Norwegian Medicines Agency

*Version 1.3, 02/2020*

# Norwegian guideline for packaging of human and veterinary medicinal products with marketing authorisation / registration

(MRP, DCP and national procedure)

# Management of packaging at NoMA

Assessment of packaging is part of the marketing authorisation procedure. Mock-ups in pdf-format shall be submitted together with Norwegian SmPC/SPC and PL as Word-files in the national phase. It is not mandatory to send Norwegian labelling text for approval.

NoMA assesses content and design of submitted mock-ups according to the Norwegian medicinal product regulation. In general, the labelling information of the outer and immediate packaging shall contain the same set of particulars.

## Readability and presentation in Norwegian

Labelling text on the package, as mentioned in Art. 3-29 and Art. 3-36 of the Norwegian medicinal product regulation, must be presented in an easily readable and comprehensible manner, and be non-erasable.

Exemptions regarding translation and omission of certain particulars may be granted in certain cases, see **Exemptions to packaging requirements**

NoMA does not require submission of layout PL intended for the patient/user. Nevertheless, it is expected from the MAH to follow the guiding rules for layout PL intended for patient/user as stated in the Readability Guideline, section 2.
See: *https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf*

## Submission

### 1. Marketing authorisation applications (national, MRP and DCP)

Mock-ups (in pdf format) for each strength and pharmaceutical form, for outer and immediate packaging, are required.

Exemption: Marketing authorisations issued without Norwegian product information.

### 2. Variations

NoMA requires submission of mock-ups together with the Norwegian SmPC/SPC and PL in cases where the variation (type II and IB) concerns the packaging.

### 3. Change in design/layout:

NoMA approves design/layout changes in the packaging. It is required with mock-ups for a representative selection of the relevant packages, including the smallest package size.

Submission for human medicinal products - 61(3) notification.

Submission for veterinary medicinal products - type IB C.II.6 variation.

### 4. Document file format

*Mock-up in* Pdf file (enabled commenting): Mock-ups are copies of the flat artwork design for a medicine's inner and outer packaging, in full colour that can be assembled into a three-dimensional replica.

### 5. Implementation

Approved packaging material must be implemented within 6 months after approval, i.e. all medicinal products with a QP-release later than 6 months from the approval date must consist of the latest approved mock-up. In case of safety issues, the NoMA may request an earlier implementation.

## Exemptions to packaging requirements

For human medicinal product that are not delivered directly to patients or where there are severe availability issues, exemption from some of the obligations for labelling may be granted. This is in accordance with Art. 63(3) of Directive 2001/83/EC (human) and Art. 61 (1) Directive 2001/82/EC (veterinary).
Translation exemptions and omission of certain particulars to appear on the labelling for human medicinal products administered by healthcare professionals only shall be sent to pi@noma.no , whereas in severe lack of availability, shall be sent to interruption@noma.no.
Veterinary medicinal products are in accordance with Art 61(1) 2001/82/EC.
Translation exemption and omission of certain particulars to appear on the labelling for veterinary medicinal products administered only by a veterinarian shall be sent to pi@noma.no.

## Appeal

Decisions made by NoMA according to the Norwegian medicinal product regulation, may be appealed to the Norwegian Health Dept. according to the rules in the Administration Act. The appeal shall be sent to NoMA.
*See*: https://legemiddelverket.no/english/appeal-against-an-administrative-decision

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***LIST OF ABBREVIATIONS***

*CP = Centralised procedure*

*EDQM = European Directorate for the Quality of Medicines*

*EC = European Commission*

*EMA = European Medicines Agency*

*DCP = Decentralised procedure*

*IAEA = International Atomic Energy Agency*

*IN = (Invented) Name*

*INN = International non-proprietary name*

*MAH = Marketing Authorisation Holder*

*MRP = Mutual recognition procedure*

*NoMA = Norwegian Medicines Agency*

*NRG = Name Review Group*

*OTC medicinal products = (Over The Counter) medicinal products not subject to medical prescription*

*PL = Package Leaflet*

*QRD = Quality Review of Documents*

*Rx medicinal product = medicinal product subject to medical prescription*

*SmPC / SPC= Summary of Product Characteristics*

# 1. GENERAL PRINCIPLES

## Scope

Labelling of medicinal products (packaging) is essential for safe and proper use of the medicinal product by the patients and healthcare professionals. The approval of the labelling information is part of the authorisation process for all medicinal products.

The guidance in this document applies to the labelling information of medicinal products for human and veterinary use authorised in Norway through mutual recognition, decentralised and national procedure.

All particulars regarding the multilingual packaging issues may be found in the Guideline on the Nordic packages, Questions and Answers document, Q&A Nordic packages.

Although this guidance document applies for both human and veterinary medicinal products, the requirements may differ in some occasions. Where the requirements for veterinary medicinal products differ from the human medicinal products this will be specified.

