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18.12.2020

Tags: [Norway](#), [Roche Diagnostics](#), [Roche](#), [Diagnostics](#), [Medtech](#)

Roche Diagnostics Norway's Daniel Malarek discusses the resurgence of diagnostics in the wake of the COVID-19 pandemic, the Norwegian approval process for diagnostic tools, and the importance of stakeholder education.

Please introduce yourself to our international readership.

I did my PhD in chemistry at the University of Melbourne, Australia and my post-doc in chemistry at the University of Basel, Switzerland. From there I joined Roche's Perspectives Program – a management development program. I then undertook various assignments ranging from head of marketing and business development for diabetes care in Russia to working on a humanitarian project in India.

I later moved to California to work on the development of molecular diagnostics, where I was responsible for developing new instruments and assays based on the polymerase chain reaction (PCR) technology that is currently being used for COVID-19 testing across the globe. I did that for four years at Roche's centre for molecular diagnostics in Pleasanton, California.

After four years of working in development, I wanted to get closer to the customers again and see the impact of the instruments and technologies we were developing in the market. An opportunity

arose in Norway and I was excited about coming back to Europe and experiencing the Scandinavian culture and mentality, so I took it.

How do Roche Diagnostics' Norwegian operations fit into the wider organization?

Roche Diagnostics takes a very decentralised approach to business. In many other multinational companies, operations are very centralised and global dictates a great deal of what happens in the country affiliates. However, at Roche Diagnostics individual countries, no matter how big or small, have the freedom to take their own approach for their local markets. We are very autonomous in the decision-making we have, on what products to bring to market, and on how we approach our customers.

That enables us to be uniquely customer-centric, because we do not have to adapt to the global organization – we adapt to our customers locally. That customer-centricity acts as a real motivating factor for our employees. We do it for the customers and we do it for the patients. To know we can do what is best for them, irrespective of what global is doing, is quite unique within a multinational corporation.

How has Roche Diagnostics Norway performed during 2020?

COVID-19 impacted various aspects of our business in very different ways. On the one hand, patients have been reluctant to go into hospitals to do routine tests, and many hospitals have been deferring patients and delaying routine procedures. The drop in routine testing has impacted our business.

In parallel to that, there has been a massive increase in demand for COVID tests. There has been a significant rise in PCR and antigen-based testing. From the onset of the pandemic, following reports in January from our colleagues in China, Roche made a fundamental decision to invest heavily in developing COVID-related products. To date, we have launched more than 11 such products, which have played a critical role in the battle against the pandemic across the globe by allowing healthcare systems to diagnose, isolate and track and trace the disease.

Norway specifically has built a very effective testing infrastructure, with a number of different platforms being utilised and capacity being ramped up. However, all the major players have faced difficulty in supplying the necessary reagents, due to the spike in global demand. Roche, from the

beginning, has invested heavily in ramping up production, the majority of which is in Germany, the US, and Switzerland. That investment has helped us meet the needs of our Norwegian customers, even though we are continuously under pressure to deliver more. As mentioned, routine testing has been down, negatively impacting our business, however, this has been compensated by the increase in COVID testing.

Was Norway sufficiently aware of the importance of diagnostics prior to the pandemic?

I do not think Norway was sufficiently aware of the importance of diagnostics and realistically, I do not believe any country was fully aware. Research shows that more than 70 percent of medical decision-making requires some form of diagnostics, yet less than two percent of healthcare budgets are allocated for diagnostics. Making the wrong decision in deciding a patient's treatment plan has a major impact on the patient and a major impact on the healthcare budget as well. Getting the diagnostic part right is absolutely critical and investing in innovative diagnostics will improve patient care and lower healthcare costs. This pandemic has given us a glimpse into the importance of diagnostics on patient care and society and I hope the Norwegian health authorities will adapt their future investment strategy to further improve patient care by making investments into innovative diagnostics.

Twelve months ago, most people did not even know what a PCR test was. Now the phrase "PCR test" is common terminology. So, there has been a massive improvement in people's understanding. In terms of spending, many hospitals have been given the go-ahead to do whatever it takes to increase their testing capacity to handle this pandemic. In addition, our customers have been extremely creative to find workarounds and other creative solutions to increase testing capacity. It speaks volumes about the Norwegian mentality of coming together, both public and private, to come up with creative solutions on how to increase testing capacity, when demand is so high. We are now in dialogue with the health authorities on a weekly basis which is incredibly important in a crisis situation.

