2015-02-25

Frequently asked questions

- Medicinal products -
- Human and veterinary -
(labelling and package leaflet)

The answers given below are valid for Denmark (DK), Finland (FI), Iceland (IS), Norway (NO) and Sweden (SE) unless otherwise specified.

General questions concerning labelling

1. Is there something specific an applicant should consider before submission of an application if the applicant plans a Nordic package, i.e. a package for two or more Nordic countries.

Last update: 2015-02-25

Before submission the applicant should carefully consider what labelling is actually required according to labelling guidelines provided in the annotated QRD and QRD vet templates. It is recommended that the applicant only proposes labelling which is considered to be necessary.

Before submission the applicant should also consider all available options for the mock-up regarding harmonised translation, e.g. the use of Latin terms for the active substance and excipients, the use of the abbreviations “Lot” and “EXP”, the use of abbreviations like “i.m.”, “i.v.” and “s.c.”, etc.

Before submission the applicant is strongly recommended to create a mock-up of the Nordic package (blister, foil, strip, label, carton) to ensure that a Nordic package will be feasible based on the proposed labelling.

2. Is it possible to achieve a Nordic package for a product, if the marketing authorisations have already been granted via the national procedure in the relevant Nordic countries? How should the marketing authorisation holder proceed in case of differences in the product information?

Last update: 2015-02-25

Yes, it is possible to achieve a Nordic package although the product has been approved via a national procedure in each country.

However, a common Nordic package cannot be achieved unless the following is fulfilled;

- The name and the strength of the medicinal product must be the same
- The SPC, package leaflet and labelling (product information) must be identical
- The legal status (POM/OTC) must be the same

Furthermore, the multilingual package is only possible if the readability is not compromised by adding 2 or more languages to the labelling elements.

If your product needs to be harmonised before a common Nordic package can be achieved, then this should be done in accordance with Commission Regulation (EC) No 1234/2008 as amended concerning variations and standard fee is required. If the outcome of the variation is to achieve common Nordic packages, a work sharing variation should be considered.

3. Should mock-ups for a Nordic package be approved in the respective Nordic medicines agencies for MR and DC procedures?

Last update: 2015-02-25

FI, NO, SE: Mock-ups should be approved by the concerned national medicines agencies.
IS: Mock-ups must be submitted. However, the Icelandic Medicines Agency does normally not assess/review the mock-ups. It is considered to be the responsibility of the marketing authorisation holder to ensure correct labelling, legibility, appropriate layout etc.
DK: Mock-ups are not assessed or approved by DHMA. Regularly DHMA carries out random compliance checks of product labelling.
The labelling text should contain the same information in all languages.

4. If an applicant plans a Nordic package and it is foreseen that for example Latin terms will be used for the active substance(s) and excipients, as well as abbreviations like “EXP” and “Lot”, should the labelling translation in word format correspond to the mock-ups?

Last update: 2015-02-25

IS, NO, SE: The labelling translation in the word format should be a strict translation of the final English labelling text. Latin and exemptions are only included in the mock-ups.

DK: DK do not assess the mock up, therefore the text in the word format should reflect the mock-up.

FI (DCP, MRP, national procedure): The applicant shall submit a word format national translation of the labelling text, with strict translations of the final English labelling texts. However, for each item which is planned to appear in a different way on the package, the text which is planned to be printed shall be stated separately in the word format labelling text. The text shall be stated in brackets following the text “Will appear on the package as:…”

5. Can a sticker with national labelling be used to fulfil national labelling requirements or be used to hide information?

Last update: 2014-01-30

For DK, IS, NO and SE this is a possible way to add information as an exemption, as long as readability is not compromised and the labelling is in accordance with the approved text and national requirements. This is common practice in Iceland. The sticker must be permanent and the addition of a sticker must be done by a manufacturer with a valid license.

FI: No.