This guidance does not apply to medicinal products authorised through the centralised procedure.
For guidance regarding parallel imported and homeopathic medicinal products please visit NoMA's web site.

LINK: NoMA

## Legal basis

The legal basis for the requirements relating to packaging are found in the Norwegian medicinal product regulation and the European legislation, as Directive 2001/83/EC (human) and Directive 2001/82/EC (veterinary). The European directives have been implemented into the Norwegian law.

For general guidance, the following EU guidelines are also applicable to labeling information and package leaflets:

- Annex to the European Commission guideline on «Excipients in the labelling and package leaflet of medicinal products for human use»
- Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use
- Compilation of Quality review of documents decisions on stylistic matters in product information for human and veterinary medicinal products
- QRD recommendations on the expression of strength in the name of centrally authorised human medicinal products
- Guideline on the acceptability of names for human/veterinary medicinal products processed through the centralised procedure

LINK: Notice to Applicants – Vol 2 – Chapter 1

LINK: The Norwegian medicinal product regulation

## Braille

Medicinal products for human use shall contain Braille on the outer packaging expressing the (Invented) Name of the medicinal product and the strength. The strength is required only when the medicinal product is authorised in more than one strength.
Braille may perforate the text on the medicinal package. MAH has the responsibility of placing the Braille on the packaging without affecting the readability of the printed text.

*Exemption from Braille* requirement: may be applied for packages intended for administration by healthcare professionals.
*Veterinary medicinal products:* no Braille requirements.

Q&A Nordic packages

## 2. OUTER AND IMMEDIATE PACKAGING

As a rule, the labelling information of the outer and immediate packaging shall contain the same set of particulars:

- (Invented) Name, strength, pharmaceutical form and active substance identify a medicinal product. This information shall be placed together on the front panel. In addition, pack size should appear on the front panel
- The packaging shall be designed in a way that minimises the risk of confusion (e.g. between different strengths and/or pharmaceutical forms)

### Different aspects of package design:

| | | |
|---|---|---|
| **Text on the packaging** | • Easily legible and readable, also for persons with impaired sight<br>• Font size (see Readability Guideline): minimum 7 points didot /Times New Roman 9<br>• Avoid use of words with all capital letters<br>• It is preferable to present all text in the same direction and on homogenous background | Q&A Nordic packages<br>LINK: Readability guideline |
| **Nordic article number**<br>See also section 14 | • should be placed on a visible and easily legible place near the trade name<br>• should normally be placed on all sides where a complete identification of the package can occur | |
| **Use of colours and graphical elements** | • Clear contrast between text and background<br>• Colours shall be chosen to enhance the focus on the text<br>• Similar colours should not be used for the text and background as legibility [b] is impaired.<br>• Red colour lettering is strongly recommended for use in special warnings, where applicable.<br>• Use of graphical elements (e.g. lines and figures) must not reduce the readability[a] | Q&A Nordic packages<br>LINK: Readability guideline |

| | | |
|---|---|---|
| | • Use different colours in order to distinguish between the different strengths of the medicinal product<br>The use of colours shall not affect the readability of the text. | |
| **Pharmacy-dispensing label** | The packaging must be designed in order to provide for space for pharmacy-dispensing label. | |
| **Symbols and pictograms** | The outer packaging may contain symbols[c] or pictograms[d] only if they are compatible with the approved SmPC/SPC, if they provide additional value and they exclude any element of promotional character. They shall neither take up too much space nor draw attention from statutory information.<br>Veterinary products: pictogram of the target species can replace target species only on small immediate packaging. The pictograms cannot replace the text “til dyr”. | Q&A Nordic packages<br>Link: EMA’s guidance on veterinary medicinal product pictograms |
| **Logo** | The logo of MAH/trademark and local representative (in accordance with the application form) are acceptable on the packaging. The logo shall neither take up too much space nor attention from statutory information. | Q&A Nordic packages |
| **INN** | It is strongly recommended that the INN is placed in connection to the (Invented)Name, the strength and the pharmaceutical form, so that it does not raise any safety and other health concerns when using the medicinal product (e.g. avoid potential risk of confusion between medicinal products) | |

[a] Readability is the quality of being easy and enjoyable to read well (Cambridge Dictionary)
[b] Legibility is the degree to which writing or text can be read easily because the letters are clear, the text is printed well (Cambridge Dictionary)
[c] A mark or character used as a conventional representation of an object, function, or process. (Lexico, Oxford)
[d] A picture or symbol that represents a word or phrase (Cambridge Dictionary)

### Fold out label (label/leaflet combinations)

The outermost face of the label/leaflet and the label face in closest contact with the packaging (at the end of the leaflet) are both considered immediate packaging. The information that appears on each of these must be identical and meet all the requirements for packaging.
The point of opening of the label/leaflet shall be clearly identifiable to the user by “åpnes her” (“open here”) or similar.

