

NORDIC PHARMACEUTICAL FORUM

STRATEGY FOR 2023-2025



Nordisk Lægemedelforum

Content

Ambition	4
Common challenges and background.....	4
Sub-strategies	6
1) Innovative and strong purchasing collaborations	6
2) Security of supply	9
3) A strong Nordic voice.....	10

Notice:

This document has been prepared by the Nordic Pharmaceutical Forum. The document solely reflects the views of the authors and their corresponding organizations.

Authors:

Flemming Sonne
(Chair of the Nordic Pharmaceutical Forum and CEO of Amgros I/S)

Tommy Juhl Nielsen
(Director, Pharma Division at Sykehusinnkjøp HF)

Einar Andreassen
(Strategic Director, Department for health economics and analysis, Norwegian Medicines Agency)

Marianne Aufrecht-Gustafsson
(Senior Legal Advisor in Health and Medical Care Administration (HSF), Stockholm Region)

Mikael Svensson
(Coordinator negotiations, regional cooperation model for pharmaceuticals, Swedish Association of Local Authorities and Regions (SALAR))

Ólöf Þórhallsdóttir
(Head of Application and Communication Unit, Icelandic Medicines Agency)

Rannveig Alma Einarsdóttir
(Clinical pharmacist and Project Manager, Medicines Committee of Landspítala)

Kerstin Carlsson
(Director, HUS Pharmacy, HUS Group, the joint authority for Helsinki and Uusimaa)

Ambition

It is the Nordic Pharmaceutical Forum's¹ ambition in 2025 to be a: "Recognized Nordic collaboration, developing and delivering sustainable solutions to supply medicines to the patients in public hospitals".

The underling purpose of this is to continue to ensure timely and affordable access to medicines for patients in public hospitals in the five Nordic countries - Finland, Iceland, Norway, Sweden and Denmark.

In order to ensure that the Nordic Pharmaceutical Forum's ambition can be achieved, the present strategy has been drawn up. The strategy proposes increased cooperation and higher ambitions across the Nordic countries.

The strategy is divided into three sub-strategies:

- Innovative and strong purchasing collaborations
- Secure supply
- A strong Nordic voice

In the following sections, the background for the Nordic Pharmaceutical Forum and the common challenges for the Nordic countries are first reviewed; then follows a review of the three sub-strategies, while finally focus is on the results achieved by the Nordic Pharmaceutical Forum.

Common challenges and background

The Nordic Pharmaceutical Forum was established in 2015. The background for the establishment of the Nordic Pharmaceutical Forum was a number of common challenges across the Nordic countries that affected access for patients to both new and old medicines:

- Increasing expenditure of medicines due to demographics, new treatment options and the development of new, often promising and expensive drugs
- Increasing supply difficulties
- Small markets like the Nordics have less opportunity for price pressure than large markets
- Small markets like the Nordics have to work harder to stay attractive for industry than large markets

It was the common assessment across the procurement organizations in the Nordic countries that these challenges could be managed more easily by cooperating.

The Nordic Pharmaceutical Forum was therefore established with the aim of ensuring timely and affordable access to new and old medicines for patients and to create a framework and space for Nordic co-operation in the field of pharmaceuticals.

For the past seven years, the focus of the collaboration has been knowledge-sharing, as well as uncovering opportunities for, and working towards, common Nordic solutions within the fields of; new pharmaceuticals, sustainability, horizon scanning, manufacturing and security of supply.

¹ The Nordic Pharmaceutical Forum consists of the following organizations from the following countries: Amgro I/S in Denmark. Sykehusinnkjop and the Norwegian Medicines Agency in Norway. The Swedish Association of Local Authorities and Regions (SKR/SALAR) and Hälso- och sjukvårdsförvaltningen (Region Stockholm) in Sweden. HUS Group, the joint authority for Helsinki and Uusimaa and Wellbeing Services County of Northern Ostrobothnia in Finland. Landspítali and the Icelandic Medicines Agency in Iceland.

