Key Opportunities and Challenges in the Nordic Pharmaceutical Markets

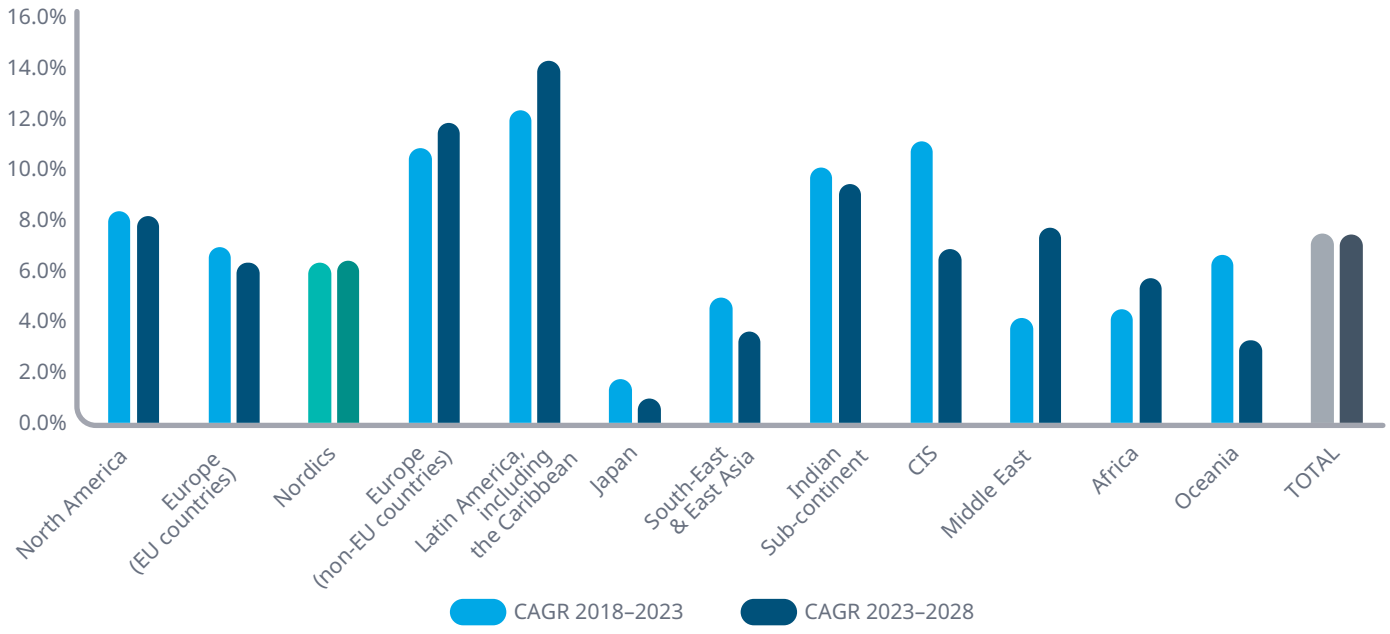
IQVIA Market Prognosis — November 2024

This article reviews the latest pharmaceutical forecasts from IQVIA's Market Prognosis, offering an overview of the key opportunities and challenges anticipated to impact the Nordic pharmaceutical markets over the next five years. The analysis is based on findings from **Denmark, Finland, Norway**, and **Sweden**, as detailed in the IQVIA Market Prognosis September 2024 edition.

Amid ongoing geopolitical tensions, global pharmaceutical sales growth is projected to slow, with aggregate growth (in US dollars at constant exchange rates) forecast to reach 8.8% in 2024, down from 10.3% in 2023. Global pharmaceutical sales are forecast to post a compound annual growth rate (CAGR) of 7.4% over 2023–2028, compared to 7.5% over 2018–2023.

Combined, the four Nordic pharmaceutical markets are forecast to grow strongly at 9.0% in 2024. However, growth is forecast to decelerate to a CAGR of 6.4% over 2023-2028, slower than the other European (EU and non-EU) countries, and below the global average.

Figure 1: Regional pharmaceutical sales growth (LC$)



Notes: Sales growth based on sales in US dollars at constant exchange rates (IQVIA Q2 2024).
Source: IQVIA Market Prognosis Global, October 2024.