## Warnings

- Medicinal products for human use containing active substance(s) stated in the warning triangle list from the Norwegian Medicine Agency shall bear the warning triangle.

  

  Orally administered medicinal products containing ethanol over 10 % w/w shall also bear the warning triangle.
  Design: red triangle on a white background. Minimum size: 10 mm long and the width of the frame is usually 2 mm. The tip of the triangle points upwards

- Medicinal products containing inflammable material shall bear the following international warning symbol on packages containing the volume of 125 mL or more:

  

  Q&A Nordic packages

  Link: Warning triangle list

  Link: Directive 2001/83/EC Art 62

  Link: Notice to Applicants, Vol 2

  LINK: EMA – human medicinal product – templates

  LINK: EMA – veterinary medicinal product - templates

- Special warning about the medicinal product to be stored out of the sight and reach of children: The sentence «Oppbevares utilgjengelig for barn» shall be presented on the packaging.

- Cytotoxic/cytostatic medicinal products shall be labelled «Cytostatikum».

Q&A Nordic packages

- Warnings and additional information may be required. For instance:
  - «Munnen bør skylles etter hver inhalasjon» (Wash the mouth after each inhalation)
  - «Kan farge hud, hår og klær» (May colour skin, hair and clothing)
  - «Kan farge urinen/avføringen» (May colour urine/stool)
  - «Kan misfarge myke kontaktlinser» (May discolour soft lenses)
  - «Unngå å få legemidlet i øynene» (Avoid getting the medicinal product in your eyes)
  - «Skal ikke brukes av skalldyrallergikere» (Shall not be used by people allergic to shellfish)
  - «Utilsiktet injeksjon er farlig.» (Accidental injection is dangerous.) (veterinary products)
  - «Utilsiktet tilførsel er farlig» «Kontakt med slimhinner er farlig.» (Accidental administration; Contact with the mucosa is dangerous.) (veterinary products)

## 3. IMMEDIATE PACKAGING

### *Specific requirements for labelling information on immediate packaging*

In cases of space limitations, EDQM patient-friendly short terms may be considered, if justified. Further abbreviations are possible, see Q&A Nordic packages.

Additional particulars to appear on the immediate packaging for medicinal products containing radionuclides are stated in the Norwegian medicinal product regulation (Art 3-32). See section 15 in this document.

LINK:EDQM

**Abbreviations on calendar days,** see Q&A Nordic packages

LINK: Abbreviation of names of days on caledarised blisters

### *Blisters or strips*

Minimum particulars to appear on blisters or strips:

a) The (Invented) Name of the medicinal product, strength and pharmaceutical form
b) The active substance
c) The full/short name of the MAH
d) The expiry date
e) The batch number
f) The statement «til dyr» in cases of veterinary medicinal products
   - State target species in cases of veterinary medicinal products (e.g «til hund»)

   Exemption: On veterinary medicinal products that have an outer package, the pharmaceutical form may be omitted

If a package is registered and approved as a unit-dose blister, all information required for blisters must appear on each unit-dose presentation.

Q&A Nordic packages

### *Small immediate packaging*

Where the labelling requirements to appear on immediate packaging cannot be applied in full on small containers, the following set of minimum particulars should be applied (normally applicable for containers sized up to and including 10 mL for human use, and 50 mL for veterinary).

a) The (Invented) Name of the medicinal product, strength and the pharmaceutical form
b) The active substance
c) The route of administration, well-established abbreviations are «i.m.», «i.v.», «s.c.»
d) The method of administration, if applicable
e) The expiry date
f) The batch number
g) The contents by weight, by volume or by unit
h) The statement «til dyr» in cases of veterinary medicinal products
   - State target species in cases of veterinary medicinal products (e.g. «til hund»)
   - Withdrawal period(s) for products for food producing animals.

   Exemption: On veterinary medicinal products that have an outer package, the pharmaceutical form may be omitted

LINK: Readability Guideline

## 4. NAME OF THE MEDICINAL PRODUCT

### General information

The name of the medicinal product may be either:

- an (Invented) Name*, or
- a common name** or a scientific name accompanied by the name of the marketing authorisation holder or a trademark

* Reference is made to the term '(Invented) Name'. This format aims to cover two possible scenarios in terms of proposed names: 1) purely 'Invented Name'; and 2) a 'Name' that can be the combination of the INN together with the name of the MAH/applicant company or its trademark.

**As common name is the international non-proprietary name (INN) recommended by the World Health Organisation understood, or, if one does not exist, the usual common name (Art. 1(21) of directive 2001/83/EC) and Art. 1(22) of directive 2001/82/EC).

