Norwegian Medicines Agency

Version 2.1, 12/2022

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

(MRP, DCP and national procedure)

Update log for the guideline

Version	Date	Content
Version 1.0/2020	22.2.2020	New packaging guideline version 1.0
Version 1.1, 02/2020	28.2.2020	section 2, Table 1– added INN information
Version 1.2, 02/2020	11.3.2020	section 13.3, 13.4 - GS1 guidelines Few adjustments – veterinary text
Version 1.3, 02/2020	11.6.2020 7.9.2020	Management section - artwork of the PL requirements Appendix: table of EDQM short forms Table of hyperlinks - new hyperlink to the Nordic Q&A
Version 1.4, 02/2020	19.2.2021	section 2, Table 1- colour codes section 7 - list updated for excipient requirements
Version 1.5, 02/2020	30.4.2021	section 9 - EXP date format
Version 1.6, 02/2020	30.6.2022	Updates according to the new veterinary legislation in whole v.1
Version 2.0, 12/2022	1.12.2022	Revised packaging guideline version 2.0
Version 2.1, 12/2022	15.2.2023	Hyperlink to the updated «CMDh position paper on the use of Mobile scanning and other technologies to be included in labelling and package leaflet (PL) in order to provide information about the medicinal product»

Content

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

NVR = New Veterinary Regulation

OTC = (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

LIST OF TABLES

PACKAGING MANAGEMENT AT NoMA

Mock-ups of the packaging of a medicinal product intended for the Norwegian market must be assessed and approved by the NoMA. The packaging content shall be based on the latest approved Norwegian labelling in Word-format.

The mock-ups in PDF-format are the full colour copies of the flat artwork design of a medicinal product, both the inner and the outer packaging, that can be assembled into a three-dimensional replica.

Human medicinal products*:* NoMA assesses content and design/layout of submitted mock-ups according to the Norwegian regulation on medicinal products for human use.

Veterinary medicinal products: For medicinal products authorised after 28 January 2022, and/or where the product information is updated according to QRD template v.9., NoMA assesses content and design/layout of submitted mock-ups according to the Norwegian Medicines Act, Section 2b. cf. Regulation (EU) 2019/6, and the information in this guideline is updated accordingly. For medicinal products using QRD template v.8.2 please see Directive 2001/82/EC. Marketing authorisation holders should update and implement their product information, in line with QRD template v.9, by 29 January 2027.

Readability and presentation in Norwegian language

Labelling text on the pack must be presented in an easily readable and comprehensive manner and be non-erasable.

Exemptions regarding translation and omission of certain particulars may be granted on an individual basis, see **Exemptions to packaging requirements**.

In the packaging management phase NoMA does not require submission of the artwork of the package leaflet (PL) intended for the patient/user. Nevertheless, it is expected from the MAH to follow the guiding rules for the artwork of the PL intended for patient/user as stated in the Readability Guideline, section 2.

Submission

First approval of mock-ups after marketing authorisation (national, MRP and DCP)

Before the product is placed on the market in Norway, mock-ups of the labelling in Norwegian must be submitted for assessment and approval by NoMA, either within the MA-procedure or as an Article 61(3) notification (human) / VRA G.I.15.z (veterinary). For MRP and DCP mock-ups can also be submitted with a variation affecting the product information (II and IB (excluding transfer) variation for human medicinal products and VRA in chapter G for veterinary medicinal products).

Mock-ups of the smallest pack sizes for each strength, each pharmaceutical form and type of pack intended to be marketed are required. Larger pack sizes that follow the same design (layout and colour, the same text content with identical location and the same font size (or larger)) shall be approved accordingly.

Variations

NoMA requires submission of Norwegian labelling text together with the Norwegian SmPC/SPC and PL in cases where the variation concerns the common labelling text.

Mock-ups shall be submitted if there are changes in design/layout. Mock-ups and Norwegian labelling shall be submitted if there are changes in common labelling text and design/layout. NoMA may request updated mock-ups, when needed.

Change in design/layout

Mock-ups of the smallest pack sizes for each strength, each pharmaceutical form and type of pack intended to be marketed are required.

When the change in design/layout is not related to a change affecting the SmPC/SPC the following types of mock-up submissions are required:

-Submission for (**human)** medicinal products – Article 61(3) notification cf. Directive 2001/83/EC or an appropriate variation type (IB or II), excluding Transfer

-Submission for **veterinary** medicinal products – VRA G.I.15.z), Regulation (EU) 2019/6

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 medicinal products that are not delivered directly to patients/caregivers and animal owners or where there are severe availability issues, exemption from some of the obligations for labelling may be granted. This is in accordance with Article 63(3) cf. Directive 2001/83/EC (human) and Article 7(1) cf. Regulation (EU) 2019/6 (veterinary).

Human medicinal products: 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 lack of availability, shall be sent to interruption@noma.no.

Veterinary medicinal products: Translation exemption for veterinary medicinal products administered only by a veterinarian shall be sent to pi@noma.no, whereas in lack of availability, shall be sent to interruption@noma.no.