In cases when the red warning triangle is required in DK, NO, IS and/or FI the triangle may be hidden by a sticker on the packages intended for SE. If the sticker is added after batch release a specific permission to do this is required from the MPA.

6. Are the EMA QRD and QRD vet templates accepted for national products?

Last update: 2014-01-30

Yes.

7. Is a global/EEA trade name logo accepted in the Nordic countries?

Last update: 2014-01-30

Yes, in general but the logo would be evaluated on a case by case basis. The readability must not be negatively affected, nor must such a logo take up space from the required information, e.g. product logos and company logos should be avoided if they prevent multilingual packages. Logos must not be of a promotional nature.

8. Must the local representative be stated on the package?

Last update: 2015-02-25

No. As space restrictions are common it is recommended not to print this information on the package, as it will be mentioned in the leaflet.

9. Is it acceptable to state the local distributor (wholesaler) on the package?

Last update: 2014-01-30

No.

10. How should the calendar days be stated on a calendar blister?

Last update: 2015-02-25

Either the name of the day or an abbreviation should be used. Please, refer to the European Medicine Agency's QRD reference documents and guidance.

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Denmark	Man.	Tirs.	Ons.	Tors.	Fre.	Lør.	Søn.
Finland	Ma	Ti	Ke	To	Pe	La	Su
Iceland	Má	Þri	Mi	Fi	Fö	Lau	Su
Norway	Ma.	Ti.	On.	To.	Fr.	Lø.	Sø.
Sweden	Mån	Tis	Ons	Tors	Fre	Lör	Sön

On a case by case basis, further abbreviations could be discussed and accepted by the authorities.

11. How soon, following approval of **non-urgent** changes in the labelling and package leaflet, must the changes be implemented?

Last update: 2015-02-25

A general rule is that changes would be expected to be implemented for the next batch manufactured of the product. However, at present different time lines apply in the Nordic countries:

NO: The changes should be implemented within 6 months after approval.
SE: Production of new packages including the changes should be started within 6 months after approval.
DK: The changes should be implemented within 6 months after approval. However if it is stated in the current package leaflet that the newest version is uploaded on the Danish Medicines Agency's web page the implementation time is 12 months.
FI, IS: The implementation should be made for the next possible batch.

On a case by case basis, depending on the urgency of the changes, authorities may request implementation earlier than the timelines mentioned above.

12. Can the Nordic agencies provide an example of a Nordic package and are there some practical advices which should be kept in mind?

Last update: 2014-01-30

See Annex I: “Dummy” mock-ups is for information purpose only.

Name of the product

13. Can the applicant ask the medicines agencies in DK, FI, IS, NO and SE to assess and approve a name of a product before submission of an application?

Last update: 2014-01-30

No.

The name of a product is assessed during a marketing authorisation application/variation procedure, or in the national phase following the procedure.

It is important that an applicant who is planning a Nordic package inform the Nordic agencies of this when proposing a name for a product. The Nordic agencies will then have the opportunity to communicate, if necessary, in order to approve the same name for all five Nordic countries.

14. For a product which is given a generic product name, can the INN be written in English?

Last update: 2014-01-30

Yes, unless the English term is very different from the national one, for example if the name includes “potassium” or “sodium”.

15. For a product which is given the generic name of the active substance, which is for example a salt, should the salt be a part of the name?

Last update: 2014-01-30

NO, SE: No, the salt should not be part of the name. Inclusion complicates the name, makes it longer and harder to remember for a patient.

DK, IS: If the strength is given in relation to the salt then the salt should be part of the name. However for common Nordic packages it is possible to be more flexible and deviate from this practice, if no safety issues are related.

FI: When the strength is given for the active moiety then the salt should not be part of the name. However, if the strength is stated for the salt form the following approach should be followed: When the first generic application for an active substance arrives, the generic name for the preparation will be approved without the name of the salt.