Key opportunities in the Nordic pharmaceutical markets

Recent and future product launches

The launch of new and innovative drugs will remain the major driver of the pharmaceutical market growth in the Nordic countries during the forecast period. Specialty drugs to treat cancer, neuromuscular diseases, and obesity, including novel biologics, as well as advanced therapy medicinal products (ATMPs) such as cell and gene therapies, will boost average drug prices, thereby fueling market growth in value terms.

Nevertheless, the market access environment in the Nordics is becoming increasingly restrictive. According to IQVIA's W.A.I.T Indicator 2023 survey, all four Nordic countries have dropped in rankings in terms of availability (the point at which the drugs gain access to the reimbursement list) of all new drugs, compared to 2022: **Norway** dropped five positions to 22nd, **Finland** fell four positions to 18th, **Sweden** fell three positions to 13th, and **Denmark** fell one position to 5th out of 37 European countries evaluated. This trend is due to increasing stress on healthcare systems, exacerbated by the pandemic, tighter budgets, cost-containment measures, as well as currency fluctuations reducing market attractiveness, particularly in **Sweden** and **Norway**. Additionally, the absence of a national negotiator for pricing and access agreements in **Sweden** and **Finland** poses a challenge for market access to new drugs.

Launch and uptake of new anti-obesity drugs

The launch of new anti-obesity drugs is driving significant market growth in the Nordics. The anti-obesity market is experiencing a transformative phase, due to groundbreaking advancements and innovation. Novo Nordisk, a leading Danish pharmaceutical company, has achieved remarkable success with its anti-obesity drug, Wegovy (semaglutide). This drug, along with Ozempic (semaglutide) for diabetes, which contains the same molecule but in a different dosage, has boosted the company's profits and played a crucial role in supporting the Danish economy. However, Wegovy was launched as an out-patient prescription drug in **Denmark** in December 2022, without public reimbursement. In a significant move, Danmark, one of the largest private payers in **Denmark**, decided

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against covering Wegovy from January 2024, citing that the cost of the drug outweighed its benefits. These changes led to an increase in off-label consumption of Ozempic, for its weight-loss properties and due to its relatively low price. Consequently, the Danish Medicines Agency (DMA) revised reimbursement rules for Ozempic in May 2024 to control its off-label use and restrict its usage to diabetic patients only.

In **Norway**, Wegovy was launched in February 2023 without public reimbursement. Similar to **Denmark**, the Directorate for Medical Products (DMP) in **Norway** implemented reimbursement and dispensing controls in July 2024 to restrict the use of Ozempic to diabetic patients only and curb its off-label use. Although Wegovy has not been officially launched in **Sweden** and **Finland**, it has been available through parallel imports since 2023. Sales of Wegovy in all four Nordic countries have been out-of-pocket.

In March 2024, in a significant global development, the US Food and Drug Administration (FDA) expanded Wegovy's label to include risk reduction of major adverse cardiovascular events (MACE) in overweight or obese adults with established cardiovascular disease, broadening its target population. Similarly, the EU's Committee for Medicinal Products for Human Use (CHMP) issued a positive recommendation for the same in July 2024, and the label for Wegovy was further expanded in September 2024 to reflect reduced heart failure symptoms (STEP HFpEF trial) and improved physical function. This label update also reflects data on risk reduction of MACE in obese adults.

Competition in the anti-obesity market is set to increase over the years, with new launches like Zepbound (tirzepatide) from Eli Lilly and CagriSema (cagrilintide+semaglutide) from Novo Nordisk expected to drive market growth in the Nordics. In June 2024, Eli Lilly submitted a US FDA application to expand

the label of Zepbound, to include the treatment of obstructive sleep apnea. The US FDA has fast-tracked this application, and a decision is expected by the end of 2024.

However, despite high demand for anti-obesity drugs, their uptake is currently limited by the lack of public reimbursement, high prices, and supply constraints. If supply improves and payers provide coverage due to further indication expansion, uptake could increase significantly. Novo Nordisk is actively seeking public coverage for Wegovy in **Norway**, having applied to the DMP for coverage for severely obese patients, with a decision expected by the end of 2024.