However, neither the collaboration nor the results in the Nordic Pharmaceutical Forum have come easily. The organizations in the Nordic Pharmaceutical Forum have invested time and resources to get a better understanding of each other, their differences and similarities. This process has laid a strong foundation for finding joint solutions and creating results together. And it is a process that the Nordic Pharmaceutical Forum is proud of.

And joint results have been developed.

The Nordic Pharmaceuticals Forum has managed to get the health ministers in Denmark, Norway and Iceland to sign a common Nordic agreement of intent on joint tendering procedures and price negotiations.

The Nordic Pharmaceutical Forum has taken steps to be recognized internationally as an actor that can contribute with valuable knowledge within negotiations on new medicines, joint tendering, and horizon scanning.

During the last year, the Nordic Pharmaceutical Forum has developed a new "Governance" that streamlines and professionalizes the work in the Nordic Pharmaceutical Forum.

Despite the good cooperation and good results, it is the common assessment of the Nordic Pharmaceutical Forum that there is a need for increased cooperation and higher ambitions across the Nordic countries. This new strategy sets the direction for future cooperation to ensure that the Nordic Pharmaceutical Forum's ambition is reached in 2025.

The need for a new and updated strategy emerges from a joint Nordic analysis of world changing around the Nordic countries. Covid-19 has emphasized that the pharmaceutical market is both global and fragile - uncertain supply chains and supply failure are not uncommon. Further, in November 2020 the European Commission launched a Pharmaceutical Strategy that sets the tone for further cooperation in Europe and the Nordics. The Pharmaceutical Strategy resulted in a revision of the European pharmaceutical legislation in the spring of 2023, and it aims to secure European supply of safe and affordable medicines to meet patients' needs, and to support the European pharmaceutical industry to remain an innovator and world leader. The revised pharmaceutical legislation combined with the non-regulatory measures set out in the Pharmaceutical Strategy will both have impact on the organizations in the Nordic Pharmaceutical Forum. The establishment of the European Health Emergency preparedness and Response Authority (HERA) just adds to the complexity and will potentially impact the Nordic countries' ability to ensure access to pharmaceuticals for patients.

It is therefore important for the Nordic Pharmaceutical Forum to adapt to the world around us, and to understand the changes. This includes in particular how the EU Pharmaceutical Strategy and the revision of European pharmaceutical legislation will impact the set-up in the Nordic countries and our ability to ensure access to pharmaceuticals for patients.

Furthermore, the Nordic Pharmaceutical Forum experiences that the pharmaceutical industry is acting and consolidating itself globally. As buyers, we must be able to match this. And we do that best by increasing our collaboration.

Sub-strategies

The strategy has been divided into three sub-strategies that were identified during two strategic workshops in Stockholm in 2021 and Copenhagen in 2022. The workshops included an online call with DG SANTE, separate discussions of the macro factors impacting each working group, and the preparation of a SWOT analysis (Strengths, Weaknesses, Opportunities, Threats). This has contributed to a common understanding of the needs for increased collaboration, and thus which areas (sub-strategies) the main strategy should focus on.

1) Innovative and strong purchasing collaborations

Innovative purchasing collaborations can contribute to ensure that patients in the Nordic countries continue to have access to new, often promising and expensive medicines; that the security of supply for older and well-known medicines is strengthened; and that procurement is more environmentally friendly. Thus, to ensure that the Nordic Pharmaceutical Forum has innovative and strong purchasing collaborations, the forum must strengthen cooperation in the following areas:

- New, often promising and expensive medicines
- Joint Nordic tendering procedures with environmental criteria.
- Horizon scanning

New, often promising and expensive medicines

As national procurers of hospital medicines in the Nordics, we are all experiencing challenges regarding access to medicines and affordability of medicines. Further, the evidence for the effectiveness of new products is often uncertain.

Increased cooperation within new medicines, e.g. in the form of joint negotiations, is an innovative way for the Nordic Pharmaceutical Forum to ensure access for patients to new and innovative pharmaceuticals. Joint negotiations between countries creates a bigger market. A bigger market can be more attractive for industry, and it can increase our possibilities to introduce new drugs affordably. It will also contribute to the Nordic Pharmaceutical Forum's ambition to be recognized as a collaboration that develops and delivers sustainable solutions to supply medicines to the public sector.

