Peter Jorgensen – Director, The Danish Generic and Biosimilar Medicines Industry Association (IGL)

> Denmark's framework conditions for generics and biosimilars are exceptionally strong. As a society we should be grateful for that and protect it.

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Peter Jorgensen, Director of the Danish Generic and Biosimilar Medicines Industry Association, discusses Denmark's robust framework for generics and biosimilars, offering insight into a system that has delivered high penetration, cost savings, and broad public trust. From legal structures and patient attitudes to incentives and hospital adoption, Jorgensen outlines why Denmark serves as a model for improving cost efficiency through medicine, and what other countries might stand to learn.

Could you give our international readers an overview of IGL's mission, its purpose, and your mandate on behalf of your members?

Our mission is straightforward: to promote the use of generics in Denmark. IGL represents 16 member companies focused on generics and biosimilars, 14 of which are international players.

While disputes occasionally arise between generic and originator companies regarding patent expiration, we at IGL do not involve ourselves in such cases. As an association, we do not support individual companies but work on broader framework conditions.

How is Denmark positioned in terms of market penetration and utilization of generics?

In Denmark, we are fortunate to have a system that ensures generics are accessible from day one after patent expiry at both hospitals and community pharmacies.

We estimate that approximately 75 percent of daily doses dispensed through pharmacies are generics. This is based on volume, not value. In hospitals, we believe that over half of all daily doses are generics or biosimilars.

Annual savings from generics and biosimilars are estimated at around DKK 10 billion. Of this, approximately DKK six billion is saved through generics at community pharmacies, with hospital savings totalling DKK three billion for generics and at least DKK one billion for biosimilars. Yet we do not often reference these figures, simply because their value is unquestioned.

This reflects how well-integrated generics and biosimilars are in Denmark. The figures are so accepted that there is rarely a need to defend or quantify their value.

What are the factors that contribute to such a strong generic positioning in Denmark's healthcare system?

Generally, there is mutual respect in Denmark regarding patent expiry dates, and there is widespread public trust in generics and biosimilars. This trust translates into practice. By law, pharmacists must offer the cheapest available product, which is typically the generic. Pharmacists play a crucial role here in Denmark. Not only are they legally obligated, but they also make the effort to reassure and inform patients. For instance, some patients might worry if a generic is offered when their doctor prescribed a branded product. In reality, Danish doctors usually prescribe the brand they are most familiar with, knowing full well that the pharmacy will supply the lowest-cost equivalent. They do not have the time or tools to identify the cheapest generic on a weekly basis.

As a result, the name written on the prescription is normally not an endorsement of that specific brand. It is simply how the system works. Nonetheless, some patients are very attached to what their doctor prescribed. They might insist on the branded version, but will then have to pay the difference out of pocket. But this actually happens quite seldom.

Interestingly, there is practically no local production of generics in Denmark. Many generics are manufactured in other countries like India and China, which is one of the key reasons these medicines are significantly cheaper. As all the R&D has already been conducted by the originator companies, generics avoid the high costs incurred by originators. We do not face the same attrition rate of products failing to reach market, nor the associated financial risks. That is why generics are dramatically less expensive.

Are there challenges, or areas you would like to see change, in terms of generic and biosimilar usage?

There are always areas for improvement. Frankly, I do not understand why generics are not more universally adopted wherever they are available. But as I mentioned, the overarching framework in Denmark is strong and effective. While the EU is currently discussing a new pharmaceutical package which is primarily focused on innovative therapies, we believe it will not affect the generics landscape in Denmark. The existing system works well.

However, in collaboration with our colleagues in other European countries, we would like to see the central elements of the Danish model exported. In many places, the introduction of generics is delayed due to various

barriers. For example, if a pharmacist earns a percentage of the drug's retail price, they have a financial incentive to offer more expensive medications. That is not the case in Denmark. Here, pharmacists are paid a fixed fee per prescription, regardless of the medicine's price. This removes any conflict of interest and strengthens the system's integrity.

Pharmacists in Demark perform well when it comes to encouraging the use of generics. It is true that the law obliges them to always deliver generic replacements when available, but people do not always follow the law. This is especially relevant when money is involved. Danish pharmacists generally do what is right, both legally and sustainably.