If the active substance has already been granted marketing authorisations under names in which the generic name includes the name of the salt, the generic name with the salt will continue to be required (also on packaging in the Nordic countries).

If marketing authorisations have been approved only under invented names, the generic name will henceforward be approved without the name of the salt.

16. When printing the name of the active substance(s) on the package, in connection with the name of the product, should the name of the active substance(s) begin with an upper or lower case letter?

Last update: 2015-02-25

The name of the active substance(s) should in these cases begin with a lower case letter, to clearly separate the name of the active substance(s) from the name of the product.

17. Should the name of the active substance(s) be printed below the name of the product, even if the name of the product is the generic name + company name?

Last update: 2015-02-25

DK, SE: Yes.
FI, IS, NO: Not required, if the strength is stated for the active moiety. However, if the strength is given for the salt form then the active substance should be printed below the name of the product.

18. Is it allowed to print the name of the product in capital letters?

Last update: 2014-01-30

It is strongly recommended that the name of a product is not printed in capital letters, except for the first letter in the name.

19. Is it acceptable to print the suffix in a name, in another colour than the name itself?

Last update: 2014-01-30

No, normally not acceptable.

20. Which suffixes are acceptable as a part of the name of a product?

Last update: 20145-02-25

In the past suffixes were sometimes considered necessary to separate strengths and/or pharmaceutical forms. Today, suffixes should generally be avoided and are discouraged as the strength and pharmaceutical form would be clearly stated on the package. This is especially relevant for Nordic packages.

Not all suffixes are acceptable in all Nordic countries. Hence carefully consider the need for a suffix if the goal is to have a Nordic package.

FI, NO, SE: The suffix ”Vet” is recommended for all veterinary products.

DK, IS: The suffix “Vet” is accepted for all veterinary products.

Suffixes that are promotional are not accepted.

Strength

21. Must the strength be stated in the same font size and font style as the name of the product?

Last update: 2014-01-30

Yes, strongly recommended whenever possible.

22. If the strength of a product is given in micrograms, can the abbreviations “mcg” or µg be used?

Last update: 2014-01-30

No. The appropriate abbreviated term in each language should be used, i.e.:

DK, FI, NO, SE: mikrog
IS: míkróg (exceptionally, the term “mikrog” can be used)

It should be noted that if the abbreviation is identical for two or more countries, it should not be repeated on the package.

23. Is it acceptable to state the strength of a product as “%” or “ppm”?

Last update: 2014-01-30

As a general rule “%” and “ppm”, as well as other similar units shall be avoided and the strength should be stated as for example mg/ml, mg/g etc. The strength cannot be stated in two different ways on the package, i.e. both as for example mg/ml and %.

24. When the strength of a product is stated in International Units, i.e. “IU” is it then acceptable to use “IU” on the Nordic packages, instead of the abbreviations “IE” (DK, NO, SE), “KY” (FI) and “a.e.” (IS)?

Last update: 2014-01-30

Yes. Please note that when the abbreviation “IU” is used, it should be the only abbreviation for International Units on the Nordic package, i.e. do not mix “IU” with the national abbreviations.

25. When the strength of a product is stated in Units, i.e. “U” is it then acceptable to use “U” on the Nordic packages? As regards International Units, please see question 22.

Last update: 2015-02-25

FI, IS, NO: Yes. “U” can be used, but if the package is shared with DK/SE who do not allow the abbreviation the units must be stated in the same way for all languages i.e. full term.
DK, SE: No. “Units” should not be abbreviated. The appropriate translations should be used:

DK: enheder
FI: yksikköä
IS: einingar
NO, SE: enheter

26. Is it acceptable to print the strength in different colours for products available in more than one strength to avoid mix-up?

Last update: 2014-01-30

Yes, packages for different strengths should be distinguished from each other. It is strongly recommended to use different colours for different strengths.

Pharmaceutical form

27. If the pharmaceutical form consists of two or more words, for example “film-coated tablet” must all the words be printed in one line?