Measures to improve access to new drugs

Across the Nordic countries, governments and healthcare providers are implementing strategies to enhance access to novel and high-cost drugs. These measures include the confidential agreements with a special push by manufacturers for alternative agreements, streamlined health technology assessment (HTA), and collaborative efforts involving various stakeholders. By adopting these approaches, the Nordic countries aim to balance the cost and accessibility of cutting-edge therapies, ensuring that patients receive timely and equitable access to life-saving treatments.

Finland introduced the use of confidential managed-entry agreements as a pilot study in 2017 to improve access to innovative drugs. These agreements, lasting up to five years, are made between the drug manufacturer and the Pharmaceutical Pricing Board (PPB), and grant 'conditional reimbursement status' to these drugs. Initially set to end in 2019, the pilot was extended to 2025 through temporary legislation. The Finnish government is discussing plans to make this temporary legislation permanent starting from 2025.

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In **Sweden**, innovative therapies are gaining access through confidential side-agreements, involving tripartite negotiations between the Dental and Pharmaceutical Benefits Agency (TLV), the regions and the industry. According to the TLV, savings from side-agreements have been increasing over the past five years and are projected to reach SEK4.69 billion by 2027, up 21% from 2024. The growth is driven by the increasing use of high-cost drugs and the inclusion of novel medicines under conditional reimbursement. However, the regions remain hesitant to participate due to the heavy administrative burden of these agreements, which could limit their wider use.

In **Denmark**, the Centralized Hospital Purchasing Agency (Amgros), secures access to new hospital therapies through confidential purchasing agreements. Recently, drug manufacturers have been advocating for more alternative price agreements as well, especially for ATMPs. In response, the Danish Medicines Council (DMC) published new guidance in 2024 on incorporating these alternative agreement models with HTA applications. However, their wider use may be constrained due to resource intensity. Additionally, the DMC implemented new, simplified and faster HTA procedures from April 2024: 14 weeks (fast-track application), 16 weeks, and 18 weeks, depending on the type of assessment process required. This aims to improve the transparency of the process, reduce processing times, and enhance resource efficiency.

In **Norway**, new methods to improve drug access are being studied. In December 2023, the Decision Forum for New Technologies, the agency responsible for the introduction of new drugs in hospitals, began piloting a new, simplified, fast-track HTA process to assess and approve new PD-1 and/or PD-L1 inhibitors considered equivalent to existing medicines, using pre-set reference prices within the therapy area. Additionally, the Norwegian government is working on the 'Healthcare Prioritization Report' to expand the Decision Forum to involve clinicians and patient group representatives and to increase the use of alternative price agreements for new drugs to improve patient access to novel, high-cost drugs.

Multi-country initiatives to improve access and supply

The Nordic countries are spearheading several multi-country initiatives to improve market access for new drugs through joint HTAs and procurement, enhancing the efficiency and quality of joint assessments of innovative medicines through resource sharing. The Nordic collaboration has not only streamlined processes but also leveraged collective negotiation power, aiming to ensure better availability of essential medications across the region. One of the key initiatives is FINOSE (**Finland**, **Norway**, and **Sweden**), an HTA collaboration that started in 2018. This alliance was renewed with the accession of **Denmark** and **Iceland** in May 2023 and April 2024, respectively, making it a Nordic-level organization. To reflect this change, the collaboration was relaunched as the Joint Nordic HTA-Bodies (JNHB). These initiatives are set to drive market growth in the future.

The state drug procurement authorities of **Denmark**, **Norway**, **Sweden**, and **Iceland** formed the Nordic Pharmaceutical Forum (NPF) in 2015, to conduct joint Nordic tendering and pricing negotiations. In February 2024, the JNHB began cooperating with the 'New Expensive Drugs' working group under the NPF to further strengthen Nordic collaboration and support joint negotiations for products assessed through JNHB's joint HTA. Additionally, the NPF also conducts joint tendering and procurement of low-cost generics. In March 2024, the procurement agencies in **Denmark**, **Norway**, and **Iceland** conducted the third joint Nordic hospital tender covering 14 low-cost generic drugs to ensure supply security and improve access.