The Nordic Pharmaceutical Forum already has experience with joint negotiations on new medicines. In 2020 and 2022, the Nordic countries carried out joint negotiations on new gene therapies. The negotiations were based on joint clinical and economic assessment from FINOSE², and a representative from each country took part in the negotiations. The aim of the negotiations was to have common terms and conditions across the countries. The result of the joint HTA and price negotiation was subsequently taken up as a basis for a reimbursement decision in each country. Through joint negotiation, the countries aimed to achieve an acceptable and sustainable price, and to ensure rapid and equal access to the medicine for patients in all five

² FINOSE is an HTA collaboration network between Fimea (Finland), NoMA (Norway) and TLV (Sweden). In practice, the cooperation means that the three agencies will write joint assessment reports for pharmaceutical products. These reports will contain both clinical and health economic assessments (https://www.fimea.fi/web/en/development/therapeutic_and_economic_value_of_medicines/nordic-collaboration-finose).

countries. Experience from this process will be taken forward as the basis for further developments for innovative purchasing collaborations.

The Nordic Pharmaceutical Forum's ambition in the future is to be able to carry out further joint negotiations with pharmaceutical companies when such negotiations are of mutual benefit to patients in the participating countries. A prerequisite is that joint negotiations must not delay access to medicines for the patients. To implement the ambition, it is necessary to have common guidelines for both the negotiations and the selection of the candidate pharmaceuticals for joint negotiation.

The Nordic Pharmaceutical Forum is focusing on developing guidelines for joint negotiations on new and expensive medicines in collaboration with national HTA bodies. The ambition is to complete development of these guidelines and criteria by early 2023.

Another focus area for the Nordic Pharmaceutical Forum is advanced therapy medicinal products (ATMPs). All Nordic countries experience that finalizing agreements on ATMPs is time consuming and can delay patients' access to treatment. ATMPs will make up an increasing share of new medical treatments approved by the European Medicines Agency (EMA) in the future. There is therefore a need to make sure that the dialogue between the pharmaceutical companies and the purchaser is more efficient. Hence, Denmark, Sweden, and Norway have entered into a collaboration on standard terms for ATMPs. This means that the countries will share their experience with standard terms for ATMPs. The collaboration will be monitored and it is open for Iceland and Finland to join.

Joint Nordic tendering procedures with and without environmental criteria

Joint Nordic tendering procedures can contribute to better security of supply, in particular for older medicines, as joint tenders mean a larger market. A larger market makes it more attractive for suppliers to deliver medicines and package sizes that suppliers have otherwise deemed too small for the individual Nordic markets. Joint Nordic tendering procedures might also, in the long run, result in better prices, as a larger market can give payers a better bargaining position.

Nordic Pharmaceutical Forum already has experience with joint tendering procedures. Denmark, Norway and Iceland have conducted two joint tenders together³. The latest joint tender incorporated environmental criteria, as a central criterion as the goal was to increase the security of supply and gain experience with environmental criteria. This will improve more sustainable access to medicines for patients over time. Incorporation of environmental criteria has been important, as the Nordic Pharmaceutical Forum has an ambition to contribute to the green agenda in all of the countries.

Joint tendering procedures and procurement across countries, with and without environmental criteria, are internationally recognized as innovative. The Nordic Pharmaceutical Forum has achieved international recognition for its joint tendering procedures and has recently been awarded the: *Innovation & Procurement*

³ Iceland, however, had challenges with the first joint tendering procedure, as suppliers did not find it financially feasible to apply for marketing authorization for such a small market. Therefore, suppliers could choose whether to bid on Iceland in their tenders. This meant that Iceland did not receive any bids. Iceland only received a bid from one company, but in that tender Iceland was mandatory. In the second joint tendering procedure, the Icelandic challenges were solved in collaboration with the Icelandic Medicines Agency. Iceland received bids for all tenders, and at a considerably lower price.