Link: Directive 2001/83/(EC)

LINK: Direcive 2001/82/EC

LINK: NRG Guideline

### Presentation of the name on the packaging

- The (Invented) Name shall be followed by the strength. The pharmaceutical form shall be placed adjacent to the (Invented) Name
- The elements shall be presented in a clear and easily legible font. Preferably same size and font are to be used on all three elements, at least for the (Invented) Name and strength
- The strength shall be placed on the same line as the (Invented) Name, if possible
- For medicinal products available in more than one strength, it is strongly recommended to use different colours for different strengths to avoid mix-up
- Avoid excessive use of upper case letters in the (Invented) Name (as well as in other text) to improve legibility
- Additional qualifiers/abbreviations such as «vet» shall be presented in the same size, font and colour as the (Invented) Name

Symbols indicating (registered) trademark such as ® and ™ in relation to the (Invented) Name of the medicinal product are accepted on the packaging. Further information on trademark related issues are not acceptable.

Link: NRG

## 5. STRENGTH

NoMA accepts the strength as decided during the procedures and as given in the EMA guidelines regarding recommendations on the expression of strength.

Link: QRD recommendations on the expression of strength

The strength should preferably be stated in the same font style and size as the (Invented) Name, as well as on the same line.

Packages for different strengths shall be distinguished from each other. It is strongly recommended to use different colours for different strengths.

**Fixed combinations**: The strengths must be stated in the same order as the corresponding active substances.
It is acceptable to separate strengths and active substances by «/» or « +»

**Total quantity per total volume:** When the strength is given as a concentration e.g. in mg/ml, it is strongly recommended to present also the total quantity per total volume on the package, e.g. x ml = y mg

**Generic medicinal products:** It is strongly recommended that the generic medicinal products have the strength expressed in the same manner as the Norwegian reference product, e.g. 1000 mg or 1 g

**Multilingual packaging**: see Q&A Nordic packages

***Abbreviations for strength:***

| Strength in the SmPC/SPC and PL | Strength on the packaging |
|---|---|
| **micrograms** | NoMA uses the QRD recommendations given in:<br><br>Link: *Compilation QRD decisions on stylistic matters in PI*<br><br>The abbreviation «mikrog» is acceptable for small immediate packaging in case of space limitation.<br><br>Q&A Nordic packages |
| **E / IE**<br>**Unit / IU** | Use the same term consequently throughout the product information and the mock-ups.<br><br>**Norwegian terms**: «E» (enhet) and «IE»– (internasjonal enhet).<br>**Multilingual packaging**: the English terms “Unit” and “IU” (international unit) are acceptable.<br><br>Due to medicinal errors “U” is not acceptable on packaging.<br><br>Same practice applies for veterinary medicinal products.<br><br>Q&A Nordic packages<br><br>Link: Acceptability of IU as abbreviation for International Units in the strength of human medicinal products |
| **% and ppm** | The strength shall be stated in accordance with the QRD recommendation for strength, e.g. mg/ml, mg/g.<br>% and ppm shall be avoided.<br><br>Q&A Nordic packages |

The qualitative and quantitative composition of all the active substances in a medicinal product shall be featured on the labelling. Their accurate presentation on the packaging is a key element aiming to reduce the risk of medication errors.

## 6. PHARMACEUTICAL FORM

### Pharmaceutical form and contents by weight, volume or number of dose

- The pharmaceutical form shall be stated as approved in the EDQM Standard Terms
- The full standard term must appear on the outer packaging at least once, and in connection with the name of the medicinal product, on the most prominent area of the packaging, e.g. the front panel on a carton. It is strongly recommended to print the full pharmaceutical form in one line
- EDQM patient-friendly short terms may be used for other locations on the carton and immediate packaging material, if necessary. Further abbreviations are possible and can replace the patient-friendly terms in cases of space limitation

**Appendix I to this guideline:** Table of EDQM patient-friendly short terms and abbreviations:

LINK – EDQM- Standard Terms

### Pack size

- It is preferable that the pack size is stated in the upper left corner
- It is preferable that the pack size appears on every side of the package where the name, strength and pharmaceutical form of the medicinal product is stated
- If the content of a package consists of more than one container (multipack), this shall be evident on the outer packaging, e.g. package with two containers each holding 25 tablets is presented as “50 (2x25) tablets”
- If the package contains syringes or other equipment, this must be stated on the outer packaging

Q&A Nordic packages

LINK: EMA – human medicinal product – templates

LINK: EMA – veterinary medicinal product – templates

## 7. ACTIVE SUBSTANCE

The INN shall be expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight. Where the active substance is present as a salt, base or similar, this should be clearly indicated.

The active substance(s) must be written in lowercase letters only and in connection with the IN, the strength and the pharmaceutical form.

