

	Sundhedsstyrelsen	 Sundhedsstyrelsen Danish Health and Medicines Authority	Danish Health and Medicines Authority
	Lääkealan turvallisuus- ja kehittämiskeskus Fimea	 Lääkealan turvallisuus- ja kehittämiskeskus Säkerhets- och utvecklingscentret för läkemedelsområde Finnish Medicines Agency	Finnish Medicines Agency
	Lyfjastofnun	 Lyfjastofnun Icelandic Medicines Agency	Icelandic Medicines Agency
	Statens legemiddelverk	 Statens legemiddelverk Norwegian Medicines Agency	Norwegian Medicines Agency
	Läkemedelsverket	 LÄKEMEDELVERKET MEDICAL PRODUCTS AGENCY	Swedish Medicines Agency

GUIDELINE ON NORDIC PACKAGES

Human and veterinary medicinal products

Edition 2

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1. Introduction

The medicines agencies in the five Nordic countries have agreed to publish this document to assist applicants / marketing authorisation holders in creating Nordic packages¹ for medicinal products for human or veterinary use.

While the agencies are committed to assist applicants and marketing authorisation holders in their goal to achieve Nordic packages for their products, it must be emphasised that labelling cannot be reduced or abbreviated to such an extent that safety is compromised.

The agencies will update this document as needed.

Applicants/marketing authorisation holders may submit questions regarding Nordic packages. For this purpose a specific form, *Question to the Nordic package group*, is published and should be used. In the e-mail subject line please state "Question or comment regarding Nordic packages + <description of the question or comment>". Questions should be submitted simultaneously to all e-mail addresses in Table 1. If relevant the Nordic countries will liaise with each other as necessary, before replying in due course of time.

Table 1

Denmark	GODPost@dkma.dk
Finland	mrp@fimea.fi
Iceland	ima@ima.is and jml@ima.is
Norway	pi@noma.no
Sweden	Registrator@mpa.se

Before sending a question please read this document completely and check [link to FAQ] to see if an answer is already available.

2. What is a Nordic package of a human or a veterinary medicinal product?

There is no legal definition of a Nordic package. Traditionally, "Nordic" refers to the Scandinavian countries Denmark, Norway and Sweden, as well as Finland and Iceland.

As each of the Nordic countries is often considered to be a small market or a very small market, the pharmaceutical industry has expressed its interest in the manufacturing of Nordic packages, even packages covering all five countries.

Depending on how detailed a Nordic package is to be, different levels of a dossier harmonisation must be achieved. For CP, MRP and DCP products such harmonisation already exists, except for blue-box requirements. For pure national products, the Nordic package option will depend on the grade of the dossier harmonisation in the Nordic countries.

¹ See section 2 "What is a Nordic package of a human or a veterinary medicinal product?"

In practice the term “Nordic package” refers to a package which is designed for two or more Nordic countries as regards at least one component of the packaging material (carton, label, blister, package leaflet).

A complete Nordic package would cover all five languages regarding labelling on primary and secondary packaging material, as well as a package leaflet in all five languages.

There are, on the other hand, several other options, e.g.:

- A common Nordic (5 languages) blister or label, while secondary packaging material and the package leaflet can be national or a combination for two or more Nordic countries.
- A common primary and secondary packaging for two or more of the Nordic countries, but a national package leaflet or a package leaflet which does not cover all countries covered by the primary and secondary packaging.
- A common SE/FI package versus a common DK/IS/NO package, when a five language package is not possible due to space restrictions. The FI/SE combination is mentioned due to the fact that in Finland a Finnish/Swedish package is required.
- Various other combinations.

For a multi language package, e.g. a five language Nordic package the package leaflet does not have to be one sheet of paper. In the case where for technical reasons it is not possible to print the package leaflet in five languages on a single sheet of paper, there could be two sheets of paper in each package, one with for example a SE/FI package leaflet and another one with a DK/IS/NO package leaflet.

There are already several 5 language Nordic packages on the market, i.e. where all packaging material contains all 5 languages. The Nordic package is therefore not an illusion but a feasible and real option.

It should be noted that the Nordic package does not prevent the combination of a Nordic country and a non-Nordic country, should the marketing authorisation holder so prefer.

3. Legal basis

Directives 2001/82 and 2001/83, as amended, lay down the basic rules concerning labelling. Each of the Nordic countries has implemented the relevant directives and some have followed up with national guidelines. Therefore, there are basically the same rules concerning labelling in all five Nordic countries.

All Nordic countries follow the Readability Guideline, the QRD template, the excipients guideline, and the recommendation of these guidelines should be reflected in the labelling and PIL along with the national requirements which can be seen on the homepage of each of the Nordic medicines agency.

4. How does an applicant / marketing authorisation holder plan for a Nordic package?

Whenever an applicant is preparing a marketing authorisation application it is of utmost importance that the proposed labelling is carefully scrutinised before submission of the

application and during the procedure. The applicant should carefully consider the minimum requirements as regards labelling.

During European procedures, a harmonised labelling is approved, except for purely national issues, which are very few in the Nordic countries. It is basically the applicant who can, by carefully preparing the dossier, have the most influence on how big or small the labelling section will be.

All labelling (except for blue-box requirements) must be the same in all languages covered by the package.

The applicant should also carefully consider how the translation into each of the national languages will be handled, as there are several options for a harmonised translation, i.e. identical translation of certain terms acceptable for all five Nordic countries.

It is advisable for the applicant, before submission of an application and for his own purpose, to prepare a five language mock-up of the primary and secondary packaging (e.g. x5 the proposed English text, but preferably the five Nordic languages), to find out if the five language option is feasible, or if there should be a combination of e.g. 3 and 2 languages.

Applicants are strongly encouraged to plan the Nordic package before submission and seek a common name for all relevant countries. An acceptable name should preferably be available before the end of a procedure.

5. Blue-box requirements

The Nordic countries are often considered to be a potential single market for medicinal products, because for example blue-box requirements for secondary packaging material are generally the same, i.e. the Nordic Article Number (Vnr) and an optional barcode or 2-D code. As the Nordic Article Number and the barcode/2-D code will normally be the same for all Nordic countries which share a package of a medicinal product, this information will consequently only be printed once on the package.

It should be noted that for the package leaflet, national blue-box requirements do not prevent the printing of a multi language package leaflet.

6. Frequently asked questions about the Nordic package

Over time the Nordic medicines agencies have come to an agreement regarding various factors which affect the Nordic package. It is also clear that in some cases there are different views on certain subjects but there are, at least in some cases, potential solutions. They may call for careful planning before submitting an application. Due to this the Nordic medicines agencies have prepared a "Frequently asked questions" document which will be updated as required. The purpose of the "Frequently asked questions" document is to give applicants/marketing authorisation holders an overview of decisions already available. As mentioned in section 1 applicants/marketing authorisation holders have the opportunity to send questions regarding labelling and the Nordic package to any of the Nordic agencies.