



# Survey of the antibiotic markets in four Nordic countries

The Public Health Agency of Sweden and PLATINEA have mapped the antibiotic market in Denmark, Finland, Norway and Sweden with a focus on clinically prioritised antibiotics with risk of insufficient availability. Lack of access to paediatric formulations is of particular concern. The results disclose noticeable differences in product range between the Nordic countries despite similar medical needs and indicate potential for harmonisation.

[PLATINEA \(PLATform for INnovation of Existing Antibiotics\) \(platinea.se\)](https://platinea.se).

The Nordic countries have relatively low levels of antibiotic resistance, which allows narrow-spectrum antibiotics to be used. Access to recommended antibiotics is crucial to be able to treat infections effectively while at the same time slowing down the emergence and spread of antibiotic resistance. Shortages of important medicines where alternative treatments are suboptimal are frequently seen for products mainly used in small markets and with vulnerable supply chains. Few or single market authorisation holders (MAH) have been shown to increase the risk of deregistration.

[Indikatorer som påvisar risk för avregistrering av antibiotika \(diva-portal.org\)](https://diva-portal.org)

## Objectives

The objective of the survey was to highlight market challenges that may contribute to an unreliable access of antibiotic products. The results of the survey is intended to be a basis for decision-makers to be able to identify opportunities for harmonisation and synergies that can lead to a more sustainable supply.

## Methods

The present survey was based on the substances/ formulations/ strengths that the Public Health Agency of Sweden had already classified as Category A in the [Priority list of off-patent antibiotic products at risk for lack of availability in Sweden \(folkhalsomyndigheten.se\)](https://www.folkhalsomyndigheten.se).

This refers to antibiotic products with a high risk of shortage and/or deregistration based on low sales volume, and which are judged to cause major clinical consequences if they are not available. A database based on sales volume was shared with appointed representatives from all participating countries. These were asked to remove unregistered products and add additional substances and formulations that they considered to be clinically prioritised and at risk of insufficient availability. For each antibiotic formulation listed, all marketed strengths and package sizes were given. The time period for data extraction was October 2023. Parallel-imported products were excluded.

Four key dimensions were applied in the analysis in order to identify market challenges for specific formulations of listed antimicrobial substances, see fact box. This quantitative analysis was then combined with a clinical assessment by three infectious disease doctors who identified substances or formulations that were considered to be clinically prioritised in the Nordic countries but not necessarily in the rest of Europe.

### Key analysis dimensions

- **Market isolation.** The substance, formulation, or package size is marketed in only one of the four countries or, if the formulation is marketed in multiple countries, at least two package sizes are only marketed in a single country;
- **Product range variety.** An antibiotic formulation is marketed in the Nordic region in a large number of strengths or pack sizes (in this survey defined as 5 or more strengths or 7 package sizes per formulation);
- **Market fragmentation.** For antibiotic formulations marketed in multiple countries and with at least three package sizes in total, high market fragmentation refers to when more than 50% of these package-sizes are marketed only in a single country;
- **Supply risk.** A single MAH offers a given formulation in the Nordic region.

## Results and analyses

The full report is available at PLATINEAs website.

[Mapping the antibiotic market in Denmark, Finland, Norway and Sweden \(uu.se\).](#)

A total of 36 antibiotic substances marketed in the Nordic region were identified, available in a total of 68 formulations with various number of strengths and package sizes. All products on the final list were categorised as prioritised and marketed in at least one country as well as considered to be clinically prioritised with a perceived risk of insufficient availability. Of these 68 formulations of substances, 19 were considered as relatively small products from a European perspective or with only one market authorisation holder (MAH) providing a given registered formulation in the Nordic region (Table). Seven of these 19 are fluids (oral suspensions), primarily intended for young children.

Almost half of the 68 formulations were characterised by market isolation, comprising 32 unique formulations of 23 listed substances. Of a total of 15 oral suspensions listed in the current survey, 10 were categorised as exposed to market isolation, further emphasising the vulnerability of paediatric formulations.

The analysis revealed a high product range variety across the four Nordic countries. Three formulations were marketed in at least five strengths (amoxicillin, phenoxymethylpenicillin and benzylpenicillin) in 5-41 pack-sizes each, and 10 additional formulations were marketed in 7-12 different package sizes.