Patients are motivated by financial logic as well. If they opt for a more expensive brand, they must pay the entire price difference. That provides a clear incentive for patients to choose generics. Bu they also seem to accept and trust the professional guidance given at the community pharmacies.

While there are always details to improve, Denmark offers a compelling case for how to build a successful, trusted, and sustainable market for generics and biosimilars.

While biosimilars have been available in Europe for nearly 20 years, their initial uptake in most healthcare systems was very slow. How are these therapies positioned in Denmark today?

There was certainly some hesitation in the beginning, especially from doctors and patients groups. Understandably, they wanted to be certain of these therapies' efficacy and safety. Biosimilars are not chemically identical to their reference products as generics are. As these are complex molecules produced through biological processes, no two batches of the therapy are the same, and natural variation is inevitable.

As per the European Medicines Agency (EMA), the sole authority empowered to approve biosimilars in the EU, there is a small tolerance for variation between biosimilars and originator therapies. However,t is important to note that these differences must not be clinically significant in order to be approved by EMA. Even if you compared multiple batches of the same branded biological, you would likely find the same kind of minor variation as between that product and its biosimilar.

Still, some scepticism was to be expected, especially when powerful global originator companies had billions at stake. Some products were enormous revenue generators, and these companies worked hard to protect their patents, which is fair. But only up to a point! Still, in 2016 a key decision was made that all EMA-approved biosimilars would be used at once in Denmark, even for well-treated patients. The decision to switch patients from the original biologic to a biosimilar when available marked a turning point. While first initiated by a predecessor organisation (RADS), this stance has been reaffirmed by the Medicines Council.

This shift saved substantial sums and helped hospitals manage their budgets more effectively. In fact, some originator products were completely phased out of hospitals within just three weeks. This is a process that can take years in other countries. A major reason for this achievement is thanks to the work done by Amgros; Denmark's hospital procurement company. They do what is called "horizon scanning" to closely monitor which biologics are nearing patent expiry. This allows Amgros to begin informal discussions with potential biosimilar suppliers up to three years in advance. Then, one year before the biosimilar launch, they initiate formal tender procedures.

While the product cannot be sold until the patent expires, tendering and planning can happen beforehand under EU law. As a result, Danish hospitals are always able to adopt biosimilars from day one.

What is the result of these biosimilar frameworks in terms of market penetration?

It is exceptional. In most cases, biosimilars reach over 90 percent market share very quickly. Early on, it took several months to fully transition away from the original product. Now it can happen in just a few weeks, and there is little public debate. The data and the experience speaks for itself.

Not only do biosimilars save money, but they also improve access. More patients are receiving biologic treatments, with some being treated earlier in life and or for longer durations. In some cases, daily dose volumes have doubled. This is why also patient organisations are now much more supportive of biosimilars. While they have perhaps come aboard more slowly than others, they have come to see that biosimilars benefit patients by expanding access to life-changing therapies.

With Denmark's newest iteration of its life science strategy seeming to focus on innovative medicines and advanced therapies, do you see this as a potential challenge for generics and biosimilars in the future?

Not really. Innovators sometimes argue that patients should always have access to the newest medicines, implying that older medicines, now available as generics, are somehow inferior. They may even refer to generics as "cheap medicines from India".

The idea that a drug suddenly becomes outdated the day after its patent expires is a flawed narrative. That said, if efforts to retain originator products in the market longer were used to boost Denmark's competitiveness, that could have an indirect impact. Still, I think this is unlikely.

Danish politicians are very supportive of the life sciences sector, particularly because originators contribute significantly to the economy. However, they still very much understand and recognize the vital role generics and biosimilars play in controlling healthcare costs. Therefore, I do not see this spotlight on access to innovation in the life science strategy as a real threat.

Is IGL active at the European level when it comes to pharmaceutical policy and regulation?

We are part of *Medicines for Europe*, which is essentially the equivalent organisation for generics and biosimilars at the EU level. That's where most of the European-level engagement happens, particularly around legislative proposals, dialogue with the European Commission, and discussions with the European Parliament.

In Denmark, we contribute to the national political process and provide input from our members, but when it comes to conversations in Brussels, *Medicines for Europe* leads the way. There's obviously some crossover as what happens at EU level has repercussions nationally and vice versa, but there's a clear division of responsibilities.