Last update: 2014-01-30

Yes, strongly recommended.

28. Which pharmaceutical forms can be abbreviated on the outer package, label, blister, etc.?

Last update: 2015-02-25

The full standard term must appear on the outer package at least once, and in connection with the name of the product, on the most prominent area of the package, e.g. the front panel on a carton. EDQM user friendly short terms can be used for other locations on the carton and immediate packaging material, if necessary.

Further abbreviations are possible and can replace the user friendly terms in cases when space is very limited. When combining the abbreviations they should be separated by a “/” and when the abbreviation is identical in two or more countries it shall only be printed once.

Following is a list of abbreviations which are acceptable

Pharmaceutical form	**DK Singular / Plural**	**FI Singular / Plural**	**IS Singular / Plural**	**NO Singular / Plural**	**SE Singular / Plural**
Capsule	kaps.	kaps.	hylki / hylki	kaps.	kaps.
Chewable tablet	tyggetabl.	purutabl.	tuggut. / tuggut.	tyggetabl.	tuggtabl.
Emulsion for injection	inj.	inj.	stl. / stl.	inj.væske/inj.	inj.
Eye drops	-	-	augndr. / augndr.	-	_
Film-coated tablet	tabl.	tabl.	tafla /töflur	tabl.	tabl.
Gastro-resistant capsule	enterokaps.	enterokaps.	magasýruþ. hylki. / magarsýruþ. hylki	enterokaps.	enterokaps.
Gastro-resistant tablet	enterotabl.	enterotabl.	magasýruþ. tafla / magasýruþ. töflur	enterotabl.	enterotabl.
Orodispersible tablet		suussa hajoava tabl.	munndr.tafla / munndr.töflur	smeltetabl.	munsönderfallande tabl.
Prolonged-release capsule	depotkaps.	depotkaps.	-	depotkaps.	depotkaps.
Prolonged-release tablet	depottabl.	depottabl.	-	depottabl.	depottabl.
Solution for infusion	inf.	-	innr.lyf / innr.lyf	inf.væske	-
Solution for injection	inj.	inj.	stl. / stl.	inj.væske/inj.	inj.
Suppository	supp.		endaþ.stíll / endaþ.stílar	stikkp.	supp.
Suspension for injection	inj.	inj.	stl. / stl.	inj.væske/inj.	inj.
Tablets	tabl.	tabl.	tafla /töflur	tabl.	tabl.

29. For capsules and tablets, is it acceptable if the pharmaceutical form is depicted on the outer package?

Last update: 2015-02-25

SE: Yes, if the pictogram is in life size.
DK, FI, IS, NO: Yes, if the pictogram is depicting the actual appearance of the capsule/tablet.

The active substance and excipients

30. Can the active substance(s) and excipients be written in Latin on a Nordic package?

Last update: 2014-01-30

Yes.

31. Is it acceptable to use an abbreviation of the Latin term for the active substance(s) and excipients on a Nordic package and if so, how should these abbreviations be?

Last update: 2015-02-25

These abbreviations are accepted and encouraged to facilitate the Nordic package. When relevant the labelling sections for active substance(s) and excipient(s) can be combined on the package, using abbreviations of the Latin terms, e.g.:

“1 ml: metoprolol. tartr. resp. metoprolol. 1 mg, natr. chlorid., aq. ad iniect.”

“1 ml: butorphanol. tartr. resp. butorphanol. 15 mg, chlorocresol., natr. chlorid., aq. ad iniect.”

Guidelines on abbreviations of the Latin name for active substances and excipients.

1) If the Latin name ends with -um, -us, -ium, -eum, these endings should be replaced with a full stop.
Example:
coffeinum → coffein.

2) If the Latin name ends with -icum (-ici), -oicum (-oici), -uicum (-uici), these endings should be replaced with a full stop.
Example:
aceticum → acet.