Appeal

Decisions made by NoMA according to the Norwegian regulation on medicinal products for human use, may be appealed to the Norwegian Health Department according to the rules in the Administration Act. The appeal shall be sent to NoMA.

See procedure specific information on NOMA's website

See list of hyperlinks for the management of packaging:

The Norwegian regulation on medicinal products for human use

Directive (2001/83/EC (human)

Directive 2001/82/EC (veterinary)

Regulation (EU) 2019/6 (veterinary)

Regulation (EC) 1234/2008 (human)

Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use

Guideline on the acceptability of names for human/veterinary medicinal products processed through the centralised procedure

Guideline on summary of product characteristics (human)

Guideline on the packaging information of medicinal products for human use authorised by the union (NtA Vol 2C human)

Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations (veterinary)

NoMA's website – Appeal against an administrative decision (human/veterinary)

NoMA's website submission specific information (human/veterinary)

1. GENERAL PRINCIPLES

1.1 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. This guideline presents the mandatory rules and regulatory recommendations for packaging design/layout during approval of the marketing authorisation and post authorisation procedures.

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. The differences in requirements and guidance between human and veterinary medicinal products are distinctly specified in the text.

Nordic packs: All particulars regarding the multilingual packaging matters may be found in the Guideline on the Nordic packages, Questions and Answers document, Nordic package cooperation - Q&A Nordic packages.

Packaging in centralised procedure: This guidance does not apply to medicinal products authorised through the centralised procedure.

Packaging for parallel imported medicinal products: For guidance regarding parallel imported and homeopathic medicinal products please visit NoMA's web site.

Procedural information: Information regarding Notification 61(3), for information, Notification 63(3), types of variations and more, related to packaging and package leaflet is placed in topic specific pages on NoMA's web site.

1.2 Legal basis

Human medicinal products: The legal basis for the requirements relating to packaging are found in the Norwegian regulation on medicinal products for human use and the European legislation, as Directive 2001/83/EC. The European directive has been implemented into the Norwegian law.

Veterinary medicinal products: The legal basis for the requirements relating to packaging are found in the Norwegian Medicines Act, Section 2b. cf. Regulation (EU) 2019/6. The legal basis for medicinal products that use QRD template v.8.2 is Directive 2001/82/EC.

1.2.1 Overall rules for human and veterinary medicinal products:

For general guidance, the following national and EU legislation is applicable to labelling information:

- Norwegian regulation on medicinal products for human use
- Norwegian Medicines Act
- Directive 2001/83/EC (human)
- Directive 2001/82/EC (veterinary)
- Regulation (EU) 2019/6 (veterinary)
- Implementing Regulation (EU) 2021/17 (veterinary)

- Regulation (EU) 1234/2008 (human)
- NoMA- Warning triangle
- NoMA-norske legemiddelstandarder NLS (Norwegian standard terms)
- EDQM Standard Terms
- Notice to Applicants-Guideline on packaging information 12/2016 (human)
- Guideline on the readability of the labelling and package leaflet of medicinal products for human Use
- Guideline on the acceptability of names for human/veterinary medicinal products processed through the centralised procedure
- Guideline on summary of product characteristics (human)
- Guideline on the packaging information of medicinal products for human use authorised by the union, NtA (hum) Vol 2C
- Guideline - Excipients in the labelling and package leaflet of medicinal products for human use, NtA (hum) Vol 2C
- Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products
- Excipients Guideline - Excipients in the labelling and package leaflet of medicinal products for human use
- Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668) Excipients and information for the package leaflet
- Best practice guide for the processing of SPC, Labelling and Package leaflet and the preparation of Multilingual/-country Packaging provided in support of MRP/DCP/SRP and Variations (veterinary)

1.2.2 QRD-documents and other recommendations:

The list and information contained in these documents is non-exhaustive. MAHs should refer to all relevant legislation and guidelines when submitting packaging for approval. It is the MAH's responsibility to ensure that the product information complies with all such requirements.

- Nordic package cooperation - Q&A Nordic packages
- Compilation of QRD decisions on stylistic matters in product information (human)
- QRD recommendations on the expression of strength in the name of centrally authorised human medicinal products
- QRD combined label-leaflet annotated template v.9.0 (veterinary)
- QRD guidance on the use of approved pictograms on the packaging of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP) and decentralised procedures (DCP)
- Human medicinal products – templates
- Veterinary medicinal products – templates
- Labelling & packaging of veterinary medicinal products recommendations
- CMD(v) Coordination Groups for MRP and DCP

1.3 Braille (human)

Medicinal products for human use shall contain Braille on the outer packaging expressing the (Invented) Name of the medicinal product and the strength. Strength is required only when the medicinal product is authorised in more than one strength.

Braille may perforate the text on the medicinal pack. MAH has the responsibility of placing Braille on the packaging without affecting the readability of the printed text.

Exemption from Braille requirement: may be applied for packs intended for administration by healthcare professionals.

