Flemming Sonne – CEO, Amgros

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Flemming Sonne, CEO of Amgros, Denmark's central pharmaceutical procurement organization for hospital medicines, outlines the organisation's evolving role in ensuring affordable and sustainable access to medicines. In this interview, Sonne discusses Denmark's forward-thinking approach to supply chain resilience, the integration of ATMPs and innovative access models, and the increasing convergence of primary and hospital care. He also shares how Amgros is preparing to expand its influence across sectors and borders, from local manufacturing to Nordic joint procurement.

The last time you were interviewed by Pharmaboardroom was in 2021 – in the midst of managing the challenges of COVID. What were the key lessons Amgros took from managing a pandemic-era supply chain, and how have those shaped your strategic priorities in the years since?

One of the main lessons we took from the pandemic was that the just-in-time supply model is no longer reliable in every situation. Before COVID, we strongly believed in just-in-time delivery, but the crisis made it clear that this principle alone isn't enough to ensure supply security.

At the time, we began stockpiling key medicines, thinking it would be a temporary measure. However, we soon realised the value of maintaining that stock over the long term. Today, we still hold a strategic reserve of medicines, and this stock is now fully owned and financed by Amgros. We manage it in close collaboration with hospital pharmacies.

This experience has re-shaped our thinking. We now actively monitor products that are at risk of supply disruptions – particularly critical medicines like chemotherapy drugs or antibiotics. These are products we simply cannot afford to run out of. We also stock certain strategic products when we anticipate they might be difficult to obtain in the future or when we receive particularly favourable offers.

Overall, our strategy has shifted to focus much more on preparedness and resilience to ensure we can continue delivering essential treatments to patients.

What steps has Amgros undertaken to strengthen the robustness and resilience of the national medicines supply chain?

We have developed a robust strategy to secure the supply of medicines for the Danish hospital market. One of the key actions we've taken has been to establish a national task force dedicated to handling supply issues. This task force brings together representatives from Amgros, the Danish Medicines Agency, the Medicines Council, and stakeholders from the clinical side of the value chain – such as hospital pharmacies. Whenever we face a supply issue, or where a product is unavailable, we work closely as a group to identify alternative treatments for patients.

Some of our supply chain initiatives are based on lessons learned during the COVID-19 pandemic, but we are also building on Denmark's long-standing tradition of domestic manufacturing of branded products and magistral preparations. For example, these pharmaceuticals are manufactured at two of the eight hospital pharmacies in Denmark, one in central Copenhagen and another in the Region Zealand. These sites will form part of the new "Eastern Denmark" region which will be established as part of the regional reorganization taking place under the new healthcare reform.

At present, Amgros owns marketing licenses for about 60 products, but we're assessing whether to maintain, reduce, or expand that number. These products generally cover patients with special needs, and in many cases they cannot be purchased from the industry. They are registered pharmaceuticals approved by the Danish Medicines Agency, and we oversee their production and pharmacovigilance. This is a matter of preparedness and understanding which products we must be able to manufacture ourselves in crisis scenarios.

If we look at Sweden, they have a target to be able to produce over 200 products domestically. The hospital pharmacies and Amgros are assessing whether Denmark should aim for a similar

level, or whether we should focus only on certain products and purchase the rest.

These are the types of strategic questions we're actively working on. One of the greatest strengths of the Danish model is the close collaboration between hospital pharmacies and institutions like Amgros and the Medicines Council. That strong coordination is at the heart of our ability to respond effectively and safeguard medicine availability.

Today, how does Amgros structure its priorities and operations across the national, Nordic, and broader EU levels to ensure coherence and impact?

Amgros structures its priorities across three main levels: national, Nordic, and European. Each plays a distinct role in our overall strategy, though the national and Nordic levels remain the most operationally active and impactful.

One of the central platforms for our regional cooperation is the Nordic Pharmaceutical Forum (NLF), which we established ten years ago. The Forum continues to play a key role as we run a number of joint initiatives, including cross-border tenders – we're currently on our fourth – and broader cooperation on manufacturing, horizon scanning, and supply issues.

This collaboration spans both operational and strategic areas. While it may not be feasible to develop a unified Nordic strategy on every front, the collaboration allows us to share best practices and inspire each other. We also work closely on topics such as environmental criteria, as well as emerging areas like advanced therapy medicinal products (ATMPs), and the introduction of new medicines to the market.

At the European level, our involvement is more limited. The landscape across EU countries is highly diverse, and the Danish setup differs in several key ways. For example, Denmark has centralized procurement of medicines – many countries have decentralized procurement – this gives us an advantage as we are coordinated across the country and it gives us a bigger buying power. Also, while Denmark does have private hospitals, they largely focus on surgical procedures. The medical side of care remains primarily public and publicly funded. These structural differences make it more challenging to find common ground for operational initiatives at the EU level, but we continue to monitor developments and engage where relevant.