Excellence Award 2022 at the Pan-European Healthcare Procurement Summit for our joint Nordic tendering procedure with environmental criteria. A Scientific Committee found that the joint tendering procedure is: "*outstanding, impactful, scalable and an inspiring role model for other organizations*".

Joint Nordic tendering procedures with and without environmental criteria are thus not only important to ensure access to medicines for Nordic patients, they also ensure the Nordic Pharmaceutical Forum's ambition to be recognized as a collaboration that develops and delivers sustainable [and innovative] solutions to supply medicines to the public sector.

The Nordic Pharmaceutical Forum's ambition is therefore to conduct joint tendering procedures for newer and older medicines where relevant, and to continue working with environmental criteria in tenders. Another ambition is to investigate the possibility of participation from one or more of the Swedish and/or Finnish regions to further strengthen the collaboration and leverage greater scale with more volume behind tendering procedures.

The organizations in the Nordic Pharmaceutical Forum have an important task to secure the supply of medicines to public hospitals in their respective countries. However, the Nordic Pharmaceutical Forum realizes that the times when supply was only a matter of quality, price and delivery have passed – there is an increased focus on sustainability and the environment. The Nordic Pharmaceutical Forum is therefore looking towards more sustainability solutions and areas for Nordic cooperation within sustainability as the Nordic Pharmaceutical Forum is committed to making its mark on the sustainability agenda.

Horizon scanning

Horizon scanning provides an overview of pharmaceuticals, extensions of indication and pharmaceutical forms that are expected to be marketed in the Nordic countries within the next two to three years. This enables us to plan future processes, prepare upcoming price negotiations with suppliers, and to organize our tendering procedures in due time. In other words, horizon scanning tells us which medicines we will see in the future and what this means for us and our budgets. Hence, horizon scanning provides an important area of collaboration and knowledge sharing in the Nordic Pharmaceutical Forum, because increased cooperation allows us to be even better prepared for the future.

In recent years, the Nordic Pharmaceutical Forum has benefitted from increased knowledge-sharing between the Horizon Scanning (HS) group and the group for New Expensive Drugs (NDL). Based on this positive experience, the Horizon Scanning group is engaging with all of the working groups in the Nordic Pharmaceutical Forum to uncover potential untapped knowledge-sharing potential and synergies.

The strong tradition of cooperation and knowledge-sharing on horizon scanning between the Nordic countries in the Nordic Pharmaceutical Forum has also benefitted others. Amgro and Region Stockholm have played an important role in the establishment of the International Horizon Scanning Initiative (IHSI), which is a collaboration on horizon scanning between eight European countries - including Denmark, Norway and Sweden. It has been possible for Amgro and Region Stockholm to share concrete experience from the Nordic cooperation. In addition, both Amgro and Region Stockholm have helped prepare requirements specifications in relation to the supply of IHSI's database and helped to assess the offers submitted. This shows that the collaboration of the Nordic Pharmaceutical Forum is creating a strong common Nordic voice that is taken on board when solutions are to be delivered.

2) Security of supply

Security of supply is key for the purpose of the Nordic Pharmaceutical Forum, ensuring timely access to medicines for patients in the five Nordic countries. On the one hand, strong security of supply entails having control and knowledge of the supply chain at both strategic and operational levels. On the other hand, strong security of supply entails having strong hospital pharmacies and pharmacies that can produce safe and effective medicines.

Thus, to ensure strong security of supply of medicines across the Nordic countries, the Nordic Pharmaceutical Forum must strengthen cooperation in the following areas:

- Strategic and operational supply chain difficulties
- Production of safe and effective medicines

Strategic and operational supply chain difficulties

Supply chain difficulties in the Nordic countries can be mitigated by having knowledge of how to deal with the day-to-day supply failures on an operational level, and by having a strategic approach and outlook to the prevention of supply chain difficulties.

The Nordic Pharmaceutical Forum is already good at sharing knowledge on how to handle, operationally, day-to-day supply problems. Focus by the Nordic Pharmaceutical Forum on supply chain difficulties has mostly been on back orders, short-term initiatives and knowledge sharing. This focus continues to be of great importance for the Nordic Pharmaceutical Forum.