Could you tell our readership about the products Roche Diagnostics Norway plans to launch next year?

The fully automated platform we use for COVID testing is called the cobas 6800 system. We are focused on expanding the test menu on this platform so that labs can consolidate the majority of

their PCR tests onto this fully automated platform. We already have a broad virology portfolio, transplant tests, HPV for cervical cancer screening and we will be expanding this further with a broadly automated platform. That, in turn, will optimize their workflow, increase their testing capacity and reduce the amount of manual labour in labs. We have received great feedback from the customers that have invested in the cobas 6800 platform and that is really great to hear! Our customers that have acquired the instrument will have opportunities to shift a lot of their portfolios onto it.

Tell us about the Norwegian approval process.

When it comes to new, innovative tests, Norway often requires a health technology assessment to be completed. The Norwegian health authorities then make an assessment as to whether the test should be included in guidelines and as to whether it should be reimbursed.

I would like to see these decisions made much more quickly. In some cases, we have submitted health technology assessments to the Norwegian authorities, and it has taken more than two years for us to get a response. I would like to see more dialogue and more transparency if we are to work together to improve the health services for Norwegian patients. Both public and industry have many of the same goals of improving patient care and reducing costs for the healthcare system, and I believe these goals are achievable if there is more open dialogue and collaboration.

What qualities are needed to succeed in the Norwegian market?

To succeed in the Norwegian market, customers need to trust you. It is vital to have the trust of your customers in smaller markets, especially in markets where customers communicate freely with each other and share their experiences. Even during the height of the pandemic, when supply was very constrained, we were completely transparent with our customers and we continue to be so. This was greatly appreciated by our customers.

Innovation is also key to success. When customers see that you are the one driving innovation, bringing new solutions to the table, and changing medical practice, that instills a certain level of confidence that they have partnered with the right organization. Norwegian customers want to be at the forefront of innovation.

What education do you provide to the customers that use your products?

As in any market you have the early adopters who are willing to pilot new technologies. In Norway, there are a lot of key opinion leaders who have that mentality. However, there is also resistance towards efforts to change medical practice and the uncertainty that comes with that change.

We work closely with key opinion leaders and support them in their research. For example, one of the current gold standards in cardiac testing around the world is the biomarker NT-proBNP which was discovered by a Professor Christian Hall at the University of Oslo. It was Roche that really looked at that biomarker and worked closely with him to prove that the biomarker was significant. Now, it is the gold standard. We still collaborate very closely with the key opinion leaders in the cardiac space, constantly looking for new innovations together.

How are large public and private organisations fostering innovation in Norway?

The Norwegian government recognize that their biggest industry – the oil industry – has an end date. The government hopes to create hundreds of thousands of jobs in the healthcare sector over the next ten years. Norway does not have a long history of working in the healthcare industry and does not have a long history of medical innovation. Through various funding mechanisms, Norway is now funding medical innovation more than they ever have before.

Two years ago, we had our first Roche innovation days, where we brought our global business development people in from Switzerland and got strategically relevant Norwegian startups to pitch ideas. Out of that, we have been able to foster a couple of collaborations. Norwegian startups are generally very focused on innovation and science. We see an opportunity in becoming a commercial partner with them and bring some of their very exciting innovations to customers and patients around the world.

How does Roche Diagnostics foster diversity in the workplace?

Norway is not a particularly diverse country. Yet within our organization, we are very international. We speak English in the office. There are at least 15 nationalities from 5 continents represented in our organization including Argentina, Ecuador, Canada, France, Turkey, Iran, Poland, Romania, and Iraq, just to name a few. We have a very international culture. Norwegian society is very receptive and open to diversity and we feel that diversity adds perspective and allows us to be more

creative.

What are your strategic priorities over the next five years?

Our number one priority is to have an extreme customer focus in everything that we do. Number two is to bring as many of our innovations to customers and patients as possible. That is absolutely critical if we are to maintain our market leadership.

The third priority is to become a leader in digital healthcare. This is becoming increasingly important for us, as all industries are shifting, and the medical industry is lagging behind.

For Roche, we must create clinical decision support tools, create algorithms that help clinicians make decisions, and help patients manage their disease in a comprehensive way. I would like to see these digital solutions come to Norway as soon as possible. The Norwegian market could be very receptive to these types of solutions, which could both improve patient outcomes and reduce costs.

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