Overall, the current structure allows us to remain deeply rooted in national priorities while also contributing meaningfully at the Nordic level and selectively engaging at the EU level where it makes sense to do so.

Within the EU context, what are the best practices and key competencies regarding access and procurement that Denmark can role model for other member states?

I wouldn't claim that Denmark is the best in all areas, but I do believe we are among the best-in-class when it comes to procurement and negotiation in the healthcare space. Other EU member states are doing great work within the context of their own systems, and their approaches are adapted to their local needs and structures. However, Denmark has developed a strong and consistent track record in this area over the past 30 to 35 years.

During my time as CEO, Amgros has grown from a team of six to more than 150 people over the last two decades. That growth has allowed us to build a highly professional and well-functioning procurement infrastructure that spans everything from tendering and manufacturing to legal frameworks and IT systems. This structure enables us to share knowledge both nationally, across the Nordic region and Europe.

One of the reasons we've been able to succeed is because we've made significant investments in this area. Today, Amgros manages a healthcare procurement of over DKK 10 billion – around EUR 1.4 billion. For a small country like Denmark, that's a substantial figure. Of course, this scale is modest compared to countries like Germany, where the market is 20 times larger. But in Denmark, we've optimised our model for our specific healthcare structure, which includes just eight hospital pharmacies.

Whether we are the best is up for debate, but from a Danish perspective, we've done well. Our model has attracted interest, in part due to a 2008 McKinsey report that highlighted the importance of regional management teams taking procurement seriously. That report led to a stronger national mandate, with clear directives to pursue savings and create a centralised system. As a result, we now operate within a unified national framework based on health technology assessments (HTAs), national clinical guidelines, and centralised tendering and negotiation processes.

This level of national coordination is quite unusual in Europe, where many systems are more decentralised or shaped by liberal market principles. In Germany, for instance, healthcare funding is managed through private insurance funds, known as Krankenkassen. By contrast, Denmark's healthcare system is publicly funded at the national level, which allows us to take a more integrated and strategic approach. This structure gives us the ability to implement best practices across the entire hospital sector. I believe this is something other EU countries can look to as a

potential model.

How does Denmark leverage procurement strategies and frameworks as negotiation tools to ensure value-based access to innovation?

In Denmark, we primarily apply our procurement strategies to two key areas: hearing aids and medicines. While medical equipment and medtech are procured through a different setup, the approach we use for medicines has become a nationally accepted standard. This is particularly due to the structured use of the anatomical therapeutic chemical (ATC) classification system. This standardisation allows us to approach procurement with a clear and consistent framework, supporting both efficient purchasing and the appropriate use of products.

Still, procurement alone isn’t enough. You can have the best contract, but if it’s not aligned with clinical practice, it won’t be used. That’s why Denmark has built a broader ecosystem around procurement that ensures value-based access to innovation. It’s not just about what we do here at Amgros, we also work closely with the Danish Medicines Council. This collaboration plays a critical role in determining how new products should be integrated into treatment guidelines.

This integration between procurement and clinical guidance is something that sets Denmark apart. In some countries, like Norway, the system for treatment guidelines is quite different. In Denmark, we have a structured, national process where Amgros handles the price negotiations for new products, while the Danish Medicines Council assesses their clinical value and decides on their place in treatment paradigms. The Council also develops national treatment guidelines, drawing on the expertise of top physicians in the country.

This approach covers the full lifecycle of a product, from innovation and new market entries to mature brands and generic medicines. Generics remain essential, especially in hospital settings and in the primary sector, where most prescriptions are generics. Ensuring access to cost-effective generics is just as important as evaluating and negotiating new, innovative treatments.

What makes the Danish model unique is the national alignment. We have a single framework where clinical, economic, and procurement perspectives come together. The Medicines Council plays a central role in this, bringing together groups of clinicians to determine the most effective treatments for somewhere between 70 to 80 percent of patients. This process has also supported Denmark’s successful adoption of biosimilars. Unlike in many other countries, Danish doctors have shown a high level of acceptance when switching from originator products to biosimilars, precisely

because these transitions are backed by clear clinical guidelines and national coordination. When a biosimilar is determined to be the national standard, doctors must comply.

In what ways does Denmark’s centralised procurement structure contribute to long-term cost savings, while safeguarding patient access and system sustainability?

As I mentioned, strict adherence to treatment guidelines is an expectation in Denmark. Even highly specialised doctors working in hospitals are expected to follow the national formularies. For instance, when the Danish Medicines Council approves a biosimilar, it becomes the standard treatment in hospitals. There’s no room for individual preference unless there’s a clinical exception such as a specific labelling requirement that justifies the use of the originator. Except for Norway, this level of enforcement is quite rare in Europe.