See list of hyperlinks at the end of this guideline for references on legal basis and other recommendations

2. OUTER AND IMMEDIATE PACKAGING

Human medicinal products*:* As a rule, the labelling information of the outer and immediate packaging shall contain the same set of particulars.

Veterinary medicinal products: See section 2.4. in this guideline for information on the particulars required for the immediate packaging and outer packaging, respectively.

- (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. See more information on pack size in section 5.2 in this guideline
- The packaging shall be designed in a way that minimises the risk of confusion (e.g. between different strengths and/or pharmaceutical forms)

Table 1: Different aspects of packaging design/layout

Text on the packaging	• Easily legible and readable, also for persons with impaired sight • Font size (see Readability Guideline): minimum 7 points didot /Times New Roman 9 • Avoid use of words with all capital letters and italics • It is recommended to present all text in the same direction and on homogenous background
Nordic article number See also section 13	• should be placed on a visible and easily legible place near the trade name • should normally be placed on all sides where a complete identification of the pack can occur
Use of colours and graphical elements	• Clear contrast between text and background • Colours shall be chosen to enhance the focus on the text • Similar colours should not be used for the text and background as legibility[a] is impaired • Red colour text is strongly recommended for use in special warnings, where applicable • Use of graphical elements (e.g., lines and figures) must not reduce the readability[b] • Use different colours to distinguish between the different strengths of the medicinal product (refers to outer, intermediate and inner packaging) The use of colours shall not affect the readability of the text.
Pharmacy-dispensing label	The packaging must be designed to provide for space for the pharmacy-dispensing labels.

Symbols and pictograms	The 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.
Logo	The logo of MAH/trademark and local representative[e] (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.
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] 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)
Different colours and good contrast for the text and background; Company logos and pictograms (if accepted in accordance with Article 62) may be presented, where space permits; line-spacing and use of white space; nonreflective packaging; sufficiently large font; paper labels (Readability Guideline)
[b] Readability is the quality of being easy and enjoyable to read well (Cambridge Dictionary)
Nonreflective material or coloured foils; Sans serif typefaces, 16-20-point, contrast: black letters on white background, word spacing, text alignment, line spacing, layout, paper quality (Readability Guideline)
[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)
[e] For veterinary medicinal products logo of the local representative can be included if requested by the applicant according to Article 13 in Regulation (EU) 2019/6

2.1 Fold out label (label/leaflet combinations)[1]

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.

Veterinary medicinal products: If a fold-out label/leaflet is proposed, the separate templates for labelling text and package leaflet shall be used and not the combined label-leaflet template.

[1] Wrap around or concertina labels ref. Readability Guideline

2.2 Warnings (human medicinal products)

- Mandatory text on the packaging: "Oppbevares utilgjengelig for barn" (To be stored out of sight and reach of children) ref. annotated template section 6
- Mandatory text on the packaging: "Les pakningsvedlegget før bruk" (Read the package leaflet before use) ref. annotated template section 5
- The warning triangle is required for medicinal products containing active substance(s) stated in the warning triangle list from the NoMA

- The warning triangle is also required for orally administered medicinal products containing ethanol over 10 % w/w

  Design of the triangle: 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

- The international warning symbol is required for medicinal products containing inflammable material for packs containing 125 ml or more:

- Cytotoxic/cytostatic medicinal products shall be labelled «Cytostatikum».
- Warnings and additional information on the packaging may be required according to the SmPC/labelling text, e.g.:

  «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)

2.3 Requirements for labelling on immediate packaging (human)

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

Additional particulars to appear on the immediate packaging for medicinal products containing radionuclides are stated in Section 3-32 cf. Norwegian regulation on medicinal products for human use. See section 14 in this guideline.

Abbreviations on calendar days, see Nordic package cooperation - Q&A Nordic packages and Abbreviation of names of days on calendar blisters.

2.3.1 Blisters or strips

Minimum particulars to appear on blisters or strips:

a. (Invented) Name of the medicinal product, strength and pharmaceutical form
b. Active substance
c. Full/short name of the MAH
d. Expiry date
e. Batch number

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

2.3.2 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).

a. (Invented) Name of the medicinal product, strength and pharmaceutical form
b. Active substance
c. Route of administration, well-established abbreviations are «i.m.», «i.v.», «s.c.»
d. Method of administration, if applicable
e. Expiry date
f. Batch number
g. Contents by weight, by volume or by unit

2.4 Specific requirements for labelling information (veterinary)

2.4.1 Immediate packaging

Particulars to appear on the immediate packaging:

a. (Invented) Name of the veterinary medicinal product, followed by its strength and pharmaceutical form
b. Active substance
c. Batch number, preceded by the word «Lot»
d. Name or company name or logo name of the marketing authorisation holder
e. Target species
f. Expiry date, in the format: «mm/yyyy», preceded by the abbreviation «Exp.»
g. Special storage precautions
h. Route of administration
i. Withdrawal period. if applicable, even if such period is zero

2.4.2 Small immediate packaging

This includes blisters, strips, ampoules or small single-dose containers other than ampoules. On a case-by-case basis, the minimum particulars could also be considered for other containers (e.g. small multidose containers up to 50 ml) where it is not feasible to include all the information. Such exceptional cases must be justified, discussed and agreed with the Competent Authority/European Medicines Agency.

a. The (Invented) Name of the veterinary medicinal product
b. The quantitative particulars of the active substances
c. Batch number, preceded by the word «Lot»
d. Expiry date, in the format: «mm/yyyy», preceded by the abbreviation «Exp.»