If the medicinal product contains three or fewer active substances, the active substance(s) shall be presented in connection with the (Invented) Name, strength and pharmaceutical form.

Q&A Nordic packages

EMA – QRD templates (human/veterinary)

### Latin/English for multilingual packaging

Active substance(s) may be written in Latin/English to facilitate a common multilingual packaging. See Q&A Nordic packages for more information

### Abbreviation of Latin names in multilingual packaging

Active substance(s) may be written in abbreviated form in order to facilitate a common multilingual packaging. See Q&A Nordic packages for more information

## 8. EXCIPIENTS

NoMA complies with Directive 2001/83/EC and the EC guideline for listing of excipients in medicinal products for human use.

- If the excipient is listed in the excipients guideline, it must appear on the packaging
- If the medicinal product is a parenteral, a topical or an eye preparation, all excipients must be stated
- *Flavour*: Shall not be part of the name, may be included as a qualifier following the pharmaceutical form. Note that pictures/drawings of fruits and berries are not permitted.

*Veterinary medicinal products:* It is not mandatory to list excipients in the packaging for veterinary medicines

### Examples on how excipients may be written on the packaging

E.g.: «Hver harde kapsel inneholder 100 mg celekoksib.» «Inneholder laktose og natrium.»

Note, if excipients are to be featured on the packaging, it is recommended that the excipient(s) are listed after the active substance(s) e.g.:

- 1 hetteglass: 50 mg doksorubicinhydroklorid, laktose, metylparahydroksybenzoat (E218)
- 3 ml: 300 mg natriumvalproat, vann til injeksjonsvæsker, kaliumdihydrogenfosfat (til pH-justering)

Link: Excipients guideline - NO

### Latin/English for multilingual packaging

Active substance(s) and excipients may be featured in Latin/English to facilitate a common multilingual packaging. See Q&A Nordic packages for more information

Link: Excipients guideline – EN

LINK: Compilation QRD decisions on stylistic matters in PI

## 9. METHOD AND ROUTE OF ADMINISTRATION

### Method of administration (MoA)

Methods of administration show the directions for proper use of the medicinal product e.g. «svelges hele», «innføres i endetarmen».

### Route of administration (RoA)

- Use EDQM standard terms

Oral RoA:

- For human medicinal products, the oral route of administration may be left out from the packaging for formulations, which are to be swallowed, e.g. tablets, capsules and oral solutions

Veterinary medicinal products: the route of administration shall always be stated, also where the product is for oral use, use the sentence “Gis i munnen” or “Gis via munnen”, as appropriate.

**Parenteral RoA:**

- The complete route of administration must be stated on both the outer and immediate packaging for medicinal products for injection/infusion, e.g. «Til intravenøs bruk»
- The following abbreviated forms may be used on small immediate packaging

| | |
|---|---|
| intramuscular use | i.m. |
| intravenous use | i.v. |
| subcutaneous use | s.c. |

**Ocular use / for ocular use**

- The term «for ocular use/ocular use” may be left out in case of space limitations on small immediate packaging. In these cases, the pharmaceutical form shall be clearly stated as «øyedråper/øyesalve»
- Accordingly, for: preparation for nasal use → «nesedråper»; preparations for auricular use → «øredråper»

Each package is evaluated individually.

**List of patient-friendly terms for method of administration (MoA and RoA):**

| EDQM standard terms for | Patient-friendly terms for RoA |
|---|---|
| okulær bruk | til bruk i øyet/øyne |
| nasal bruk | til bruk i nesen |
| bruk på hud | til bruk på huden |
| oral bruk | svelges/tas/gis gjennom munnen |
| rektal bruk | til bruk / innføres i endetarmen |
| sublingval bruk | til bruk/legges/plasseres under tungen |
| transdermal bruk | til bruk på huden |
| parenteral bruk | til parenteral bruk |
| subkutan bruk | til bruk under huden |
| vaginal bruk | innføres i skjeden |

| | |
|---|---|
| orofaryngeal bruk | til bruk i munn og svelg |

**The sentence "Read the package leaflet before use" must always be included on outer and immediate packaging.**

Q&A Nordic packages

LINK:EDQM

## 10. EXPIRY DATE, STORAGE CONDITIONS, DISPOSAL AND WASTE MATERIALS

### Expiry date

Expiry date shall be presented in the following format in accordance with annotated QRD template:
Month – full name «januar» or at least three letters «jan», or in two digits «01»
«januar 2020»
«jan. 2020»
«01.2020»
Year – presented with 4 digits: «2020»

Where relevant, dedicate space for writing of the date for first opening.

### Storage conditions

Storage conditions shall be stated on the packaging. However, for medicinal product where SmPC/SPC states, «This medicinal product does not require any special storage conditions», no information about storage is mandatory in the labelling information.

