Ida Sofie Jensen – CEO, The Danish Association of the Pharmaceutical Industry (Lif)

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Ida Sofie Jensen introduces the strong fundamentals underpinning the Danish innovative life sciences industry, including governmental support for early access to medicines, a collaborative approach to pricing and reimbursement, a highly centralised hospital system, and excellent digitalised patient records. Jensen highlights that thanks to these fundamentals, Denmark is home to the highest number of clinical trials per capita in Europe and will continue to prioritise the industry for the foreseeable future.

Can you begin by introducing the role of Lif within the Danish life sciences ecosystem?

As an association, we have three strategic pillars. The first is life science policy, with the aim of setting up a life science growth plan. We recently succeeded in establishing such a plan along with the new Social Democrat government. This is the second such national plan – the first being with the Liberal government a few years ago – and is the best we have ever seen. The Social Democrats are cognizant of the benefits of being a small country with an open economy and a homegrown life sciences industry owned by Foundations. As well as Danish companies, international firms have a significant footprint and employ a lot of staff here, investing DKK 36 billion (EUR 4.8 billion) annually in clinical trials and other direct investments.

Our second pillar is access to medicine. We want to be one of the top three countries in Europe for access to new, innovative medicines.

The third pillar is stakeholder engagement. As an interest organisation, we need to ensure that all our key stakeholders understand who we are and what our positions are, but also see that we can contribute on general business politics and healthcare policy. The Danish life sciences industry wants to be a trusted partner and provider for the healthcare sector.

Looking at this foundation model, to what extent is it a differentiator for Danish pharma companies and their role within the broader picture of healthcare in Denmark?

The fact that Danish companies are owned by foundations means that they are here for the long term, investing in the entire ecosystem. This model is not limited to the big Danish pharma companies like Novo Nordisk, LEO Pharma, and Lundbeck, but can also be found in shipping (Maersk), brewing (Carlsberg), and machinery (Danfoss). Foundation ownership has historically arisen in Denmark in connection with generational change in family-owned, large, exporting companies, where the foundation then becomes the major shareholder.

What messaging do you give to stakeholders about the value of the pharma industry, especially in terms of access to innovation and pricing?

Pharma is a global industry by nature, with research in its DNA. Bringing a new product all the way to market means that the whole world can be reached, but to do so takes a long time and a lot of investment. Additionally, pharma is not a normal market in that it is financed by a third party. Nowhere in the world does the end consumer (the patient) pay the producer (the pharma company) directly for medicines; its either the tax-financed public healthcare sector or health insurance. This means that pharmaceutical pricing will always be up for discussion.

Because of the variety of stakeholders in the healthcare ecosystem, as the pharmaceutical industry, we have to work collaboratively to find appropriate and fair levels of pricing.

The pandemic has shown how our industry is providing society with solutions and the tools to navigate such a seismic health crisis. The pharmaceutical industry is providing a win-win situation for society through bringing medicines to patients that need them, creating high value jobs at home, and providing a high-value export.

How well accepted is this messaging by the stakeholders in government?

Even for a country like Denmark, where 20 percent of exports are pharmaceuticals or other life science products, we still have to consider pricing because taxpayers' money is spent. There has been an agreement in place for more than 14 years to ensure we pay no less and no more than nine comparator countries. This is not a reference pricing system as such, but more of a common understanding framework.

Denmark is a country where patients normally get easy and quick access to new innovative products. Of course, our politicians demand a fair price, but at the end of the day, they want the Danish people to have fast and equal access to innovation.

This is a difficult balance to strike, especially with expensive next-generation technology like cell and gene therapies. Is there an openness to innovative pricing and access models and new ways of valuing these innovations?

Yes. Significantly, a Medicine Council of specialists and doctors has been established to evaluate the value of medicines. We see this not as a negative, but as a positive development. Moreover, I am a member of the Council, which shows the public sector's willingness to take the concerns of private industry into account. Together with the regions, regulation for getting an application through the Medicine Council has been established, with the ultimate goal of being as transparent as possible.

The last part is the negotiation on the price. In Denmark, quality-adjusted life years (QALYs) were recently accepted as a tool. QALYs will be used as a benchmark, rather than a threshold, which we accept as an industry, and which we hope will continue to contribute to the good access situation here.

In neighbouring Sweden, the decision-making process is very regionalised, which creates access issues and disparities. Is there a similar issue in Denmark?

Decision-making is much more centralised here in Denmark. Around fifteen years ago, Denmark went through structural change, moving from 15 county councils to five, and removing the regions' ability to write out taxes themselves. In a small country like Denmark it makes sense to centralise

things, as small regions were often not able to finance healthcare to sufficient levels.