High market fragmentation in the Nordic countries was seen for 7 substances (amoxicillin/clavulanic acid, ampicillin, cephalexin, ciprofloxacin, erythromycin, phenoxymethylpenicillin, and gentamicin). In addition, common tablet strengths of amoxicillin, phenoxymethylpenicillin, flucloxacillin, and pivmecillinam had an unexpectedly fragmented market, related to the number of pack-sizes marketed in the Nordics (10-41).

Of the 68 listed formulations, 12 formulations were marketed by a single MAH across Denmark, Norway, Finland, and Sweden, making them especially vulnerable for shortages. Seven of these 12 substances are classified as “Access” by [The WHO AWaRe antibiotic book \(who.int\)](#).

In some cases, different but relatively interchangeable substances are used in the different countries, for example cephalexin is used in Denmark, Finland, and Norway, while Sweden uses cefadroxil. In Denmark and

Norway, dicloxacillin is marketed, which is not available in Sweden or Finland, where flucloxacillin is used. Two substances that particularly stood out are amoxicillin and phenoxymethylpenicillin, especially for tablets, for which there was a high market fragmentation in terms of strengths. Amoxicillin is a large product both in Europe and globally, but despite this, there have been and are long-term and repeated shortages for oral suspensions and tablets in the last two years.

Table. Clinically prioritised antibiotic formulations in the Nordic countries categorised as having vulnerable availability

Substance	Formulation	No of countries	Unique pack-sizes in a single country	No of pack-sizes in the Nordics	No of MAH in the Nordics
Amoxicillin/clavulanic acid	IV	1	1	1	1
Benzylpenicillin	IV	4	3	6	3
Cefadroxil	Fluid	1	1	1	2
Cefadroxil	T/C	1	4	4	3
Cefuroxime	T/C	1	2	2	2
Ciprofloxacin	Fluid	1	1	1	4
Dicloxacillin	T/C	2	1	4	4
Doxycycline	Fluid	1	1	1	2
Phenoxy-methylpenicillin	Fluid	4	2	5	4
Phenoxy-methylpenicillin	T/C	4	33	41	11
Fluocloxacillin	Fluid	1	1	1	1
Flucloxacillin	T/C	3	3	11	2
Cloxacillin	IV	4	1	3	5
Linezolid	Fluid	1	1	1	1
Nitrofurantoin	T/C	3	1	5	3
Nitrofurantoin, Vit C	T/C	1	3	3	1
Pivmecillinam	T/C	4	2	10	2
Rifampicin	Fluid	1	1	1	1
Trimethoprim - sulfamethoxazole	IV	1	1	1	1

IV: intravenous; T/C: tablet or capsule; Fluid: children's formulation

Both phenoxymethylpenicillin and amoxicillin are widely marketed in the four countries, by a total of 14

and 11 MAH, respectively. Amoxicillin tablets are marketed in a total of five strengths and in 19 pack sizes, nine of which were only available in a single country. Phenoxymethylpenicillin tablets are marketed in a total of 10 strengths and in 41 different package sizes, 33 of which in a single country only.

Denmark and Norway rely on licensing prescription (named-patient based prescribing) for a number of products, especially paediatric formulations. Access to tuberculosis drugs is very limited in Norway, which also stresses a critical vulnerability regarding access to benzylpenicillin, a corner-stone of infection treatment.

### **Discussion and conclusions**

The market for antibiotics in the Nordic countries is small, for example the Nordic countries together make up about a quarter of the Italian market for antibiotics. The present survey of clinically important and low-selling antibiotics in the Nordics shows that several products, often narrow-spectrum antibiotics, face availability problems. This manifests as market isolation, market fragmentation and the risk of uncertain supply chains. Powerful measures and joint Nordic efforts are needed to secure the availability of important antibiotics.

Differences in strength and package size are strongly related to differences in treatment guidelines, including duration of treatment for common infections. A harmonisation of treatment guidelines throughout the Nordics would be desirable and pave the way for a less fragmented antibiotic market. Another powerful approach to strengthen the availability of priority antibiotic products in the Nordics could be to agree on a co-Nordic regulatory system for older, nationally approved antibiotics or medical products in general. Such harmonisation could create larger and more attractive markets.

In conclusion, this survey highlights the weaknesses of small markets like the antibiotic markets in the Nordic countries. As a next step, joint measures at the Nordic or European levels are proposed to reduce vulnerability and increase resilience in supply chains.