Human medicinal products: storage conditions shall be in accordance with template sentences in Appendix III – QRD template for human medicinal products.
Veterinary medicinal products: storage conditions shall be in accordance with template sentences in QRD template for veterinary products.

Q&A Nordic packages

Link: Appendix III to the QRD templates for human medicinal products

Link: Quality Review of Documents – information template version 8- veterinary

### Disposal and waste materials

If applicable, special warnings and precautions for disposal and waste materials and reference to existing suitable collection systems shall be included on the back (or side) panel of the package.

# 11. MARKETING AUTHORISATION HOLDER (MAH)

### Name and address of the MAH are mandatory:

- Outer packaging: MAH name, city and country
- Immediate packaging: MAH name
- Blister: Full/short MAH name

Local representatives, as stated in the application form, may be accepted.
Distributer, manufacturer and local representative that only give information, function as sales office and similar shall not be presented on the packaging.
It is important to distinguish between the roles of responsibility, if both the MAH and the local representative are presented,

Telephone number + fax + e-mail address may be included.
Web sites are *not acceptable* in line with annotated QRD template**.**

### Logo

Only logo of the MAH and the local representative (if applicable) in accordance with the application form may be accepted. Since space restrictions are common, it is recommended not to state the local representative on the packaging, as it will be mentioned in the package leaflet.
See also section 2.

Q&A Nordic packages

LINK: EMA – human and veterinary medicinal products – templates

# 12. MARKETING AUTHORISATION NUMBER AND BATCH NUMBER

### Marketing Authorisation number (MA number)

The MA-number is preceded by the term «MTnr.» and shall be placed adjacent to the name and address of the MAH.
The country abbreviation, «(NO)» must be used on multilingual packaging. The country abbreviation shall not be included on single market packs.

### Designations:

| | |
|---|---|
| Marketing Authorisation number(s) | MTnr. xx-xxxxx (NO) |
| Parallel Import number(s) | MT.(PI)nr xx-xxxxx (NO) |
| Traditional Herbal Medicinal Product registration number(s) | Reg. nr. xx-xxxxx (NO) |

Q&A Nordic packages

### Batch number

The batch number shall be placed together with the expiry date on the packaging and preceded by the approved abbreviation <Batch> or <Lot>.

For small immediate packaging and blisters, the abbreviation for batch number and expiry date may be omitted on request. In this case, only the actual batch number and expiry date are printed.

For approved abbreviations for batch/lot and expiry see:

Link: Appendix IV terms abbreviation for batch numbers and expiry dates(human)

Link: Appendix IV terms abbreviations for batch numbers and expiry dates(veterinary)

## 13. CONDITIONS, INSTRUCTIONS AND RESTRICTIONS REGARDING SUPPLY AND USE

Conditions or restrictions regarding supply and use, ATC-code, price and refund status must not appear on the medicinal product package.

Veterinary medicinal products: Information regarding use may be acceptable on the package. From the QRD template labelling section 9: "Indicate any particulars essential for safety or health protection, including any special precautions relating to use and any other warnings."

Q&A Nordic packages

### Instructions for use

Some examples of mandatory instructions for use on the package to be used, when appropriate:

- «ristes før bruk» eller «omrystes» («shake before use»)
- «må fortynnes» («to be diluted»)
- «oppløses i et glass vann» («dissolve in a glass of water»)
- «svelges hele» («swallow whole»)
- «skal ikke tygges» («do not chew»)

### Labelling information on OTC (over the counter) packaging and active substance reports for human medicinal products

Approved OTC indication(s) and common dosing regimen for corresponding indications shall be presented on the packaging.
OTC active substance reports are available for human medicinal products on NoMA's web site for some ATC-codes. The reports contain indication, dosage and information about use.

- If an active substance report is available, the approved indication shall be written with identical wording as in the active substance report.
- If the full indication is written on the back panel of the package, the suggested short form (ref. the active substance report) may be used on the front panel.

Link: NOMA's website for OTC active substance reports

## 14. NORDIC ARTICLE NUMBER AND SAFETY FEATURE

### Nordic article number

The Nordic article number shall be stated at least once on the outer packaging and in the following format: «Vnr. XX XX XX»
For location of the Nordic article number on the packaging, please see section 2 in this guideline.

### Multipacks

It is sufficient that the Nordic article number is presented on the outer packaging.
If the Nordic article number also appears on each intermediate pack, this number shall not be the same as the number on the outer packaging, i.e. each intermediate pack shall not have the multipacks' Nordic article number.

Q&A Nordic packages

Link: VnrWiki

For further information regarding Nordic article number, contact the Pharmaceutical Information Centre (PIC).

Link: PIC

### Safety features

Safety features only concern human medicinal products subject to prescription. Medicinal products that are required to bear safety features according to Regulation (EU) 2019/161 have to implement the unique identity (PC, SN and 2D Data matrix) and the anti-tampering device. For further information, see the Commissions Q&A.

