and developing our organisation. We are well set to change the situation in Norway for the better and achieve our goal of allowing patients to access the medicines they need.

What are your strategic priorities for the affiliate?

We have a transformative portfolio already in place as well as a very innovative pipeline. Our first priority is to ensure that our medicines are available to each patient who needs them and that they can be freely used where they create the highest value for the individual patient.

The second priority is to become more customer- and patient-centric. We recently switched from being part of a Nordic organisation to a fully localised setup here in Norway to better understand and address local needs, delivering more tailored solutions to Norwegian physicians, payers, and patients. That is a big change for the organisation and will hopefully allow us to immerse ourselves in the market, better understand local perspectives, and drive access.

Thirdly, as a research-driven company we want to be innovation leaders in the six therapeutic areas in which we are active: haemato-oncology, neuroscience, immunology, pulmonary hypertension (PH), cardiovascular diseases, and infectious diseases and vaccines – which is becoming even more relevant now.

The pandemic has made these efforts slightly more complex, but we have been able to adjust well.

What can Norway, as a comparatively small market, offer for Janssen?

For Janssen, it does not matter if a market is small or big, rich or poor. Each market is made up of individual patients who have the right to access the best treatment. Norway is certainly on the wealthy side, but we have a huge opportunity here to improve patients’ lives by bringing more of our innovative medicines to them.

Can you give some concrete examples of how Janssen's solutions help meet unmet patient needs in Norway?

We divide areas of unmet medical need into three categories. The first is areas where current interventions are ineffective, the second is where interventions exist but are not accessible, and the third is where interventions exist but are difficult to use. Often, unmet medical need is only talked about in terms of the first category, but we have several exciting innovations coming up in all three categories.

One of our new products launched this year addresses an unmet need in treatment-resistant depression, which has not seen material innovation for more than 30 years. Besides representing a new chance for relief in patients who do not respond to traditional anti-depressants, this could potentially have a positive impact from an overall societal perspective: The economic impact of depression, especially in developed countries like Norway, is significant.

In oncology, we have just obtained reimbursement a new hormone treatment, which when used early in the treatment cycle, is delaying prostate cancer from becoming metastatic. This showcases our ability to work together with healthcare authorities to find access solutions for innovative treatments.

Other types of innovations include moving from intravenous administration to subcutaneous administration in the treatment of multiple myeloma. This reduces the administration time for patients and caregivers, and implies savings in both time and money to a healthcare system – which may be even more relevant in a geographically large country like Norway.

Cell therapies are another exciting technology Janssen is working on as part of the trend of providing more individualised treatment. This may hold the key to making cancer preventable or curable in the future.

What are the key access challenges today in Norway?

Pharmaceutical science is rapidly shifting towards highly individualised medicine. In cancer treatment, it is critical that physicians can freely choose the right combination regimens for their patients. Cell therapies are on their way, and there are more products which have one specific target in a disease pathway but also have multiple indications. In our view, the current system is

not adequately prepared for those new paradigms.

Focusing too narrowly on price and hospital budgets may result in sub-optimal treatment outcomes and can lead to increased costs in the long run. Currently, Norway is utilising an ‘Equal Enough’ principle whereby similar drugs are grouped together. Ranked through a tender mechanism, physicians should choose the cheapest drugs first. In practice, this can lead to sub-optimal treatment sequences where physicians may need to cycle through a row of treatments that are not effective or suitable for the individual patient, before they can actually use what this patient really needs.

Hence, we will only see the massive advantages of individualised medicine in Norway when we really change the system. Janssen is working on improving the situation via roundtables with various stakeholders and authorities where we are proposing different mechanisms such as indication-based pricing or outcomes-based access models. We are hopeful that through this, we will be able to find a solution.

How would you characterise Norway’s medical innovation ecosystem and what role can a global innovator like Janssen play within it?

There are two remarkable initiatives here. One is the government’s white paper on the health industry which sets out a positive direction for Norway with a strong commitment to facilitating innovation and R&D and strengthening public-private partnerships (PPPs). We are a smaller unit of Janssen, but we stand on the shoulders of a global giant. The specialised J&J innovation team looks to facilitate PPPs early on and scans the horizon of life science innovators working in our six prioritized therapeutic areas.

In November there will be a virtual scouting event from J&J innovation for the Nordic Life Sciences industry, which is an example of how we, together with our global colleagues, can contribute to fostering and building an innovation ecosystem here. We are currently conducting both local and global research in Norway, which is complementary to this push.

The second initiative is the Clinical Trial Action Plan which is in preparation by the government, and which sets out a strategy to provide a better environment for clinical trials in Norway. Janssen already conducts trials here, with a particular focus on oncology, neuroscience and immunology, where Norway is a strong player. We have research collaborations with the Oslo Myeloma Centre – one of Europe’s leading myeloma centres – and also support for example the Oslo Cancer Cluster,

and the Janssen neuroscience network in their activities.

This plan – when put into action – has the potential to significantly strengthen the position of Norway in the global research landscape.

What changes do you hope to see from this Clinical Trial Action Plan?

One element that the Action Plan clearly outlines is creating one-stop shops for clinical trials in the country's leading coordination centres. It is also about providing the right environment to quickly initiate studies, execute them, and then follow-up when trials end.

A stronger clinical trial footprint is also connected with market access; while we place clinical trials under global scientific and feasibility considerations, the question whether a drug can be used afterwards, is also an ethical consideration.

In terms of real-world evidence (RWE) and data access, the Nordic countries have a strong history in patient and population registries. We already conduct RWE studies in Norway, but there is a pressing need for a pragmatic framework on how the industry can better access this data. This will be crucial for both research purposes, and also for enabling outcome-based access schemes without adding administrative workload. There is great potential for more PPPs to solving some of these data integration puzzles.

Globally, J&J and Janssen are at the forefront of the fight against COVID-19, with Phase III trials for a vaccine now underway. What are your hopes and expectations for this vaccine and what role will country managers play in the commercialization process?

The results from the Phase II trials of Janssen's COVID-19 vaccine has been published and we will hopefully able to confirm the safety and efficacy of the vaccine in the ongoing Phase III trial which started in September.

Janssen has continued scaling up its manufacturing capacity in order to be ready to provide the vaccine for a pandemic use scenario in early 2021. We also have committed to providing the vaccine on a not-for-profit basis during emergency pandemic use. If approved, we will work with the authorities on the necessary steps to bring the vaccine to the public.

The big hope for the vaccine is of course that we all can return to a more normal way of working and way of life. For us in Janssen, that means that we can put even more energy into the various many unsolved medical problems outside of COVID-19.

You have been with Janssen for 14 years, what keeps you wanting to come into work every morning?

What excited me about working for Janssen is having a clear purpose – I can see a direct impact on patients' lives. This is also connected to our Janssen promise, working on a future where disease is a thing of the past, which for me is a great motivation. Janssen also has a strong culture, rooted in the J&J Credo which puts patients, physicians, healthcare givers, and customers first. Within Our Credo, the needs of employees are also always considered, and we are committed both to the communities we serve and to our shareholders. This balance is deeply rooted in our culture and ultimately guides the decisions that we make.

In the different roles in which you have worked, what lessons have you learned that help you to lead the affiliate today?

There are three main lessons. I started in an expert function working in market access, but when you move into a more general role you need to give up on some of your expert roots and build up a more well-rounded experience.

The second lesson is always to listen and learn. It is easy to take things from the past and apply them directly to the future, but we must be vigilant and guard against potential mistakes.

The third is the importance of people. As a team leader you are only as good as your people, so developing talent and creating an inclusive work environment has become close to my heart and something which is crucial for success.

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