In addition to these Nordic-level developments, the impending roll-out of the European Union HTA Regulation in January 2025 is driving efforts to harmonize HTA approaches for retail and hospital drugs across the Nordic countries. In support of these efforts, **Finland's** Ministry of Social Affairs and Health (STM) appointed a working group in May 2024 to investigate proposals for a single HTA system for all drugs. In **Sweden**, the TLV, the Swedish Medicines Agency and the Swedish Agency for Medical and Social Evaluation, formed a new collaborative structure for HTA within the country's healthcare system in August

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2024, aligning national case handling processes with those at the EU level. Collectively, these initiatives are poised to accelerate market access for new drugs and improve their supply, thereby fostering market growth in the Nordic countries.

Initiatives to improve healthcare provision

Although the Nordic healthcare systems offer high-quality care, in-country regional variations in accessibility and health inequalities persist, exacerbated by the COVID-19 pandemic. Recognizing this fact, governments across the Nordic region are taking steps to improve healthcare provision in their respective countries. In September 2024, **Denmark** proposed a healthcare reform 'Sundhed tæt på dig' (Health Close to You) to strengthen primary care and enhance resource efficiency across the country's regions. Among other measures, the reform proposes the centralization of healthcare and ensuring equal access by reducing the number of regions from five to four and introducing new healthcare 'packages' for patients with chronic diseases, to provide coherent, individually adapted treatment plans. Similarly, the **Norwegian** government is pursuing measures to improve primary and secondary care. It increased educational positions for general medicine specialization and funding for general practitioners (GPs) in 2023, in a bid to address the shortage of GPs and improve primary care. An additional NOK2.2 billion was allocated in the 2024 budget to reduce hospital waiting times.

Furthermore, Nordic governments are implementing e-health initiatives to improve the quality and efficiency of healthcare, and facilitate the flow of information between providers, patients, and other stakeholders. **Finland** is expanding its national e-health infrastructure, 'Kanta services', with

'OmaKanta' (MyKanta) and 'Kanta Medication List' at its core. The usage of the 'OmaKanta' patient platform surged during the COVID-19 pandemic, and over 3.5 million Finns (>50% of the total population) are currently using the platform. A mobile 'OmaKanta' app will launch in spring 2025 to improve accessibility of health and social care. **Denmark** is also advancing digital healthcare by establishing a national organization 'Digital Health Denmark' through the 'Health Close to You' reform. These measures are set to drive market growth in the Nordics region in the medium-to-long term.

Key challenges in the Nordic pharmaceutical markets

Cost-containment measures

Governments are facing increasing pressure to expand access to innovative, often high-cost drugs while managing pharmaceutical budgets. Recent events such as **Finland's** and **Sweden**'s accession to NATO in April 2023 and March 2024, respectively, along with increased defense spending and national debt, may strain fiscal positions and impact healthcare spending. Consequently, regulators are considering ways to reduce pharmaceutical costs, potentially limiting market growth in the Nordic region.

Denmark has experienced a significant rise in pharmaceutical expenditure in recent years, driven by the high-demand for new drugs to treat obesity, diabetes, and attention-deficit/hyperactivity disorder. The DMC seeks to promote price competition among hospital drugs by introducing comparable alternative drugs through a fast-track HTA process, which aims to limit drug spending and speed up drug assessments. Additionally, the government is exploring methods to rein in retail drug spending by imposing dispensing and reimbursement restrictions for Ozempic, starting July 2024, and is considering national-level pricing and procurement negotiations for selected high-cost retail drugs through Amgros. These measures are expected to put downward pressure on drug prices in the future.

Norway is also pursuing similar strategies to contain costs. The Norwegian Medical Products Agency (NOMA) restricted the reimbursement and dispensing of Ozempic to diabetic patients from July 2024 to control off-label anti-obesity use. The government

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is also centralizing drug procurement for certain reimbursed outpatient ('blue-prescription') drugs by 2024, based on the results of a pilot tender for PCSK9 inhibitors conducted in 2022. Additionally, it implemented higher patient co-payments in 2023 for reimbursed outpatient drugs to transfer drug costs partly to patients and generate savings.