2.4.3 Outer packaging

In addition to the information in the immediate packaging, the outer packaging shall contain the following information:

- the contents by weight, volume or number of immediate packaging units of the veterinary medicinal products
- a warning that the veterinary medicinal product must be kept out of the sight and reach of children
- a warning that the veterinary medicinal product is «for animal treatment only»
- a recommendation to read the package leaflet (except if all information is provided on the packaging)
- in the case of homeopathic veterinary medicinal products, the statement «homeopathic veterinary medicinal product»
- in the case of veterinary medicinal products not subject to a veterinary prescription, the indication or indications
- the marketing authorisation number
- Nordic article number

Where there is no outer packaging, all the information that is required on the outer packaging shall appear on the immediate packaging.

According to Regulation (EU) 2019/6 Article 13, Member States may, within their territory, and on request of the applicant, allow an applicant to include on the immediate packaging or outer packaging of a veterinary medicinal product additional useful information which is compatible with the summary of the product characteristics, provided it is not an advertisement for a veterinary medicinal product.

See section Legal basis for references on overall rules

See list of hyperlinks for section specific references:

Abbreviation of names of days on calendarised blisters

Nordic package cooperation - Q&A Nordic packages

QRDh – MRP, DCP and referral product-information template v.4.2 (Norwegian)

Warning triangle list

Labelling & packaging of veterinary medicinal products recommendations

QRDv - Veterinary product information templates

QRD guidance on the use of approved pictograms on the packaging of **veterinary** medicinal products authorised via the centralised, mutual recognition and decentralised procedures - Species pictograms

IAEA - GHS pictograms

3. NAME OF THE MEDICINAL PRODUCT

3.1 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.
**Common name is the international non-proprietary name (INN) recommended by the World Health Organisation or, if one does not exist, the usual common name, according to Article 1(21) cf. Directive 2001/83/EC and Article 4(20) cf. Regulation (EU) 2019/6.

3.2 Presentation of the name on the packaging

- The (Invented) Name shall be followed by the strength. The pharmaceutical form and active substance 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
- It is not recommended to use upper-case letters in the (Invented) Name, since capitalisation of the (Invented) Name decreases the 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 is not acceptable.

See section Legal basis for references on overall rules

4. STRENGTH

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

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

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

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

Fixed dose combinations: The strengths must be given in the same order as the corresponding active substances.

Different strengths of fixed dose combination medicinal products should be separated by a slash "/". However, when the units of the strength are given with a slash "/ " (concentrations) it may be acceptable to separate the strengths by either a plus "+" sign or a slash "/" sign.

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

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

Multilingual packaging: see Nordic package cooperation - Q&A Nordic packages

Table 2: Specific abbreviations for strength

Strength in the SmPC/SPC and PL	Strength on the packaging
micrograms	• The strength shall be presented in accordance with the QRD recommendations cf. "Compilation QRD decisions on stylistic matters in PI" • The abbreviation «mikrog» is acceptable for small immediate packaging in case of space limitation.
E / IE **Unit / IU**	• Use the same term consequently throughout the product information and the mock-ups. • Norwegian terms: «E» (enhet) and «IE»– (internasjonal enhet). • Multilingual packaging: the English terms "Unit" and "IU" (international unit) are acceptable. Due to medicinal errors "U" is not acceptable on packaging. The same practice applies for veterinary medicinal products.
% and ppm	• % and ppm shall be avoided. • The strength shall be presented in accordance with the QRD recommendation for strength, e.g. mg/ml, mg/g.

See section Legal basis for references on overall rules

See list of hyperlinks for section specific references:

Nordic package cooperation - Q&A Nordic packages

QRD - recommendations on the expression of strength

QRD - Acceptability of IU as abbreviation for International Units in the strength of human medicinal products

QRD - Compilation of QRD decisions on stylistic matters in product information

5. PHARMACEUTICAL FORM AND CONTENT

5.1 Pharmaceutical form

The pharmaceutical form shall be presented as approved in the EDQM Standard Terms

- The full standard term must appear on both the outer and immediate packaging at least once, and in connection with the name of the medicinal product, on the most prominent area of the packaging. It is strongly recommended to print the full pharmaceutical form in one line
- The full standard term must appear on the outer pack at least once, and in connection with the name of the medicinal product, on the most prominent area of the pack, such as the front panel.
- EDQM patient friendly short terms may be used for other locations on the carton and immediate packaging material, if necessary.
  Further abbreviations according to the Nordic package cooperation - Q&A Nordic packages
- are possible and can replace the full form or the patient friendly term in cases when space is very limited

