Lars Bo Nielsen â?? Director General, Danish Medicines Agency

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In a wide-ranging interview, incoming director general of the Danish Medicines Agency Lars Bo Nielsen discusses the challenges that personalised medicine presents to regulators, building a stronger international presence for the Agency, and better leveraging the countryâ??s world-class data infrastructure while respecting the EUâ??s data protection regulation.

Can you begin by introducing our readers to your career and how you arrived at your upcoming role as head of the Danish Medicines Agency?

I trained as a medical doctor and my early career was mostly focused on research at the University of Copenhagen, but I also spent time abroad in the United States and Sweden. I began building a research group in parallel with my clinical duties at the hospital and gradually drifted into leadership positions, becoming more interested in engaging with organisational issues.

I went to administration and leadership positions, always with a keen interest in collaboration across sectors which proved to be helpful in breaking through silos and uniting the private and public sectors. Breaking barriers is also key on an international level where I have always prioritised collaboration for the benefit of all people. Public-private sector collaboration and synergy building is crucial to achieving the key healthcare goals of the modern age, from prevention to public health

measures, or individualised strategies to treat rare diseases.

Denmark is a prime example of how all sectors can work together. The Danish Medicines Agency has a very defined role in securing safe and efficient medicines and therefore must have a regulatory framework around improving medicines. However, we must also continue engaging in discussions with the public on how they perceive the area of medicines, particularly today, with vaccines at the forefront of national debate, the rise of internet sales, and the growth of alternative medicine. The former director was extremely good at engaging with the public and explaining the importance of vaccines and why the approval process must be thorough.

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We talk to different regulators across the world, all of which have slightly different roles and mandates. Can you explain the mandate of the Danish Medicines Agency, what it does and does not do?

Our overall mission is to provide safe and efficient medicines and medical technology for the benefit of individual people and society. The Agency oversees clinical trials, creating the framework for them, and also advises clinical researchers and the pharma industry on how to conduct them. On an international level, we collaborate with the European Medicines Agency (EMA) on pharmacovigilance projects.

Another of our roles is overseeing the pharmacy system in Denmark to guarantee that medicine is available for the entire population. In addition, the Agency has the role of inspecting production facilities.

Under the leadership of the former director, Dr Thomas Senderovitz, the Agency has transformed itself over the past five years, spearheading some of the challenges around personalised medicine and utilising Danish data infrastructure and the copious number of records that the system has generated for decades. We need to find a way to use the electronic patient files to continuously monitor the efficacy and side effects of medicines, developing the system to do it in a reliable manner. Therefore, the Agency has embarked on creating a data analytics centre where we can collaborate with key stakeholders, including academia to use existing data and answer questions about existing therapies.

We must engage in a close dialogue with the industry in terms of regulatory framework, speed and professionalism in order for them to fulfil their tasks and missions, bringing medicines to market as fast as possible.

Bio-innovation is very strong here in Denmark and we have many start-ups doing excellent work with whom we must continue to engage in dialogue. I have seen many researchers make wonderful discoveries and attract substantial venture capital, but unfortunately not fully understand the exact regulatory framework around their science.

While dialogue with the private sector is crucial, at the same time we are a public institution with the mission of safeguarding the health of the population. We must be open about our mission when engaging in dialogue because we are not here as a service organ for the industry, our primary focus is the health of the Danish people.

The Agencyâ??s mission for the future is to continue the path that has been paved over the last five years as it relates to engaging with the public and patient organisations in discussions. This will help us to better understand the level of security that society expects and weigh that against new treatments for rare diseases that might be expensive but also might help people in grave need of treatment. We want to bring people to a situation where they have the information at hand to make a qualified choice.

The issue of speed in the regulatory decision-making process has been put in the spotlight recently, with COVID-19 vaccines receiving authorisations in record time. How are you planning to manage this issue and how important will the utilisation of data be?

Data is going to be key. From a bureaucratic point of view, the Agency should grasp the possibilities of IT to use new technology capabilities and advance paperwork procedures.

That is an internal consideration that I will review when I start. In any case, it is not only the Danish Medicines Agency that needs to work on IT; almost every organisation is struggling to decide how to invest in infrastructure, hardware, software, and staff education. From what I understand, the Agency is in a very good position to take on this challenge.

Denmark is sitting on a treasure trove of data with holistic healthcare data sets for the entire population from cradle to grave. Having the data is one thing but being able to access and use it is another. Are there any gaps that need to be bridged for data to be better utilised in Denmark?

The Nordic countries are now focusing on the problems around the sharing of data that the EU General Data Protection Regulation (GDPR) has created. Sharing data across hospital systems, universities and government organisations has become extremely complicated. The system is already looking at ways to use encrypted data and engaging with the public to obtain consent.

I am sure that Denmark will find a balance, but it is a tricky question because data needs to be organised and annotated in order for it to be used in a smart manner. This has to be dealt with on a technical level. Moreover, we must engage in ethical discussions with the population since we have to avoid compromising their confidence in the healthcare system; their data belong to them.

The Danish government recently instituted a new growth plan for the life sciences industry. What do you see as the impact of the plan?

It is fantastic that we have a plan as a country, and I really commend our government for it. The plan is extremely ambitious and visionary in terms of maintaining life science as an important foundation of the Danish economy. One of the issues we must deal with now is how this life science strategy will improve the lives of patients in Denmark and the Danish Medicines Agency has a central role to play in this. We look forward to engaging in discussions with other countries across the world in order to understand the regulatory framework that Danish companies need to address in order to offer their innovative medicines to the international market.

You have touched on the Danish Medicines Agency having an international role to play, how do you foresee that role evolving during your tenure?

With most of the new medicines in Denmark being approved at a European level, we must have a strong presence within the EMA to better understand what is going on but also influence how the regulatory framework will evolve. We need to bring Danish values and knowledge into the decision-making process. The use of data gives us an advantage; if we can engage in the development of the European Health Data Space and the use of healthcare data in Europe, it will benefit both Danish patients and their counterparts across Europe.

A great example of the advantages of sharing data occurred during the COVID-19 pandemic, when the Danish Medicines Agency as one of the very first agencies in the world detected and shared data about the rare and serious side effect VITT/TTS after vaccinations with AstraZenecaâ??s vaccine.

We have to look beyond Europe and build collaborations in places like Asia to understand advancements and warning signs; at the same time offering them the best of Scandinavia.

Other Danish stakeholders have talked about the transformation of the countryâ??s healthcare system in the last 10-15 years with a move towards centralisation and investment in hospitals. Having had a front-row seat to this transformation, what do you see as the biggest achievements that Denmark has made and where would you like to see it moving forward?

I believe that the centralisation of Danish hospitals has been a huge advance in terms of lifting quality and making it possible to have electronic patient files. If you are a patient coming to essentially any hospital in Denmark, the doctor will be able to see your health records immediately.

Denmark is now moving to transition where we have to bridge from super hospitals to rehabilitation and long-term treatment in a more local setting, which is where we are struggling to find solutions. Another challenge is creating a more unified approach across regions and municipalities. I expect the government will engage more broadly with e.g. patient organisations as well as the general public to create the best possible solution.

On a personal management level, what are the first items on your priorities list for when you take over as director general?

The most dangerous approach in any field, but especially healthcare, is ignorance in action. Therefore, I need to first take the time to understand the organisation completely, listening to its needs and challenges, before I start making major decisions. The work of the Agency has a significant impact on the population, so this learning period is critical. Finally, we have to work on building collaborations with key private and public stakeholders, both at home and abroad.

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