In parallel with this regional restructuring, hospital investments also shifted, with a move from almost 100 hospitals to 21. The five regions established the Medicine Council and agreed to follow its recommendations, which gave them much more buyer power than before.

The current system is beneficial for pharma companies in that if they get a product through the Medicine Council, they can immediately enter the market the next day in all five regions. Of course, the reverse is also true and a refusal from the Medicine Council signals the end of the road. In Denmark, we use a lot of generics so when the patent expires, there is obligatory generic substitution.

Denmark's high level of generics penetration is probably a boon for patients, but potentially a business challenge for your members. How do you see it?

In some countries, pricing for innovative products is squeezed while generics are priced highly. However, Denmark rewards innovation by allowing higher price level for on-patent innovative products while keeping generic pricing low. This leads to high levels of generic penetration, allowing cost savings for the system, while ensuring that innovation remains rewarded.

One issue we are facing is that because of the higher price level for innovative products and our straightforward market access system, parallel imports in Denmark are much higher than anywhere else in Europe at 13.3 percent.

The average time between European marketing approval and availability for patients in Denmark was 169 days. Germany has the shortest average time between approval and availability on the market of 50 days, and Switzerland has the second shortest of 87 days. In European countries, it takes an average of 504 days for new products to become available after obtaining marketing authorization.

Part of this access piece is clinical trials, where Denmark performs well as the country with the highest number of trials per capita in Europe. Why are so many companies choosing to use Denmark as a testing ground?

First and foremost, the Danes are very interested, and willing to participate, in clinical trials. They are also quite willing to give up data for use in research. Unlike some other countries, where quality

data is locked in specific hospitals, we have excellent data across the country and a central personal register, which is crucial. The aforementioned regional reform has also helped, centralising expertise within 21 hospitals and allowing for greater collaborations between clinicians.

Moreover, Denmark has established the 'Trial Nation' initiative, which offers a single, national entry point for global companies, patient organisations and clinical researchers who wish to conduct clinical trials in the country, which has proved to be a great success. Additionally, ten years ago, we centralised a Phase I clinical trial unit, which was almost genius as it allows access to patients from across the whole country in one place.

Finally, governmental procedures on clinical trials are extremely efficient. Denmark, as a high price country will never compete on price with low-cost countries but has a lot to offer in terms of speed, efficiency, quality, and security. This also forms a world-class platform for the development of personalized medicine. Culturally, we are extremely efficient and straight to the point (sometimes to the point of rudeness!) and therefore get things done. The Danish government recognises the benefits of clinical trials, as do patients; they represent tangible gains in terms of giving patients new medicines and creating the possibility of treatment options that previously did not exist.

Internationally, Denmark's COVID-19 response is perhaps best known for culling the country's entire mink population at the end of last year. However, beyond that slightly sensational headline, how deeply has Denmark been affected by the pandemic and how would you characterize the industry's response to it?

We have coped fantastically. Very few people died and there was none of the chaos in the hospitals seen in other countries. We have had two "lockdowns", but they were not as severe as in some other European countries and – although we had to wear masks and practise social distance – both the public and private sectors were allowed to continue operations.

The beginning of the pandemic was characterised by fantastic collaboration between the public healthcare sector and the industry to provide personal protective equipment (PPE). Following that period, the industry led in setting up testing centres which now test 200,000 people per day. The Novo Nordisk Foundation was the first to set up such a centre before the government stepped in and established more.

Now, we have almost completed vaccinating the population, although Denmark is not using the AstraZeneca or J&J vaccines and is one of the only countries in the world just using the mRNA

vaccines from Pfizer and Moderna. The Danish people are happy to be vaccinated and vaccine scepticism is very low.

This vaccination push is going to be a global effort with no one safe until everyone is. Does Denmark have a wider role to play in potentially producing vaccines?

Vaccine access is part of a country's critical infrastructure, although the nationalisation of vaccine production is not on our agenda, given Denmark's relatively small size and because we are working in a truly global industry. Europe has done well in vaccine acquisition and without this, Denmark may have struggled to ensure supply.

What is your final message to our international audience on the Danish life sciences and Denmark as a country?

We are a very well-organised country with a high level of education and are home to several leading foundation-owned pharmaceutical companies. There is a good dialogue with the government across both major parties who understand that good framework conditions for the pharmaceutical industry are extremely important to ensure that Denmark can compete with other countries. Broad agreements are in place to ensure that, whichever way the political winds blow, life sciences will continue to be a national priority. Denmark is also leading the way within Europe via the creation of a Life Science Council – bringing together government, industry, and academia – and which is now being replicated at a European level.

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