5.2 Content - pack size

- It is preferable that the pack size is stated in the upper left corner and that it appears on each side of the pack where the medicinal product name, strength, active substance and pharmaceutical form of the medicinal product are presented
- It is acceptable to include the pharmaceutical form as part of the declaration of pack size (e.g. "20 tabletter") only if the pharmaceutical form is already stated together with the name, strength and active substance
- For certain types of pharmaceutical forms e.g. solutions, powder, inhalation vapor, ointment, it is strongly recommended to include the nature of the container in the declaration of the pack size, e.g. ampoule, vial, syringe, tube, box
- If the content of a pack consists of more than one container (multipack), this should be evident on the outer packaging
- If the pack contains syringes or other equipment, this must be stated on the outer packaging

Appendix to this guideline: Table of EDQM patient-friendly short terms and abbreviations for outer and immediate packaging

See section Legal basis for references on overall rules

See list of hyperlinks for section specific references:

Nordic package cooperation - Q&A Nordic packages

QRDh – MRP, DCP and referral product-information template v.4.2 (Norwegian)

QRDv - Veterinary product information templates

6. ACTIVE SUBSTANCE

The active substance (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 on the packaging.

For medicinal products approved through MRP/DCP, the declaration of active substance shall be in accordance with the common labelling approved during the procedure.
For medicinal products approved in purely national procedures, the declaration of active substance shall be in accordance with the approved SmPC/SPC.

The active substance(s) must be written in lowercase letters only and in connection with the (Invented) Name, 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.

Monolingual packaging shall contain full form active substance(s) declared in Norwegian.

Multilingual packaging may contain full form/abbreviated active substance(s) declared in Norwegian or, to facilitate multilingual packaging, in Latin or English.

See section Legal basis for references on overall rules

See list of hyperlinks for section specific references:

Nordic package cooperation - Q&A Nordic packages

QRD - Compilation of QRD decisions on stylistic matters in product information

QRDh – product-information annotated template (English) version 10.3

QRDv - combined label-leaflet annotated template v.9.0

7. EXCIPIENTS

Human medicinal products:

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

1. Excipients with known action /effect are listed in the Excipients Guideline must appear on the packaging:

    a. For medicinal products approved through MRP/DCP, the declaration of excipient(s) shall be in accordance with the common labelling approved during the procedure
    b. For medicinal products approved in purely national procedures, the declaration of excipient(s) shall be in accordance with the approved SmPC/SPC

2. All excipients must be declared on the outer pack[2], if the medicinal product is one of the following preparations:

    - preparation for parenteral use
    - preparation for ocular use
    - preparation applied externally to the skin (including transdermal patches)
    - preparation for respiratory use delivered to the lung by inhalation
    - ear preparations (local or transdermal delivery)
    - oral preparations (local or transdermal delivery)
    - nasal preparations (local or transdermal delivery)
    - rectal preparations (local or transdermal delivery)
    - vaginal preparations (local or transdermal delivery)

3. Excipients must be declared on the packaging. It is recommended that the excipient(s) are listed after the active substance(s) as in these examples:

    - «Hver harde kapsel inneholder 100 mg celekoksib.» «Inneholder laktose og natrium»
    - «1 hetteglass: 50 mg doksorubicinhydroklorid, laktose, metylparahydroksybenzoat (E 218)»
    - «3 ml: 300 mg natriumvalproat, vann til injeksjonsvæsker, kaliumdihydrogenfosfat pH -justering)»

Monolingual packaging shall contain full form excipient(s) declared in Norwegian.

Multilingual packaging may contain full form/abbreviated excipient(s) declared in Norwegian or, to facilitate multilingual packaging, in Latin or English.

Flavour *s*hall not be part of the name and may be included as a qualifier following the pharmaceutical form. Note that pictures/drawings of fruits and berries are not permitted.

[2] When there is no outer package, the excipients must be declared on the immediate packaging.

See section Legal basis for references on overall rules

See list of hyperlinks for section specific references:

Nordic package cooperation - Q&A Nordic packages

QRD - Compilation of QRD decisions on stylistic matters in product information

8. METHOD AND ROUTE OF ADMINISTRATION

Methods of administration (MoA) give the directions for proper use of the medicinal product e.g. «svelges hele» (swallow whole), «skal ikke tygges» (do not chew).

Routes of administration (RoA) are the ways by which the medicinal product is taken into the body. RoA according to the EDQM should be presented at least once on the outer and immediate packaging.

8.1 Oral RoA

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.

8.2 Parenteral RoA

- The complete route of administration must be presented on both the outer and immediate packaging for medicinal products for injection/infusion, e.g.«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.

For veterinary medicinal products the abbreviated forms may be used on immediate packaging in case of space restrictions.