We also have a long-standing tradition of substitution. This is true not just in hospitals but also in the retail pharmacy sector. If a patient goes to a pharmacy and asks for a particular medicine, they’ll typically be offered the cheapest available equivalent. If they insist on the originator or a more expensive version, they can still get it, but they’ll only receive reimbursement equal to the price of the cheaper option.

One of the pillars of Denmark’s Life Science Strategy toward 2030 is to accelerate access to emerging innovations such as ATMPs. How prepared is the local environment to adopt and integrate these therapies?

Over the past few years, Denmark has been actively building the foundations needed to adopt and integrate ATMPs, including gene therapies. The Danish Medicines Council actually started from within Amgros before becoming a separate entity. Since then, it has evolved significantly to play a key role in the assessment and integration of new innovations like ATMPs.

ATMPs are already part of our daily work. For the past three years, both Amgros and the Danish Medicines Council have been involved in evaluating and negotiating access to these therapies as they come onto the market. Applications are submitted to the Council, we negotiate the price and contract terms, and then the Council determines whether the treatment can be recommended as standard care for a specific patient population.

More recently, the Ministry of Health launched a new national initiative, ATMP Denmark. The secretariat is placed here in Amgros – we began this work around two and a half months ago and it is state-funded for an initial three-year period. The aim of this initiative is to build up national expertise and infrastructure for both commercial and academic ATMPs. This includes studying best practices in other countries, understanding how to manage regulatory pathways, and exploring how public–private collaborations can support the development and delivery of these therapies.

The setup has been endorsed by the Ministry of Health and the Danish regions, and we're now leading the work on their behalf. Still, we have a challenge ahead, how do we deliver more healthcare value from the same budget? ATMPs are not expected to receive a separate or expanded budget, so they must be integrated within existing funding structures.

Of course, ATMPs will also fall under the EU-wide HTA framework. Once evaluated at the European level, decisions will still need to be localised through the Danish Medicines Council, followed by national negotiations. In this sense, our preparedness is about aligning Danish processes with European developments.

To what extent has Amgros been able to make meaningful progress in utilising more innovative access models, such as outcome-based agreements or real-world evidence frameworks?

When it comes to ATMPs, they're often seen as "wonder drugs". In many ways they are, particularly for rare diseases. However, a common challenge we face with ATMPs and other new products is the lack of sufficient data at the time of market entry. We often don't know enough about their real-world effectiveness or long-term outcomes. So, while millions are spent on new therapies, we have to ask: are we following up effectively to see how patients are actually doing months or years later?

At Amgros, we've taken steps to explore alternative access models. We've already established several special agreements with industry. Companies can submit applications to propose alternative contract models which might include subscription-based payments, agreements linked to treatment effectiveness, or other arrangements tailored to specific therapeutic areas.

One of the most important principles for us is ensuring some level of insurance or protection around the clinical effect of a product. For example, if a gene therapy doesn't deliver long-term results after several years, who bears that cost? In many cases, the data is weak, the price is high,

and long-term efficacy is unknown. We also don’t always have post-approval studies to clarify those uncertainties.

The challenge lies in finding measurable outcomes. In oncology, for instance, it can be difficult to evaluate effect – particularly for third-line therapies. But when a clear clinical target exists, outcome-based models become more feasible. A recent example is an agreement we reached for a gene therapy for patients with haemophilia B. It’s an extremely expensive treatment, but we’ve structured a customised contract to ensure both Amgros and the manufacturer can collect and share data after the therapy is administered. While I can’t share details, it’s a strong example of how we’re adapting to the realities of high-cost innovation.

This isn’t just a Danish issue, but a global one. All health systems face the same question of how to monitor the long-term effectiveness of new treatments? And does the private sector have the incentive to help generate and share real-world data?

Ultimately, the best form of insurance is to build strong agreements that provide some security for the public investment being made in each patient. Everything we do is centred on the patient; therefore, we must ensure that new treatments deliver real value.

How is Amgros engaging in meaningful dialogue with industry stakeholders to foster access while upholding the principles of safety and affordability?

Creating dialogue is important, and at Amgros, we engage with industry stakeholders on a daily basis. We regularly host meetings with companies, industry associations, and patient groups as these conversations are vital to understanding both the needs of the healthcare system and the priorities of industry. It’s through this dialogue that we can find common ground to deliver value for patients.

Each stakeholder brings a different perspective to the table. Doctors prescribe treatments, public authorities ensure access and safety, and the industry naturally wants to reach patients and build a strong market presence. Everyone is working toward the same goal of patient care, but from different angles. I think of it as a Venn diagram. On one side, you have the healthcare system and the patients, and on the other, the industry. Amgros sits in the middle, helping to balance both sides.