For further recommendations regarding PC/GTIN, please see the Healthcare GTIN Allocation Rules (GS1 guideline).

Link: Regulation (EU) 2016/161

Lnk: Safety features for medicinal products for human use - Commision Q&A

Link: Farmalogg

Link: Healthcare GTIN Allocation rules

### 2D data matrix / 2D barcode on immediate packaging

There are no legal requirement for a 2D barcode on the immediate packaging. However, it may be included on immediate packaging as long as it does not affect the readability of the statutory information.

For further recommendations regarding 2D barcode on immediate packaging, please see the Healthcare GTIN Allocation Rules (GS1 guideline).

Link: Farmalogg

Link: Healthcare GTIN Allocation rules

### Mobile scanning and other technologies

Mobile scanning and other technologies (including quick response (QR) codes) may be requested. Such requests shall be made in accordance with the CMDh position paper on mobile scanning for human medicinal products and the Quick response (QR) codes for veterinary medicinal products.

Link: Mobile scanning and other technologies in the labelling and package leaflet of centrally authorised medicinal products

Link: Quick response (QR) codes in the labelling and/or package leaflet of veterinary medicinal products authorised via CP, MRP, DCP and NP

# 15. SPECIAL REQUIREMENTS

## Veterinary medicinal products

In addition to the information above, the packaging shall contain the following information:

- The species of animal for which the veterinary medicinal product is intended
- The withdrawal period for veterinary medicinal products to be administered to food-producing species, for all the species concerned and for the various foodstuffs concerned (meat and offal, eggs, milk, honey), including those for which the withdrawal period is zero
- The words “Til dyr” or, in the case of the medicinal products that are to be supplied only on veterinary prescription, the words “Til dyr” and “Reseptpliktig”.

## Radioactive medicinal products

Medicinal products that contain radioactive nuclides shall contain information according to the requirements in Art. 3-29, Art. 3-30 and Art 3-32 of the Norwegian medicinal product regulation.

Additional particulars to appear on the shielding and immediate packaging (vial) for medicinal products containing radionuclides:

- The name or the chemical symbol of the radionuclide
- The international radioactivity symbol
- The name and address of the manufacturer
- The amount of radioactivity as stated in the Norwegian medicinal product regulation (Art. 3-32)

Link: GHS pictograms

LINK: Norwegian medicinal product regulation

## Traditional herbal medicinal products

Traditional herbal medicinal products shall contain information according to the requirements in Art. 3-29 to Art. 3-38 of the Norwegian medicinal product regulation. Additional particulars to appear on the outer packaging:

- legemidlet er et tradisjonelt plantebasert legemiddel til anvendelse med særlig(e) bruksområde(r) utelukkende basert på erfaringer fra lang brukstradisjon
- brukeren bør konsultere lege dersom symptomene fortsetter ved bruk av legemidlet, eller dersom det skulle oppstå bivirkninger som ikke er nevnt i pakningsvedlegget
- Reseptfritt legemiddel

The Norwegian Medicines Agency may require further information on the pack regarding the traditional use.

**Appendix I:** Table of EDQM patient-friendly short terms and abbreviations:

| Standard term EDQM - English | Standard term EDQM - Norwegian | Patient-friendly term EDQM - Norwegian | Abbreviated patient-friendly term Norwegian |
|---|---|---|---|
| solution for injection | injeksjonsvæske, oppløsning | **injeksjonsvæske** | **inj.væske/inj.** |
| suspensjon for injection | injeksjonsvæske, suspensjon | **injeksjonsvæske** | **inj.væske/inj.** |
| emulsion for injection | injeksjonsvæske, emulsjon | **injeksjonsvæske** | **inj.væske/inj.** |
| solution for infusion | infusjonsvæske, oppløsning | **infusjonsvæske** | **inf.væske /inf.** |
| dispersion for infusion | infusjonsvæske, dispersjon | **infusjonsvæske** | **inf.væske /inf.** |
| emulsion for infusion | infusjonsvæske, emulsjon | **infusjonsvæske** | **inf.væske /inf.** |
| concentrate for solution for infusion | konsentrat til infusjonsvæske, oppløsning | **sterilt konsentrat** | |
| concentrate for solution for injection | konsentrat til injeksjonsvæske, oppløsning | | |
| concentrate for solution for injection/infusion | konsentrat til injeksjons-/infusjonsvæske, oppløsning | | |
| powder for solution for injection | pulver til injeksjonsvæske, oppløsning | **pulver til injeksjonsvæske** | **pulver til inj.** |
| powder for suspension for injection | pulver til injeksjonsvæske, suspensjon | **pulver til injeksjonsvæske** | **pulver til inj.** |
| powder for solution for infusion | pulver til infusjonsvæske, oppløsning | **pulver til infusjonsvæske** | **pulver til inf.** |
| powder for dispersion for infusion | pulver til infusjonsvæske, dispersjon | **pulver til infusjonsvæske** | **pulver til inf.** |