8.3 Ocular, auricular and nasal RoA

- Preparations for ocular use: the term «Okulær bruk» may be left out in case of space limitations on small immediate packaging. In these cases, the pharmaceutical form shall be clearly stated as e.g. «øyedråper», «øyesalve»
- Preparations for nasal use e.g. «nesespray»
- Preparations for auricular use e.g. «øredråper»

Table 3: List of patient-friendly terms for RoA*

EDQM standard terms RoA	Patient-friendly terms for RoA
Okulær bruk	Til bruk i øyet/øyne
Nasal bruk	Til bruk i nesen
Aurikulær bruk	Til bruk i øret
Bruk på hud	Til bruk på huden
Transdermal bruk	Til bruk på huden
Subkutan bruk	Til bruk under huden
Oral bruk	Svelges/Tas i/Gis gjennom/via/munnen
Sublingval bruk	Til bruk/Legges/Sprayes/Plasseres under tungen
Orofaryngeal bruk	Til bruk i munn og svelg
Parenteral bruk	Til parenteral bruk
Rektal bruk	Til bruk / Innføres i endetarmen
Vaginal bruk	Innføres i skjeden

*Not exhaustive, see EDQM Standard Terms

See section Legal basis for references on overall rules

See list of hyperlinks for section specific references:

Nordic package cooperation - Q&A Nordic packages

9. EXPIRY DATE, STORAGE CONDITIONS, DISPOSAL AND WASTE MATERIALS

9.1 Expiry date

Expiry date on the packaging shall be presented in the following format in accordance with annotated QRD template:

Human medicinal products: Month presented in 2 digits; year presented with 4 digits, e.g.:

«01/2021»
«01-2021»
«01.2021»

For expiry date in letters for the month only Norwegian transcription is acceptable, e.g:

«Januar 2021»
«Jan. 2021»

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

Veterinary medicinal products: Month presented in 2 digits: year presented with 4 digits, e.g.:

«01/2021»

Veterinary medicinal products:

Month presented in 2 digits; year presented with 4 digits:

«01/2021»

9.2 Storage conditions

Storage conditions shall be stated on the packaging. However, for medicinal products where SmPC/SPC says, «Dette legemidlet krever ingen spesielle oppbevaringsbetingelser» (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.

9.3 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 pack.

Veterinary medicinal products: Information regarding use may be acceptable on the packaging according to Article 13 cf. Regulation (EU) 2019/6. See section 2.4 in this guideline.

See section Legal basis for references on overall rules

See list of hyperlinks for section specific references:

Nordic package cooperation - Q&A Nordic packages

QRDh – Storage conditions

QRDv – Storage conditions

QRDh – MRP, DCP and referral product – information template v. 4.2 (Norwegian)

QRDv - Veterinary product information templates

10. MARKETING AUTHORISATION HOLDER (MAH)

Human medicinal products:

- Outer packaging: MAH name, city and country
- Immediate packaging: MAH name
- Blister: Full/short MAH name
- Telephone number + e-mail address may be included
- Web sites are not acceptable in line with annotated QRD template
- Local representatives, as stated in the application form, may be accepted
- Distributors, manufacturers and local representatives 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

Veterinary medicinal products:

- Outer packaging: only MAH name, company name or logo name
- Immediate packaging: only MAH name, company name or logo name
- Small immediate: Not required/only allowed if requested through Article 13
- For veterinary medicinal products the local representative can be included if requested by the applicant according to Article 13 in Regulation (EU) 2019/6
- Distributors or manufacturers shall not be given on the packaging
- It is important to distinguish between the roles of responsibility, if both the MAH and the local representative are stated

Logo

Human medicinal products*:* Only the logo of the MAH and the local representative (if applicable) in accordance with the application form may be accepted.

Veterinary medicinal products*:* The logo name of the MAH is acceptable. The logo of the local representative may be included if requested by the applicant according to Article 13 in Regulation (EU) 2019/6.

For human and veterinary medicinal products:
It is not recommended to present the local representative on the packaging, as information on the local representative is found in the package leaflet. See also section 2 in this guideline.

See section Legal basis for references on overall rules

See list of hyperlinks for section specific references:

Nordic package cooperation - Q&A Nordic packages

QRDh – MRP, DCP and referral product – information template v. 4.2 (Norwegian)

QRDv - Veterinary product information templates

11. MARKETING AUTHORISATION NUMBER AND BATCH NUMBER

11.1 Marketing Authorisation number (MA number)

It is recommended that the MA number is 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.

Table 4: Designations for marketing authorisation and registration number

Human and veterinary medicinal products	MTnr. xx-xxxxx (NO)
Parallel Import	MT(PI)nr. xx-xxxxx
Traditional Herbal Medicinal Product registration number(s)	Reg. nr. xx-xxxxx (NO)

11.2 Batch number

Human medicinal products: 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 upon request. In this case, only the actual batch number and expiry date are printed.