We work to define aspects like what kind of dialogue is needed, what IT systems should be in place, and what kind of financial arrangements are required to ensure value, for example. These are the

questions we help answer, always aiming to balance innovation with affordability, safety, and long-term sustainability.

Just this morning we held a meeting with one of the organisations representing the generics industry. That kind of exchange is invaluable as it allows us to stay informed about market developments, whether in generics, advanced therapies, or broader innovation trends. It gives us the knowledge we need to make better decisions and helps the system adapt to the rapid pace of scientific and technological change.

Beyond the increasing complexity and cost of innovative medicines, what other disruptive trends do you anticipate will significantly impact healthcare procurement in the coming years?

I believe one of the most disruptive trends will be the growing strain on global supply chains. We need to start viewing medicines through a broader lens that accounts for geopolitical instability, global demand, and the commercial realities of pharmaceutical manufacturing. Conflicts and wars remind us of the importance of being prepared, and at the same time, increasing global demand is placing more and more pressure on manufacturing capacity worldwide.

This global dynamic has direct consequences for Europe and the US. If countries like India or China are able and willing to pay higher prices for essential medicines, manufacturers will naturally prioritise those markets. In Europe, we've historically placed strong emphasis on low prices, but if we continue to focus solely on cost, we risk losing access to key products. For manufacturers, it's a commercial decision in the end. If they can sell their products at double the price somewhere else, they will.

As healthcare stakeholders, we want industry to invest in R&D and develop new therapies, but we also need to make sure those therapies remain affordable and accessible. Balancing those two demands will become increasingly challenging as global demand and purchasing power in what have been historically considered developing markets continues to grow.

Furthermore, supply will be one of the biggest issues we face over the next decade. The question is, are we willing to invest in preparedness? That means paying for things we might never use, such as stockpiles of APIs or local manufacturing capacity that remains on standby. It's difficult to prioritize that hypothetical preparedness, especially when other sectors like education are also competing for public funds. As long as medicines are available on the global market, we'll keep

buying them of course, but if that access breaks down as we saw during COVID, we'll wish we had local production in place. Preparedness and supply are the key words.

Looking ahead, what are the key strategic priorities for Amgros, and where do you hope to see the organisation positioned in the next five years to meet the evolving demands of healthcare and life sciences?

It's always difficult to predict exactly where we'll be in five years, but there are several strategic priorities that I believe will shape the future direction of Amgros.

First, we face a fundamental challenge in healthcare of simply not having enough people to meet the growing demand. This is not just a Danish issue, but a global one. One of our top priorities will be to support hospitals and patients by developing solutions that help the system operate more efficiently. How can we make life easier for healthcare providers and ensure patients still receive high-quality care?

We also expect to see a continued wave of ATMPs and gene therapies entering the market. These innovations will place additional pressure on the system, so we must be ready with a tailored setup that can manage both their clinical value and financial impact.

Environmental sustainability is also a prominent part of our agenda as well. While we've started incorporating environmental criteria into procurement decisions, it's still at an early stage. Over the coming years, we'll need to consider the broader environmental impact of medicines such as including water pollution and overall emissions and take more concrete steps to reduce it.

As I mentioned, supply chain resilience will remain a top priority. We'll need to strike the right balance between supporting access to new and innovative medicines and driving savings through generic and analogue substitution for mid-life products. Preparedness will also continue to be an important consideration, not just in the hospital sector, but in primary care as well.

In fact, one of the major shifts we will see as part of Denmark's new healthcare system reform is a move away from a two-sector view of healthcare towards a more unified system. Instead of differentiating between the hospital, primary care, and even private sectors, we hope to support access wherever patients are treated. I expect our role in procurement and negotiation will increasingly extend across the whole care pathway.

Another area of focus will be the EU’s evolving pharmaceutical strategy. While there’s still uncertainty around how it will take shape by 2030, we are already engaged and prepared to respond to whatever direction it takes.

In this vein, we’ve recently taken on a new task from the state to pilot procurement and negotiation in the private sector. This initiative is initially set for the next three years, but I expect it will continue on. More treatments are being delivered outside of hospitals, and that calls for a new approach. Although legislation currently restricts public price setting in the primary sector, we’re exploring how we can use our expertise to support savings, even if through confidential pricing. This mechanism isn’t ideal, but sometimes necessary to ensure affordability given different levels of affordability across the EU.

Finally, we’ll continue to invest in technology and digital infrastructure to prepare for greater collaboration outside of Denmark, particularly with other Nordic countries. Joint procurement across borders will be a key focus, and we want to ensure we’re ready to contribute to and lead that process where possible.

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