However, strategic actions have so far rarely been a part of the agenda in the Nordic Pharmaceutical Forum. It is the belief in the Nordic Pharmaceutical Forum that, going forward, the Nordic countries can benefit greatly from more knowledge-sharing regarding strategic initiatives to improve security of supply in each country. This is due to the fact that the Nordic countries have many identical issues within supply chain. As part of this, the Nordic Pharmaceutical Forum will focus more on the impact of the EU pharma strategy and the establishment of HERA on the daily business in supply chain. Knowledge-sharing and experience gained from implementing the EU pharma strategy in the EU and the Nordics will be key going forward.

It may also be relevant for the Nordic Pharmaceutical Forum to discuss whether there is a possible need to establish a common Nordic stock of pharmaceuticals in order to improve security of supply across the Nordics.

Production of safe and effective medicines

Production from hospital pharmacies in the Nordics plays an important role in ensuring access to treatments for patients. Further, production from hospital pharmacies is essential to preserve Nordic preparedness for a future crisis, as hospital pharmacies manufacture unlicensed pharmaceutical preparations and pharmaceuticals for individual patients or small groups of patients with special needs that cannot be met by industrial products.

Production at the hospital pharmacies requires strict documentation for the quality of raw materials, manufacturing processes and the finished pharmaceuticals. Development of an unlicensed drug is time

consuming and quite expensive. Furthermore, development and validation of analytical methods can also be time consuming.

Cooperation and knowledge-sharing across the Nordic countries on manufacturing of pharmaceuticals is therefore meaningful, and the ambition of the Nordic Pharmaceutical Forum is to look at possibilities for collaboration within the Nordic countries regarding development and production of unlicensed pharmaceutical preparations, especially in situations with medical shortages.

For instance, if an unlicensed pharmaceutical preparation is needed in several of the Nordic countries, it would save time and costs if we could collaborate. The Nordic Pharmaceutical Forum is therefore drawing up an overview of manufacturing facilities for different types of non-industrial medicines across the Nordics. However, import and export of non-industrial medicines manufactured at the hospital pharmacies in the Nordic region is restricted, as the legal framework is not harmonized. If the rules were harmonized, it would make collaboration easier, and we would be better able to secure more robust access to commercially unavailable medicines across all the Nordic countries.

The Nordic Pharmaceutical Forum also has as an ambition to draw attention to the need for legislation at EU level that will enable stockpiling of unlicensed pharmaceutical preparations. Stockpiling of unlicensed pharmaceutical preparations can contribute to better patient safety, lower prices, and stronger security of supply, as the medicines can be prepared in advance and under less pressure.

3) A strong Nordic voice

A strong Nordic voice and increased visibility is key to ensuring that the Nordic Pharmaceutical Forum's ambition of being recognized as a collaboration that develops and delivers sustainable solutions to supply medicines to the public sector is met.

Further, a strong Nordic voice and increased visibility for the results and initiatives from the Nordic Pharmaceutical Forum is important to ensure that the interests of the Nordic Pharmaceutical Forum are heard internationally. Taking care of the forum's interests internationally is increasingly important in a fast-changing world where global suppliers and regional and international cooperation sets the tone for the future.

The Nordic Pharmaceutical Forum is therefore developing a visibility plan with two main elements:

- Visibility of the results of the Nordic Pharmaceutical Forum
- Dialogue with stakeholders

Visibility of the results of the Nordic Pharmaceutical Forum

This covers results generated within individual groups and between the seven working groups. There will be special focus on creating extra visibility of initiatives concentrating on better access to medicines for patients, including the joint tendering procedures and the ambitions for joint negotiations on new and often promising medicines. In addition, it will be important to draw attention to common ambitions within the fields of environment and sustainability.

Dialogue with stakeholders

The Nordic Pharmaceutical Forum is interested in dialogue and cooperation with authorities, networks with other payer organizations, industry and suppliers. Dialogue and cooperation are important to gather learnings and insights from others, and to share our proposals and concerns regarding changes within the pharmaceutical field, e.g. regulation at European level or initiatives by national authorities.