The healthcare budget in **Finland** is under growing pressure as the government attempts to rein in public debt and boost defense spending amid weak economic growth. The government proposed a raft of cost-containment measures in April 2024, aimed at saving €90 million in drug expenditure by 2025. Key measures include increasing patient co-payments, implementing a 1.5% cut to wholesale prices for certain reimbursed drugs, and revising pricing regulations for generics and biosimilars entrants to promote competition. Furthermore, the implementation of the social welfare and healthcare service (SOTE) reforms in 2023 transferred the organizational responsibility for healthcare services from 309 municipalities to the 21 wellbeing services counties and the City of Helsinki, aiming to improve the cost-effectiveness of healthcare provision. The government is also implementing other measures to generate savings such as expanding the reference price system to include inhalation products. These measures are expected to curb average price growth in the medium-to-long term.

In **Sweden**, the TLV was tasked by the government to save SEK800 million from drug expenditure between 2021 and 2024. The TLV is implementing savings through price reductions for melatonin products, price reductions for older medicines under the '15-year rule', by conducting frequent drug re-assessments, and through rebates from side agreements. Although the agency has yet to attain the target, it is proposing to extend the assignment to 2025 to identify new approaches to generate savings. These measures will exert downward pressure on the average drug price per standard unit.

Loss of exclusivity and measures to improve uptake of generics and biosimilars

As patents expire, opportunities will open up for more affordable generic and biosimilar alternatives, which can significantly reduce healthcare expenditure. Consequently, Nordic governments are adopting pro-generic and biosimilar strategies to increase their uptake, which will place downward pressure on the average price per standard unit.

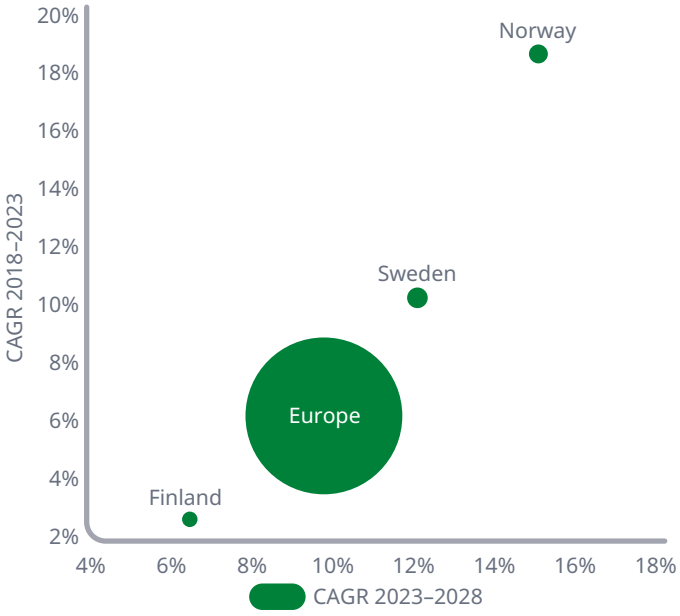
Measures to improve uptake of generics

The generics markets in **Norway** and **Sweden** have historically grown at a faster rate than the average growth of the European (both EU and non-EU countries) generics market, due to effective generic substitution systems and widespread acceptance among physicians and patients. In contrast, the generics market in **Finland** has grown at a slower rate than the average growth of the European generics market.

Further growth in the Nordic generics market will be driven by the loss of exclusivity of leading brands between 2024 and 2028, including Xarelto (rivaroxaban), Jardiance (empagliflozin), Ibrance (palbociclib), Imbruvica (ibrutinib), Eliquis (apixaban), Xtandi (enzalutamide) and Forxiga (dapagliflozin).

Other measures to improve usage and supply security of generics in the Nordics region include for example **Sweden's** TLV increasing the ceiling prices of selected generics in 2023, to ensure the stable supply of critical generics. Additionally, the agency is working on designing a new ceiling price system for a sustainable generics market in the future. Together these steps will drive growth of the generics segment in **Sweden**. However, the increasing use of generics will place downward pressure on the average price per standard unit, thus restricting overall pharmaceutical market growth.