3) The endings -as, -oas, -ias, -eas should be replaced with a full stop.
Example:
citras → citr.

4) The endings -i and -ii should be replaced with a full stop.
Example:
calcii → calc.

5) Nominative and genitive cases have the same abbreviation.
Example:
natrium → natr.
natrii → natr.

<u>Exemptions:</u>
aluminium → alum.
aqua → aq.
argentum → arg.
bismuthum → bism.
carbonas → carb.
hydrargyrum → hydrarg.
magnesium → magn.
salicylas → salic.

<u>Other abbreviations - excipients:</u>

water for injections → aq. ad iniect.
purified water → aq. purif.

32. Is there a way to shorten the translation of “Each tablet contains xx mg <active substance>”, “Each capsule contains xx mg <active substance>”?

Last update: 2014-01-30

Yes. In many cases it would be possible to abbreviate this sentence. For example “1 tabl./tafla: xx mg <active substance (in Latin)>”, “1 kaps./hylki: xx mg <active substance (in Latin)>”, “1 ml: xx mg <active substance (in Latin)>”. This abbreviated text covers all five Nordic countries.

It should be noted that if excipients are to be stated on the package, they could follow the active substance, e.g. “1 kaps./hylki: xx mg <active substance (in Latin)>, lactos.”.

Pharmaceutical form and contents

33. Must the number of e.g. tablets and capsules be stated in the same row as the pharmaceutical form?

Last update: 2014-01-30

No.

Routes of administration

34. Can the parenteral routes of administration be abbreviated?

Last update: 2015-02-25

The following abbreviations are accepted by all Nordic authorities for small immediate packaging:
For intramuscular use: i.m.
For intravenous use: i.v.
For subcutaneous use: s.c.
Other routes must be stated in their full form.

DK, IS, SE: The above mentioned abbreviations are also accepted for the outer packaging.

35. Is it acceptable not to print the sentence “For oral use” on the package for all formulations of tablets and capsules which are to be swallowed?

Last update: 2014-01-30

Yes. It is acceptable to leave out “For oral use” on the package. Please note that in these cases the text must be left out on the package for all countries which share the package.

36. Is it acceptable not to print the sentence “For ocular use” on the package for pharmaceutical forms which are clearly stated as eye drops or eye ointment?

Last update: 2014-01-30

In case of space restrictions for such products, which are often small packages, a case by case decision to leave out the route of administration can be considered for a Nordic package.

Special warnings

37. Should cytostatic products be labelled “Cytostaticum” on the outer package, or immediate package, if there is no outer package?

Last update: 2014-01-30

Yes, this is a requirement for cytotoxic/cytostatic medicinal products.

Expiry date

38. When is it acceptable to use the abbreviation “EXP” on the outer/immediate packaging material?

Last update: 2015-02-25

It is always accepted to use the term “EXP” if the abbreviation is explained in the leaflet.

If *not* explained in the leaflet:

	DK	FI	IS	NO	SE
Small immediate packaging and blisters	No	Yes	Yes	Yes	Yes
Also for the outer labelling in case of multilingual packs	No	Yes	Yes	No	Yes

39. Is it enough only to print the actual expiry date and leave out the abbreviation “EXP”?

Last update: 2014-01-30

Yes, for small immediate packaging and blisters.

Storage conditions

40. Must storage conditions always be printed on the package, for example “Do not store above 25°C” and “Do not store above 30°C”?

Last update: 2014-01-30

Yes. The only exemption is “No special storage conditions”, in which case nothing regarding storage conditions should be printed on the package.

DK, IS: For nationally authorised products “Do not store above 30 °C” can be left out on the package.

Name and address of the marketing authorisation holder

41. As regards the address of the marketing authorisation holder which is to be printed on the outer/immediate package must the country be mentioned and does it have to appear in each language covered by the package?

Last update: 2014-01-30

Yes, the country must be mentioned in the different languages.