For approved abbreviations for Batch/Lot and Expiry date see: Terms and abbreviations for batch number and expiry date on labelling

Veterinary medicinal products*:* The batch number shall be placed together with the expiry date on the packaging and preceded by the approved abbreviation «Lot»,

See section Legal basis for references on overall rules

See list of hyperlinks for section specific references:

Nordic package cooperation - Q&A Nordic packages

QRDh–Terms and abbreviations for batch number and expiry date on labelling

12. CONDITIONS, INSTRUCTIONS AND RESTRICTIONS REGARDING SUPPLY AND USE

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

Veterinary medicinal products: Information regarding use may be acceptable on the packaging according to Article 13 cf. Regulation (EU) 2019/6. See section 2.4 in this guideline.

Instructions for use (human medicinal products only): Some examples of mandatory instructions as in the SmPC/labelling text:

- «ristes før bruk» eller «omrystes» (shake before use)
- «må fortynnes» (to be diluted)
- «oppløses i et glass vann» (dissolve in a glass of water)

Labelling information on OTC packaging and active substance reports (human)

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 pack, the suggested short form (ref. the active substance report) may be used on the front panel

See section Legal basis for references on overall rules

See list of hyperlinks for section specific references:

NoMA – Active substance reports

Nordic package cooperation - Q&A Nordic packages

13. NORDIC ARTICLE NUMBER AND SAFETY FEATURES

13.1 Nordic article number (human and veterinary)

The Nordic article number shall be presented 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, see section 2 in this guideline.

13.2 Multipacks (human and veterinary)

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.

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

13.3 Safety features (human)

Safety features apply only to human medicinal products subject to prescription. Medicinal products that are required to bear safety features according to Regulation (EU) 2019/161 must implement the unique identity (PC, SN and 2D Data matrix) and the anti-tampering device. For further information, see the document: Safety features for medicinal products for human use/EC– Questions and Answers.

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

13.4 Data matrix 2D/2D barcode on immediate packaging (human)

There is no legal requirement for a 2D barcode on the immediate packaging. However, it may be included in 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).

13.5 Mobile scanning and other technologies (human and veterinary)

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.

See section Legal basis for references on overall rules

See list of hyperlinks for section specific references:

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

CMDh position paper on the use of Mobile scanning and other technologies to be included in labelling and package leaflet (PL) in order to provide information about the medicinal product

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

Farmalogg

Healthcare GTIN Allocation rules – GS1

Safety features for medicinal products for human use/EC – Questions and Answers

VnrWiki

14. SPECIAL REQUIREMENTS

14.1 Radioactive medicinal products

Medicinal products that contain radioactive nuclides shall contain information according to the national requirements in Norway. Additional particulars that 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 symbols
- The name and address of the manufacturer
- The amount of radioactivity as stated in the Norwegian regulation on medicinal product for human use, Section 3-32

14.2 Traditional herbal medicinal products

Traditional herbal medicinal products shall contain information according to the requirements in the Norwegian regulation on medicinal product for human use, Section. 3-29 to 3-38.

The additional particulars to appear on the outer packaging are:

- «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»

NoMA may require further information regarding the traditional use that should be presented on the packaging.

See section Legal basis for references on overall rules

See list of hyperlinks for section specific references:

IAEA - GHS pictograms

Appendix: Table of EDQM patient-friendly short terms and abbreviations for outer and immediate packaging

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

LIST OF HYPERLINKS

Abbreviation of names of days on calendarised blisters https://www.ema.europa.eu/en/documents/other/abbreviation-names-days-calendarised-blisters_en.pdf
Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668) Excipients and information for the package leaflet (English version) https://www.ema.europa.eu/en/annex-european-commission-guideline-excipients-labelling-package-leaflet-medicinal-products-human#current-version-section
BEST PRACTICE GUIDE for the processing of SPC, Labelling and Package leaflet and Packaging provided in support of MRP/DCP/SRP and Variation (veterinary) https://www.hma.eu/fileadmin/dateien/Veterinary_medicines/CMDv_Website/Procedural_guidance/SPC__Labelling_and_Package_leaflet/BPG_Processing_PI.pdf
CMDh position paper on the use of Mobile scanning and other technologies to be included in labelling and package leaflet (PL) in order to provide information about the medicinal product https://www.hma.eu/human-medicines/cmdh/procedural-guidance/general-info.html
CMD(v) Coordination Groups for MRP and DCP CMD(v)
Directive 2001/83/EC (human) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0083&from=en
Directive 2001/82/EC (veterinary) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0082&from=EN
EDQM (Standard Terms) https://standardterms.edqm.eu/
Excipients and information for the package leaflet (Hjelpestoffer og informasjon til pakningsvedlegg) (Norwegian version) Norwegian translation of excipient guideline
Farmalogg https://www.farmalogg.no/en/
Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations (veterinary) https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-details-classification-variations-requiring-assessment-according-article-62-regulation-eu/6-veterinary-medicinal-products-documentation-be-submitted-pursuant-those-variations_.pdf

Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use *https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf*
Guideline on the acceptability of names for human medicinal products processed through the centralised procedure https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure_en.pdf
Guideline on the acceptability of names for veterinary medicinal products processed through the centralised procedure https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-acceptability-names-veterinary-medicinal-products-processed-through-centralised-procedure_en.pdf
Guideline on summary of product characteristics (human) http://www.kardio.hr/wp-content/uploads/2012/12/spcguidrev1-oct2005_en.pdf
Guideline on the packaging information of medicinal products for human use authorised by the union (NtA Vol 2C human) https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-2_en
Guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EU) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products and on the documentation to be submitted pursuant to those procedures https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013XC0802(04)&from=EN
Healthcare GTIN Allocation rules – GS1 https://gs1.no/gs1-healthcare-gtin-allocation-rules/
Human medicinal products – templates https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/product-information-templates
IAEA - GHS pictograms GHS pictograms
Labelling & packaging of veterinary products recommendations https://www.hma.eu/fileadmin/dateien/Veterinary_medicines/CMDv_Website/Procedural_guidance/SPC__Labelling_and_Package_leaflet/POS_Labelling_and_packaging_recommendations.pdf
Mobile scanning and other technologies in the labelling and package leaflet of centrally authorised medicinal products https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/mobile-scanning-other-technologies-labelling-package-leaflet-centrally-authorised-medicinal-products_en.pdf
NoMA (Norwegian Medicines Agency) https://legemiddelverket.no/English

NoMA- Appeal against an administrative decision https://legemiddelverket.no/english/appeal-against-an-administrative-decision
NoMA - Norwegian guidance on labelling https://legemiddelverket.no/english/regulatory-affairs/product-information-templates-and-guidance#labelling
NoMA- Warning triangle list https://legemiddelverket.no/english/regulatory-affairs/product-information-templates-and-guidance/warning-triangle
NoMA – Active substance reports NOMA's website for OTC active substance reports
NoMA – norske legemiddelstandarder NLS (Norwegian standard terms) https://legemiddelverket.no/godkjenning/nls
NoMA submission specific information (human/veterinary) **See NoMA's website:** https://legemiddelverket.no/
Nordic package cooperation - Q&A Nordic packages https://www.lakemedelsverket.se/sv/tillstand-godkannande-och-kontroll/forsaljningstillstand/produktinformation/att-utforma-markning#hmainbody1
Norwegian regulation on medicinal products for human use https://lovdata.no/dokument/SF/forskrift/2009-12-18-1839
Norwegian Medicines Act https://lovdata.no/dokument/NL/lov/1992-12-04-132?q=lov%20om%20legemidler
Notice to Applicants (hum) – Volume 2C – Guideline - Excipients in the labelling and package leaflet of medicinal products for human use https://health.ec.europa.eu/system/files/2018-03/guidelines_excipients_march2018_en_0.pdf
Quick response (QR) codes in the labelling and/or package leaflet of veterinary medicinal products authorised via CP, MRP/DCP, DCP and NP 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
QRD – 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 - Compilation of QRD decisions on stylistic matters in product information https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/compilation-quality-review-documents-qrd-stylistic-matters-product-information_en.pdf

QRDh – product-information annotated template (English) varsion 10.3 https://www.ema.europa.eu/en/documents/template-form/qrd-product-information-annotated-template-english-version-103-highlighted_en.pdf
QRDh – MRP, DCP and referral product-information template v. 4.2 (Norwegian) https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/product-information-templates-human
QRDh 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
QRDh – Storage conditions Appendix III
QRDh–Terms and abbreviations for batch number and expiry date on labelling Appendix IV
QRDv - Veterinary product information templates https://www.ema.europa.eu/en/veterinary-regulatory/marketing-authorisation/product-information/veterinary-product-information-templates
QRDv combined label-leaflet annotated template v.9.0 (veterinary) https://www.ema.europa.eu/en/documents/template-form/particulars-appear-immediate-package-combined-label-package-leaflet-track-changes_en.pdf
QRDv – Storage conditions https://www.ema.europa.eu/en/veterinary-regulatory/marketing-authorisation/product-information/veterinary-product-information-templates
QRD guidance on the use of approved pictograms on the packaging of veterinary medicinal products authorised via the centralised, mutual recognition and decentralised procedures - Species pictograms https://www.ema.europa.eu/en/qrd-guidance-use-approved-pictograms-packaging-veterinary-medicinal-products-authorised-centralised
Regulation (EU) 2019/6 (veterinary) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0006&rid=1
Regulation (EU) 2021/17 (veterinary) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0017&from=EN
Regulation (EU) 1234/2008 (human) https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:334:0007:0024:en:PDF
Safety features for medicinal products for human use/EC – Questions and Answers https://health.ec.europa.eu/system/files/2022-06/qa_safetyfeature_en_0.pdf
Veterinary medicinal products – templates https://www.ema.europa.eu/en/veterinary-regulatory/marketing-authorisation/product-information/veterinary-product-information-templates
VnrWiki

https://wiki.vnr.fi/?lang=no