Figure 2: Growth of generics markets in the Nordic countries versus Europe (both EU and non-EU countries) (LC$)



Notes: Sales growth based on sales in US dollars at constant exchange rates (IQVIA Q2 2024). Bubble size represents the size of generics markets in 2023 in US dollars at ex-manufacturer prices. A generics market forecast is not available for Denmark.
Source: IQVIA Market Prognosis Global, October 2024.

Measures to improve uptake of biosimilars

The uptake of biosimilars in **Denmark** is effective, as they are prescribed exclusively in the hospital sector. Stringent prescribing guidelines, Amgros' diligent monitoring, tendering, and procurement processes facilitate the rapid uptake of biosimilars.

In **Norway**, tender-based procurement ensures that biosimilars are prescribed widely in the hospital sector, though their uptake in the retail sector remains limited. The introduction of pharmacy-level biosimilar substitution in 2021 has seen limited success due to the small number of biologic molecules suitable for pharmacy substitution and conservative attitudes from physicians and patients. NOMA will gradually expand the list of biosimilars substitutable at the pharmacy level during the forecast period.

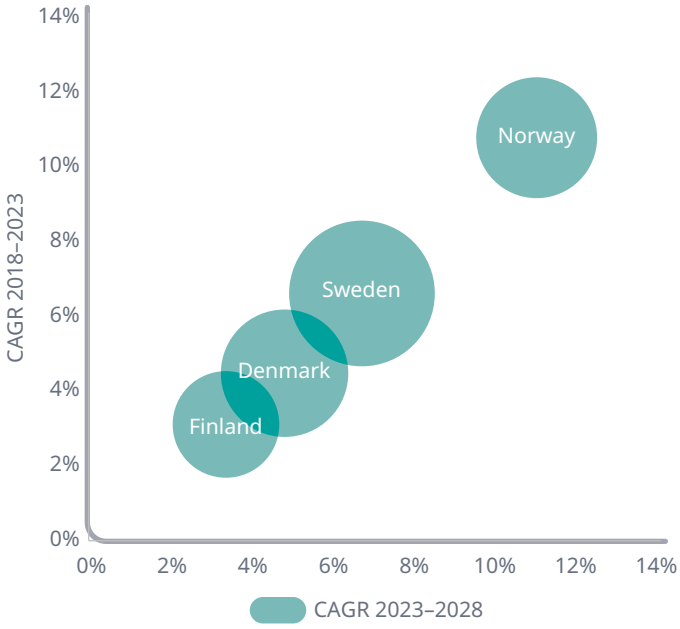
On the other hand, **Finland** is implementing mandatory substitution of biosimilars at the pharmacy level in three phases between 2024 and 2026. From April 2024, enoxaparin products and all low-molecular-weight heparins within the same medicinal group (as defined by the Finnish Medicines Agency (FIMEA)) are interchangeable in pharmacies. By the end of 2024, most remaining biosimilars, including high-cost drugs such as adalimumab and etanercept, will be included in the substitution scheme, becoming substitutable from January 2025. These steps aim to increase the uptake of biosimilars and generate savings, potentially encouraging other Nordic countries to follow suit. The higher use of biosimilars is expected to negatively impact market value, as biosimilars will erode market value due to lower prices.

Summary

Growth in the Nordic region will primarily be driven by the recent and future product launches of novel, innovative drugs, and government efforts to improve market access and supply. There is also an increasing focus on strengthening primary care to ensure equal and timely access to healthcare. Nevertheless, due to budget constraints and rising costs, governments are taking several steps to limit drug spending, which include reimbursement and dispensing restrictions, drug price cuts, reimbursement reassessments, and centralized procurement of certain drugs. They are also promoting the use of generics and biosimilars, thus limiting overall market growth.

The Nordic pharmaceutical market is forecast to grow at a CAGR of 6.4% between 2023 and 2028, marginally faster than in the previous five years. Among the four Nordic countries, **Norway** will be the fastest-growing market, posting a double-digit CAGR. However, growth in all four countries will slow gradually over the forecast period.

Figure 3: Sales Growth in the Nordic Pharmaceutical Markets (LC$)



Notes: Sales growth based on sales in US dollars at constant exchange rates (IQVIA Q2 2024). Bubble size represents the market size in 2024 in US dollars at ex-manufacturer prices.
Source: IQVIA Market Prognosis, September 2024.

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