42. Is it acceptable to print the marketing authorisation holder's phone number and e-mail address on the package?

Last update: 2014-01-30

Yes. The contact information to the marketing authorisation holder is however mentioned in the package leaflet. If there are space restrictions due to the extent of the labelling text/size of the package it is not recommended to print such information on the package.

43. Is it possible to have common Nordic packages for products with different marketing authorisation holders (which are legally independent companies with the same owner)?

Last update: 2015-02-25

If the names for the marketing authorisation holder are clearly different it is not possible to have a common package. However, if the names of the marketing authorisation holder are very similar, e.g "XXXXXXX AS", "XXXXXXX OY", "XXXXXXX AB" a common package could be possible.

Marketing authorisation number

44. What is the format of the marketing authorisation numbers in the Nordic countries?

Last update: 2014-01-30

The format is as follows:

DK: MTnr xxxxx (DK)
FI: MTnr xxxxx (FI)
IS: MTnr xxxxxx (IS) or IS/x/xx/xxx/xx
NO: MTnr xx-xxxx (NO)
SE: MTnr xxxxx (SE)

When printing the marketing authorisation numbers on the package they can be arranged in such a way that "MTnr" only needs to be printed once. For example the numbers can be printed in a line or in a column.

Batch number

45. Is it acceptable to use the abbreviation "Lot" for the batch number on the outer and immediate packaging material?

Last update: 2014-01-30

Yes.

46. Must the abbreviation "Lot" be printed on blisters or is it enough to only print the actual batch number?

Last update: 2014-01-30

It is preferred to print "Lot" in logical connection to the actual batch number, but if that is not possible, it is acceptable to print only the actual batch number, i.e. without the abbreviation "Lot."

General classification of supply

47. Is it acceptable not to print on the package the text “Medicinal product subject to medical prescription” and “Medicinal product not subject to medical prescription” (in national languages)?

Last update: 2014-01-30

Yes, for human products. None of the Nordic countries require this information. The sentence can be left out on the mock-up even if it is stated in the word format approved labelling text.
For veterinary products this is a legal requirement.

48. Can a potential applicant ask the medicines agencies in DK, FI, IS, NO and SE to confirm, before submission of an application, if a product will be granted an OTC status?

Last update: 2014-01-30

No. A possible OTC status will be assessed during the marketing authorisation application procedure or during the national phase.

Information in Braille

49. Is it necessary to state the pharmaceutical form in Braille?

Last update: 2015-02-25

No, this is not a requirement. In certain cases when a product is available in different similar pharmaceutical forms it is however recommended.

EDQM user friendly terms could be used if they are also used as printed text on the labelling.

General questions concerning the package leaflet

50. Can the symbol for a trademark (™ and ®) be used in the printed version of package leaflets?

Last update: 2015-02-25

These symbols can be used at the top of the PIL, i.e. where the product name is mentioned the first time in the package leaflet for medicinal products for human and veterinary use.

51. Is it necessary to print the list of names of the product in each member state which participates in a DCP or MRP in the package leaflet?

Last update: 2015-02-25

DK: Yes.
FI, IS, NO, SE: No, this list does not have to be included. However, if the list is part of the nationally approved package leaflet text it has to be included in the printed version too.

For a Nordic multilingual package with DK included:

Include the list in the nationally approved leaflet text. In the printed version the list only needs to be printed once, e.g. after the last language in the printed package leaflet. The heading of this section shall however be stated in all relevant languages. The names of the countries can be stated by using the ISO abbreviations for the countries, i.e. the names of the countries must not be stated in the different languages. Note that if the name of the product is the same in two or more countries, this can be stated in one line.