## HYPERLINKS:

| | |
|---|---|
| Classification regulation | https://lovdata.no/dokument/SF/forskrift/1999-12-27-1565 |
| CMD(h)/<br>CMD(v)<br>Coordination Groups for MRP and DCP | CMD(h)<br><br>CMD(v) |
| Directive 2001/83/EC | https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0083&from=en |
| Directive 2001/82/EC | https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0082&from=EN |
| EDQM | https://standardterms.edqm.eu/ |
| Excipients Guideline<br>(English version) | Excipients in the label and package leaflet of medicinal products for human use |
| Excipients Guideline<br>(Norwegian version) | Norwegian translation of excipient guideline |
| EMA - human medicinal products – templates | https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/product-information-templates |
| EMA - veterinary medicinal products – templates | https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/quality-review-documents-veterinary-product-information-annotated-template-english-version-81-clean_en.pdf |
| EMA – human<br>Readability Guideline | Guideline on the readability of the label and package leaflet of medicinal products for human use |
| EMA – Annex to the EC guideline on excipients in the labelling and the package leaflet of medicinal products for human use | See Excipients Guideline (English version) |
| EMA's guidance on veterinary medicinal product pictograms | https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/draft-quality-review-documents-qrd-guidance-use-approved-pictograms-packaging-veterinary-medicinal_en.pdf |
| EMA - Abbreviation of names of days on calendarised blisters | https://www.ema.europa.eu/en/documents/other/abbreviation-names-days-calendarised-blisters_en.pdf |
| EMA – Mobile scanning | https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/mobile-scanning-other-technologies-labelling-package-leaflet-centrally-authorised-medicinal-products_en.pdf |
| EMA – Quick Response (QR) codes | https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/quick-response-qr-codes-labelling/package-leaflet-veterinary-medicinal-products-authorised-centralised-cp-mutual-recognition-mrp_en.pdf |
| EU Commission<br>Readability Guideline | *https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf* |

| | |
|---|---|
| Farmalogg | https://www.farmalogg.no/en/ |
| Healthcare GTIN Allocation Rules (GS1 guideline) | Healthcare GTIN Allocation Rules |
| IAEA | GHS pictograms |
| Nordic package cooperation | Q&A Nordic packages |
| Norwegian medicinal product regulation | https://lovdata.no/dokument/SF/forskrift/2009-12-18-1839 |
| NoMA (Norwegian Medicines Agency) | https://legemiddelverket.no/English |
| Norwegian Association of the Blind and Partially Sighted | Blindeforbundet |
| Notice to Applicants – human<br>Guideline on packaging information 12/2016 | https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/2016_12_packaging_guidelines_revision_14_4.pdf |
| Notice to Applicants –<br>Vol 2 – Chapter 1 | https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/vol2a_chap1_en.pdf |
| NoMA -<br>Norwegian guidance on labelling | https://legemiddelverket.no/english/regulatory-affairs/product-information-templates-and-guidance#labelling |
| NoMA-<br>Warning triangle | Warning triangle list |
| NoMA –<br>active substance reports | NOMA's website for OTC active substance reports |
| Norwegian declaration regulation | https://tema.miljodirektoratet.no/no/Regelverk/Forskrifter/Deklareringsforskriften/<br>https://lovdata.no/dokument/SF/forskrift/2015-05-19-541?q=kjemikalier |
| QRD compilation document on stylistic matters | https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/compilation-quality-review-documents-decisions-stylistic-matters-product-information_en.pdf |
| QRD – human<br>Acceptability of IU as abbreviation for International Unit in the strength | https://www.ema.europa.eu/en/documents/other/acceptability-iu-abbreviation-international-units-strength-human-medicinal-products_en.pdf |
| QRD - recommendations on the expression of strength | https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/quality-review-documents-recommendations-expression-strength-name-centrally-authorised-human_en.pdf |
| QRD – human<br>Terms and abbreviations for batch number and expiry date to be used on the labelling | Appendix IV |
| QRD – veterinary | Appendix IV |

| | |
|---|---|
| Terms and abbreviations for batch number and expiry date to be used on the labelling | |
| QRD – human<br>(storage conditions) | Appendix III |
| QRD – veterinary<br>(storage conditions) | Quality Review of Documents veterinary product-information template version 8 |
| QRD – veterinary<br>Guidance on the use of approved pictograms | https://www.ema.europa.eu/en/qrd-guidance-use-approved-pictograms-packaging-veterinary-medicinal-products-authorised-centralised |