Another topic that has been raised is the EU's new Urban Wastewater Directive. Is that something IGL is engaged with?

We find ourselves closely aligned with other sectors, like cosmetics. The directive poses a serious challenge, particularly in terms of cost and fairness. We don't believe that the pharmaceutical sector is responsible for the majority of pollution in urban wastewater, and yet we are expected to cover up to 80 percent of the related expenses.

The European Commission has significantly underestimated the total cost of implementation. This will lead not only to higher prices, but potentially to supply issues as well. Some of our members may find that it's no

longer economically viable to continue supplying small markets like Denmark where prices are already low. Instead, they may choose to redirect distribution to countries with better margins. Seven of our members have already brought a legal challenge to the European Court, focusing on proportionality and other legal principles.

In Denmark specifically, the issue is even more sensitive. The public is strongly committed to the green transition, and the "polluter pays" principle is widely accepted. So arguing against the intensions of the directive carries reputational risks. The pharmaceutical industry is already perceived by some as overly profitable. Any objection risks being framed as an attempt to avoid responsibility. It's a delicate balancing act, and we will need to tread carefully in the years ahead. There is no easy fix.

This directive is a challenge not just for the generics sector, but for the entire pharmaceutical industry. And this is a challenges not just in Denmark, but across Europe. That said, the implications may be felt more acutely in smaller countries with lower price points, such as Denmark.

Do you foresee any other challenges related to supply or manufacturing?

The supply chain remains a key issue, and it is impossible to predict how it will evolve. With the current global uncertainties, it is not unrealistic to imagine a renewed push for onshoring pharmaceutical production to Europe. If such a shift became mandatory, it would present significant challenges.

At present, much of the know-how for manufacturing active pharmaceutical ingredients and generics resides in countries like China and India. Production costs are also substantially lower in those regions. Rebuilding that capacity in Europe would require extensive training and infrastructure investment. In parallel, patients and society would need to accept that medicine prices could rise significantly.

If that is ultimately deemed necessary for the sake of security and resilience, then so be it. But there is no doubt it would represent a major challenge. This is not a discussion we are eager to initiate, and we certainly see no reason to question the safety or quality of the medicines currently produced abroad. Nonetheless, it may become a political priority in the future, whether we support it or not.

There is also a broader debate taking place at the European level not only about competitiveness with the US, but also about ensuring medicine supply across the EU. One proposal from the European Commission is to adapt the existing procurement criteria. Instead of evaluating tenders solely on price, environmental performance, and availability, the question of and whether a product is manufactured within the EU, may become a new criterion which are also considered.

For example, tender scoring could allocate a small, fixed percentage to medicines produced in Europe. This is not a policy that we advocate for, but it is under consideration. And admittedly, it does have a certain intuitive appeal. Many people would feel reassured knowing that essential medicines are produced closer to home. What once seemed stable is now more unpredictable across multiple regions.

Looking ahead over the next few years, what are IGL's main priorities or areas of focus?

One major issue right now in Denmark is healthcare reform. There's a strong political ambition to move more treatment closer to people's homes, shifting some of the care that currently takes place in hospitals into the community. This shift could have a direct impact on how medicines are used and distributed.

For example, more products become available at community pharmacies instead of being administered in hospital settings. That sounds simple, but it introduces complexity, especially for biologics. The healthcare system will need to consider how these medicines are administered: is it an oral medication, or does it require an injection? In hospitals, trained staff manage this. But in a pharmacy or home setting, someone else will need to provide that guidance.

Doctors may not have the time or incentive to do it. Pharmacists might have the capacity, but then a system will need to be created to reimburse them appropriately. So, while it's a manageable issue, it's one that will require thoughtful planning to ensure a smooth transition.

Is there any message you would like to share on behalf of IGL and its members with regard to the Danish generics ecosystem?

Denmark's framework conditions for generics and biosimilars are exceptionally strong. As a society we should be grateful for that and protect it. Any future changes to how we prioritize medicines should be approached with great caution. We must resist the temptation of seemingly simple solutions that could jeopardise a system that works remarkably well for patients, providers, and the healthcare budget alike.

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