Example for a 5 language package leaflet:

"Dette legemidlet er godkjent i EØS-landene med følgende navn:/ Tällä lääkevalmisteella on myyntilupa Euroopan talousalueeseen kuuluvissa jäsenvaltioissa seuraavilla kauppanimillä:/ Dette lægemiddel er godkendt i EEAs medlemslande under følgende navne:/ Detta läkemedel är godkänt inom Europeiska ekonomiska samarbetsområdet under namnen: / Þetta lyf hefur markaðsleyfi í löndum Evrópska efnahagssvæðisins undir eftirfarandi heitum:

AT, CZ, DE, DK, EL, FI, IS, NO, PL, SE, SL: <Product name A>.

BE: <Product name B>.

FR: <Product name C>.

IE, UK: <Product name D>.

IT, PT: <Product name E>."

52. Is it necessary to print the name and address of the manufacturer responsible for batch release in the package leaflet?

Last update: 2015-02-25

Yes, but if the marketing authorisation holder and the manufacturer are the same, i.e. the same company and address, the general heading "Marketing Authorisation Holder and Manufacturer" can be used and this information can be stated only once.

In cases where more than one manufacturer responsible for batch release is designated, all should be listed in the word version of the package leaflet.

In the printed version of the package leaflet:

DK, IS, SE: Only the actual batch releaser must be included.

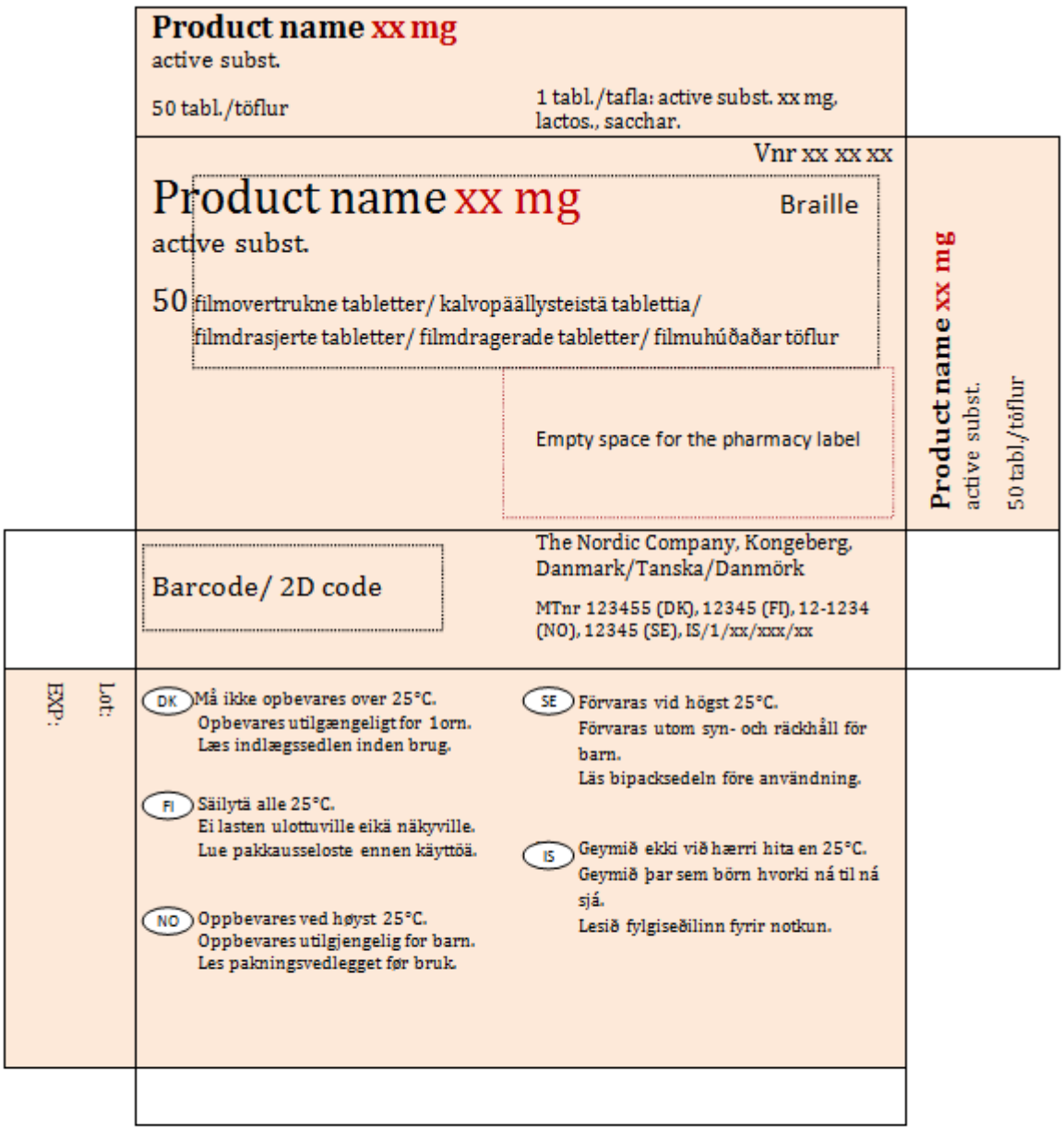
FI, NO: Either only the actual batch releaser is included or the actual batch releaser is clearly identified.

