Lars Bo Nielsen – Director General, Danish Medicines Agency (DKMA)

What does AI really mean? How can we make the equipment safe? The solution will be to start with low hanging fruit where risk is low and with equipment that has a lower risk of hurting the patients

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In conversation at DIA Europe 2024 in Brussels, Lars Bo Nielsen lays out the digital transformation that the Danish Medicines Agency has undergone over the past three years and how AI can best be integrated into the work of national regulatory bodies.

When we last spoke in mid-2021, you talked about the need to better utilise IT to speed up the DKMA's processes and reduce bureaucracy. How have things progressed in the two and a half years since?

It is moving forward well. Given that Denmark was one of the countries at the early forefront of digitalization, some of our IT systems are now becoming outdated. We have needed to make infrastructure investments, but this is demanding on our budget and not necessarily visible from the outside; you can compare is to having an old car that needs new brakes or other unseen components under the bonnet.

At the same time, when we reinstall systems, we are thinking about how we can adapt them to the digital transformation we are trying to run throughout the agency. We are moving along the right lines and trying to find economy as well as change management to run some of these processes.

One of the things that we are particularly proud of is the installation of several robotic process automations (RPAs); product solutions for handling some of our document and case flows. Additionally, we have adopted an AI-based solution for our information centre.

AI is the current buzzword across all industries, but how is a national regulator like DKMA making use of this technology in a practical sense today?

It is something that we are trying to set up as a strategic aim. We already decided last year to define some use cases of low hanging fruit to make the first moves. The first of these was our information centre, where we get thousands of calls or approaches every week. There, we have adopted an AI-based language model that can search our document database, which includes more than 3,000 documents, as well as the websites of our agency and sister agencies to provide a faster and more structured solution.

Previously, the service we were able to provide at this information centre was largely dependent on the seniority and experience of the person who picked up the phone. However, the AI-based system is now bringing all our people to a higher level. It is amazing how it changes the work culture; we have onboarded people this year who, within a week, are already at the level of far more longstanding colleagues. AI has meant that our people can spend more time on skill development, rather than learning a system.

Has there been any resistance from your team to getting on board with these kinds of solutions?

There were a lot of discussions about whether using AI based solutions would take away the human factor. In Denmark, we like humans to be advised by other humans and not by machines. We all know the experience of calling a service provider, talking to a chatbot, and two hours later wondering how can I eventually talk to a real person? We did not want to get into that situation, but following those discussions, our teams have really embraced AI and are now proud to be first movers.

Regulating AI products like software and medical devices that frequently upgrade, learn, and change post-deployment is tricky and requires a process-based approach.

How does DKMA perceive this issue?

Our strategic approach to AI solutions is built on three pillars. The first is working on how can we use AI for our internal processes. The chatbot I mentioned earlier is a good example of this, and the next step will be using AI in our assessment processes. An important part of our IT department is a specially created unit – Digital Transformation – with a core task to push and guide the digital development of our processes and systems.

Secondly, we are looking at how to use AI as part of the European system. Together with the EMA, the Heads of Medicines Agencies (HMA) is part of the Big Data Steering Group Initiative, where we now have an AI workplan for the coming years. Even though everybody knows the agenda is going to change due to technological developments, it is important that we have a strategic direction.

The third pillar is – as a regulator that also covers medical devices – how we are going to regulate the healthcare sector and adopt AI-based solutions for patient treatment. It is on this third pillar that we are struggling to find our feet. What does AI really mean? How can we make the equipment safe? The solution will be to start with low hanging fruit where risk is low and with equipment that has a lower risk of hurting the patients. This experience will be vital in terms of the maturity of our regulatory system and the trust of our population as more and more of this AI-based technology becomes available.

Will this increased importance of AI necessitate bringing new profiles into your team? Or will your existing staff be able to upskill?

Every institution, whether private or public, is struggling to bring in and onboard the right competencies in relation to AI. Our approach will be a mix, pushing the educational system to develop people with the skills we need while also training up our existing staff.

At the DKMA, we hope to train a subset of our staff to spearhead the three pillars I mentioned previously, but more broadly we want to increase the general level of awareness about what AI solutions are and how can they help. We recently set up an AI Forum at the agency, which has proved incredibly popular!

On a European level, there have been some great steps forward, such as the establishment of the EU Network Training Centre (EU NTC), with the aim of ensuring the exchange of good scientific and regulatory practices across the European medicines regulatory network. I co-chair the EU NTC Training Steering Group as a representative of the HMA along with Zaide Frias of the EMA. Within

the EU NTC, we are encouraging people to use our Digital Academy training tool, which has a big section on AI. We are going to try to use that as a broad basis for our staff at the agency to establish a common language, identify gaps, and plan for the future.

Last time we spoke, you also explained how Danish data gives the country an advantage in influencing the European regulatory framework, including in areas like the EU Health Data Space. Ahead of the potential implementation of the EHDS later this year, how active has the DKMA been in that sphere?

Within Danish society, there is a constant conversation and plenty of strategic initiatives every year about improving the use of healthcare data. While we are gradually ironing out the problems that exist, we must maintain public trust in providing their data to healthcare providers as this is the basis for the entire system.

All of that provides us with the foundation to play a role in the European system. From a regulatory point of view, we are embarking on trying to onboard Danish healthcare data as part of the DARWIN EU project along with our sister agency, the Danish Health Data Authority.

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