Annex I

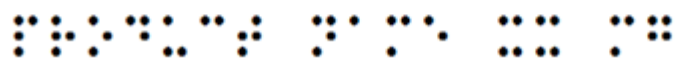
Last update: 2015-02-25

Carton

The below drawing of a five language carton is an example of how a five language carton could be prepared. There should be a clear demarcation between the different languages used; the information provided in each language should be assembled.



Dim: 117*61*20 mm



Braille: Product name xx mg

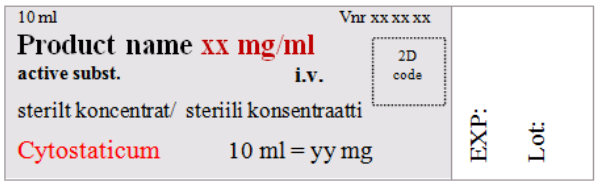
Small label (e.g. vial, ampoule)

Product name xx mg/ml active subst.	
Inj./Stl.	2 ml
i.v.	Lot: Exp:

Carton for a SE/FI package (the format also applicable for DK/IS/NO), concentrate for solution for injection

10 ml Vnr xx xx xx **Product name** **xx mg/ml** koncentrat till infusionsvätska, lösning/ infuusiokonsentraatti, liuosta varten			
10 ml Vnr xx xx xx **Product name** **xx mg/ml** **active subst.** koncentrat till infusionsvätska, lösning/ infuusiokonsentraatti, liuosta varten **Cytostaticum** 10 ml = yy mg Intravenös användning/ Laskimoon	1 ml: active subst. xx mg, natr.hydr. et aqua ad iniect.  The Nordic Company, Kongeberg, Danmark/Tanska MTnr 12345 (FI), 12345 (SE) Lot: EXP:	**10 ml** Vnr xx xx xx **Product name** **xx mg/ml** **active subst.** koncentrat till infusionsvätska, lösning/ infuusiokonsentraatti, liuosta varten **Cytostaticum** 10 ml = yy mg Intravenös användning/ Laskimoon	Ska spädas. Läs bipacksedeln före användning. Förvaras vid högst 25°C. Förvaras utom syn- och räckhåll för barn. Laimennettava. Lue pakkausseloste ennen käyttöä. Säilytä alle 25°C. Ei lasten ulottuville eikä näkyville.
		Barcode/ 2D code	

Label (bottle)


10 ml
Vnr xx xx xx
Product name xx mg/ml
active subst.
i.v.
2D code
sterilt koncentrat/ steriili konsentraatti
Cytostaticum
10 ml = yy mg
EXP:
Lot: