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CMDh Best Practice Guide on Multilingual Packaging

1. Introduction

'Multilingual packaging' refers to the use of two or more languages for at least one component of the packaging material for a medicinal product e.g., immediate and/or outer packaging and/or package leaflet or for all components.

Directive 2001/83/EC, Article 63 permits the use of multilingual text, with the proviso that the same information appears in all the languages used. The exception to this is national specific information captured within the 'blue box'. Information that applies to all Member States (MSs) should be included in the main text.

The establishment of multilingual packaging is an important mechanism for maintaining medicinal products in EU markets, especially in so called "small markets". This document serves to assist applicants in creating a multilingual package. There are successful initiatives already in place to facilitate multilingual packages e.g., the Nordic, Baltic or BE procedures (see Annex 1), therefore the following guidance is intended to be complementary to those procedures, in order to extend use of multilingual packaging in MSs where those procedures are not appropriate for the countries involved in the multilingual package. Other initiatives ongoing, for example electronic product information (ePI) projects are also complementary to multilingual packaging to ensure availability of medicines.

In order to further facilitate a multilingual packaging with the aim of improving the availability of medicines in MSs, CMDh started a pilot exercise in 2020, and it is still ongoing. The purpose of the pilot is to agree during the MR/DC procedure not only on EU full harmonised labelling text, but also on EU reduced harmonised labelling text. The EU reduced harmonised labelling text can be further used for creation of the multilingual packaging and further details of this pilot are outlined in Section 3.2 below.

2. Scope

This guidance covers the preparation of multilingual packages for MR/DCP products, although the principles outlined may be useful for preparing a multilingual package for purely national products where the product authorisation details e.g., SmPC, are already harmonised between member states (MS). It should be noted also that the guidance may not be applicable in all aspects for all member states, therefore applicants are advised to consider the additional national guidance referenced in Annex 1.

3. Requesting multilingual labelling - procedural aspects

3.1. General aspects

Preparation of harmonised text

The need for a multilingual packaging should be considered at the beginning of an application for a product authorisation, in order to achieve a multilingual packaging in a timely and efficient manner. In situations where a multilingual packaging would be advantageous, the level of detail proposed in the EU harmonised labelling text should be carefully considered by the applicant in preparing their MRP/DCP submission and throughout the EU assessment phase.

The EU harmonised text is assessed and agreed during the EU assessment phase of the application procedure before the mock-up review process.

The applicant should aim to resolve potential barriers to achieving a multilingual packaging, while retaining information required by current QRD guidelines and Directive 2001/83/EC. Thus, superfluous or redundant text should be avoided in the harmonised text. The applicant should explore the existing possibilities at a national level which are permitted for shortening text, e.g., use of patient friendly short standard terms for pharmaceutical form, use of common abbreviations for routes of administration (see Section 5 and Annex 2 below), while ensuring that no safety issues arise. Space constraints, including the feasibility of the proposed number of languages, should therefore be considered by the applicant before approval of the EU harmonised text. For example, the applicant could themselves test the likely wording in several languages on their proposed pack sizes in order to evaluate any potential issues. In any case, readability must not be compromised by multilingual packaging.

The applicant should highlight in the cover letter for MRP/DCP applications (see templates on HMA/CMDh website), that they propose to apply a multilingual packaging, and list the MSs involved in the 'cluster'. They may also indicate whether they intend to participate in the CMDh pilot on full/reduced harmonised text (see Section 3.2 below). A 'cluster' is considered to be the group of MSs which will share a mock-up (a multilingual packaging). This information will facilitate communication between MSs for a multilingual packaging, if necessary. Identifying the cluster at this early stage is advisable but does not preclude development of further clusters at end of procedure or later by Article 61.3 based on the final agreed text. In establishing such 'clusters', the applicant should carefully consider any additional national 'blue box' requirements and stylistic requirements as stated in the published guidance (see Section 5 and Annex 1), and naming conventions (see Section 3.3). Such awareness of potential constraints for multilingual packages early in the procedure should facilitate earlier agreement of harmonised text and subsequent multilingual packages.

3.2. Multilingual packaging pilot

The purpose of the multilingual packaging pilot is to agree on a EU reduced harmonised labelling text during the MR/DC procedure if the preparation of a multilingual packaging is foreseen. Participation in the pilot is not a prerequisite for the preparation of a multilingual package, however it is considered useful in order to facilitate agreement of such packages.

The pilot is limited to applications for prescription-only products.

The process of the pilot procedure is described below (please see also the flow chart in Annex 3):

3.2.1. New Marketing Authorisation (MA) applications in pilot

EU phase

When the new MA application is submitted, the applicant should clearly state their willingness to participate in the pilot in the cover letter and indicate the MSs involved in a 'cluster' in the cover letter (templates on cover letters for MRP/DCP are available on HMA/CMDh website).

The **applicant**, in the submitted dossier, should:

a) Provide one set of labelling (a standalone document) including the proposed text reductions highlighted as 'dark grey shaded italics' of the full text. Thus, separate documents are not required for the full text and the reduced text for a multilingual packaging. Dark grey shaded italics indicate that this text will be omitted from the final labelling for a multilingual packaging, thus creating the 'reduced' text;
b) Title the document either *'EU full harmonised labelling text' – no text reductions required'* or *'EU full/reduced harmonised labelling text'* as appropriate. The title is used to convey that the labelling has undergone assessment for consideration of multilingual packaging reductions, even where no text reductions result;
c) For the purposes of gaining experience in the pilot the applicant can also submit their proposed template and a completed cover letter later in the procedure e.g., in the clock stop phase of a DCP.

The **RMS**, in order to support the pilot:

a) Assesses the EU full/reduced harmonised labelling text proposal, focussing on safety issues (i.e., can the requested text be removed without significantly affecting safety of the product and legal requirements as far as applicable?). This assessment is done on behalf of all involved MSs in a multilingual packaging (including in circumstances where a multilingual packaging is not applicable for the RMS);
b) Can let CMSs know that the procedure has been included in the pilot by stating this in Day 70 AR (or Day 120 AR) for DCP, highlighting any directly affected CMSs where known so those CMSs can comment
c) RMS is not responsible for assessing the multilingual mock-ups on behalf of other MSs or for reviewing space considerations on the mock-ups (see also section 3.4).
d) At Day 70 (or Day 120) for DCP the RMS circulates the *EU full/reduced harmonised labelling text* for CMSs comments along with the AR, the full PL and SmPC.

The **CMSs** involved in a 'cluster' actively comment where *EU harmonised reduced text* is proposed. MSs involved in a 'cluster' who can't accept the reduced labelling text on their market following their scientific evaluation of the reduced text proposal are advised to let the applicant know and copy the RMS, at their earliest opportunity before EOP, and the full text would be expected for that market.

At Day 210 for DCP (EOP) the **RMS** circulates the harmonised labelling text template, including the appropriate title i.e., 'EU full harmonised labelling text' - no text reductions required' or 'EU full/reduced harmonised labelling text' so that the outcome of the pilot is reflected and it is clear for future procedures and preparation of a multilingual packaging what has been agreed by the RMS.

National phase

The **applicant** provides the national translation of the product information agreed during the procedure, retaining the dark grey italic shading of any reduced text as agreed. The applicant submits national mock-ups for the multilingual packaging for those MSs in a 'cluster' which routinely require submission of mock-ups. The applicant, in preparing those mock-ups, uses the agreed text reductions for a multilingual packaging outlined in the Day 210 for DCP (EOP) *EU full/reduced harmonised labelling text.* The submission of the translations and mock-ups will be in line with the usual national practices for MSs and no further discussions on text reductions are envisaged.

MSs involved in a 'cluster' finalise the national phase of the procedure according to their existing national approaches which may include for example, approval only of the translation of the product information, review of mock-ups during the national phase, request to submit Art 61.3 at time of launch, no review required for mock-ups.

Recommendations

The following points should be taken into account during the pilot procedure:

- For the immediate packaging, a level of detail equivalent to that required in Directive 2001/83/EC Article 55.3 for a small immediate packaging may be proposed in all cases by the applicant if a multilingual packaging is foreseen. In consideration of the critical information required on the outer packaging, a level of detail intermediate to the minimum particulars and full text may be proposed in all cases by the applicant for the outer packaging if a multilingual packaging is foreseen (see Annex 2).
- The preferred option is that *EU full harmonised text* is used where space permits on a multilingual packaging. However, in case of space constraints *EU reduced harmonised text* may be used by the applicant.
- The *EU reduced harmonised text* option is only applicable for a multilingual packaging, as it not acceptable to use the reduced labelling text where there is only one language on a packaging.
- Only one set of reduced text is agreed by the RMS, not a set per a 'cluster'. No further reductions in text beyond the *EU reduced harmonised text* are then envisaged. The *EU reduced harmonised text* option can then be used wherever a multilingual packaging has been proposed in the cover letter. This will also facilitate preparation of future multilingual packs as a new cluster will follow this template and provide mock-ups nationally by Art 61.3 according to national practice.
- It is acknowledged that the marketing plans of MAHs may change during the new application procedure. Therefore, as both labelling texts – full and reduced – are approved during the MA procedure, it is expected that where a monolingual package is prepared the full text is used, and if a new MS 'cluster' is proposed the reduced text may be used. Furthermore, if space permits the applicant can change their approach to use full labelling text on a multilingual packaging rather than reduced text.
- As outlined above, no further text reductions are should be requested after agreement of the EU full/reduced harmonised text. However, text simplifications (e.g., abbreviations in MSs who accept these nationally e.g., Nordic MSs - see Annex 2) should be agreed with MSs involved.
- The pilot applies to labelling text only; package leaflets are not involved.

3.2.2. Introduction of new MS 'cluster' where an 'EU reduced harmonised text' is already approved

When agreed, the 'EU reduced harmonised text' may be used to develop further multilingual packages with different MS's.

Where an applicant wishes to introduce a new multilingual packaging in an Art 61.3 or variation affecting product information, the applicant should highlight the request to use the agreed *EU reduced harmonised text* (if text reductions are necessary, if not then the *full EU text* is used), and the proposed MSs 'cluster' should be highlighted in the cover letter or in the 'background' section of the MR Art 61.3 or variation form.

For the principles around agreement on mock-ups, including those for pilot procedures, please see Section 3.4.

3.2.3 Existing (authorised) medicinal products and preparation of EU reduced harmonised text - pilot

Agreement of an 'EU reduced harmonised text' may be requested for existing products by submission of an MR Article 61.3 notification to the RMS and CMS, indicating the proposed 'clusters' in the cover letter, and describing the request.

The principles of procedure and actions of the involved parties are as described in the section 3.2.1.

3.3. Product names

Applicants and MSs are requested to discuss product names (especially, proposed invented names) early in DCP/MRP submissions if a multilingual packaging is proposed. A list of three names in order of preference should be initially suggested in Annex 5.19 for the MSs involved in a 'MLP cluster', having due consideration of national recommendations for names, and existing names in those MSs. The following should be considered:

- If a medicinal product name is being created using the 'INN accompanied by MAH product name' format, the INN for the active moiety instead of the salt format should be used in order to limit translation issues;
- Applicants are reminded that a generic medicinal product of a reference medicinal product authorised by the Community is authorised under the condition that it has the same name in all MSs where the application has been made;
- The impact of the length of the proposed name, on the Braille version, and the relevance of including the pharmaceutical form in Braille should be carefully considered when proposing product names;
- The impact of the length of the proposed name, for example inclusion of company styles such as B.V., D.A.C., on the possibility for preparation of a multilingual pack, should be carefully considered when proposing the product name.

Discussions to agree the name of the medicinal product may continue during the clock stop phase in order to reach a single name for a 'cluster' before the EOP. The applicant is asked to contact the affected MSs individually during the clock stop to agree on the name, as although the agreement of a name remains a national issue, this should expedite issuing of marketing authorisations.

3.4. Agreement of mock-ups

The following provides guidance on the principles around agreement of mock-ups, in MSs which review mock-ups:

IMPORTANT:

Multilingual packaging can still be prepared outside of the pilot procedure outlined in Section 3.2, according to agreed practice and procedures in MSs following the approaches outlined below.

The following procedural stages provide opportunities to expedite final agreement of mockups:

European phase of the procedure

Mock-ups for a multilingual packaging may be submitted during the new MA procedure or Article 61.3 procedure for layout and design review, for comment by applicable MSs (those involved in clusters who routinely review mock-ups). Such early comments should expedite final agreement when the final EU harmonised text is available. It is emphasized that the RMS is not responsible for assessing the multilingual mock-ups on behalf of other MSs or for reviewing space considerations on the mock-ups. CMSs may comment nationally on their own mock-ups during procedure, in order to expedite assessment in the national phase (please see Annex 1 on national requirements below);

After the end of the European phase of the procedure (EOP)

After the EOP, mock-ups for a multilingual packaging, prepared using the final translated texts for the involved MSs, are assessed where applicable in line with national approaches, either as part of the national phase at the end of MR/DCP new applications/variations, or by way of an MR Article 61.3 or separate national Article 61.3 notification at a later date.

In case of MS that routinely assess mock-ups, the MS involved in MS 'clusters' should remain available to liaise on mock-up issues arising as notified by the MAH, or, are requested to indicate early where they do not wish to review the mock-ups. It should be noted that some MSs do not routinely assess mock-ups but still permit a multilingual packaging for their market, therefore those MSs will not usually participate in the discussion of mock-ups, however mock-ups must be provided to those MS if requested.

To progress efficiently, where national phase mock-ups and/or separate national Article 61.3 notifications for multilingual packages are submitted to the proposed MSs, the applicant needs to keep the MSs in the relevant MLP 'cluster' informed, submit the mock-ups in a similar timeframe and co-ordinate the contemporaneous review by impacted MSs of the mock-ups, the text of which should be accordance with the already agreed EU (reduced) harmonised text. It is recommended that the applicant appoints one contact point for discussion of a multilingual packaging by MS where there is more than one MAH involved.

Similarly, the MSs involved in the MLP 'cluster' should progress the national phase for procedures in a timely manner and indicate when the mock-ups are considered acceptable by them, in order for the review to be concluded. MSs involved in clusters, whether they assess mock-ups or not, are advised to conclude the national phase promptly to facilitate co-ordination of approval and marketing timelines.

The references in Annex 1 can be consulted to establish national approach to mock-up review.

3.5 National derogations

Any translation exemptions, for example the use of one language only on packaging, are considered a national issue. Where an applicant proposes to include particulars for one MS in another language this should be discussed directly with the affected MS. Similarly, although the packaging should reflect exactly what is in the harmonised text, in very exceptional cases proposals for further abbreviations of the common text in the final packaging e.g., use of ultrashort terms other than those listed under Section 5 below, should be discussed directly with the affected MS.. Links to national guidance from MS including further detail on MSs facilitations are included in Annex 1.

3.6 National requirements

It is noted that national requirements for packaging exist in MS, usually relating to the healthcare systems in that MS e.g., symbols, standard statements. Links to national guidance from MS outlining such requirements are included in Annex 1. Where applicants encounter particular national requirements, which may impede a multilingual packaging leading to availability issues e.g., Falsified Medicine Directive Codes, this may be raised by MAH's via their Interested Parties Industry representatives for future consideration of the particular MS involved.

4. Key principles

Multilingual packaging is possible for medicinal products authorised through the MR, DC and national-only procedures if the medicinal product in the involved MS has:

- The same invented name and strength
- Harmonised SmPC, package leaflet and product labelling text
- The same legal status

Additional practical recommendations to be taken into consideration for a multilingual packaging for MR/DC procedures are outlined below. These are complementary to the QRD guidance on stylistic matters which details positions on specific technical issues as currently agreed by MS (see under Section 5 below).

Recommendations:

Labels

a. Information in each language should be blocked together where possible (rather than one sentence appearing in three languages, followed by the next sentence in three languages as that may interrupt the readability for the patient).

b. Repetition of the name strength and form, or grouping information relating to the strength and form on labels could be applied to address national requirements, for example where there is a requirement for different number separators in the strength:
Brandname 10.5mg/ml solution for injection
Brandname 10,5mg/ml solución inyectable

c. Where a number of countries share a common package, the 'blue box' requirements for all countries should be listed on the same panel/side. Country-specific requirements, such as 'blue box' text, must specify the country to which this applies.

d. The applicant should confirm that the same information as stated in the harmonised text is presented in each language in the mock-ups.

e. As space is the main constraint for multilingual packages, applicants are advised to consider this during technical design phase for packaging, should multilingual packages be envisaged. The impact of design on available space must be carefully considered for multilingual packages, in that company logo and corporate styles may need to be reduced. The impact of space constraints e.g., whether it is possible to include the translations of days in calendar packs, or choice of multi-pocket blister versus unit dose blister for the involved MS should be carefully considered.

f. The abbreviations 'Exp' and 'Lot' are common to many MSs and the QRD guidance (see Section 5 below) should be considered by applicants. Further currently agreed abbreviations are also highlighted in the QRD guidance on non-standard abbreviations (see Section 5 below).

g. Use of EDQM patient friendly short terms in the EU harmonised text may help with space constraints on labelling in order to facilitate a multilingual packaging. These are agreed EQDM shortened standard terms that may be used where justified and authorised for labelling only, in case of space limitation, and must be accompanied by the full term in the SmPC, e.g., for pharmaceutical forms. Where no suitable short term exists MS could be consulted whether there is a possibility to request a new term from EDQM.

h. As pictograms are not permitted to replace text due to the possibility of their misinterpretation by patients, they are not considered a viable solution to space constraints in the preparation of MLP's. Similarly, the configuration of MS clusters including MS where mandated symbols such as 'red triangle' are required, should be carefully considered to avoid any risk of confusion for MS where such symbols are not mandated.

i. The challenges apparent in the preparation of multilingual packaging for small immediate vials are noted. Some options which could be considered for some MSs are the use of 'peel-back' labels to allow multiple languages to be printed on the vial. Where this is applied an arrow should be used to denote the peel back section. Such an approach allows, for example, critical warnings to be presented in the national language.

j. It is expected that originator products are formulated having a strength in the name relating to quantity of active moiety and not the quantity of salt. This will avoid translation issues regarding the statement of the salt, and will simplify the agreement of multilingual packages. Further guidance on the expression of the INN within the name of the product and current MS agreements is available in the QRD stylistic matters (see Section 5 below). Such an approach could be further communicated to HCP and patients in the SmPC or PL as necessary.

k. In the case of space constraints, such as on blisters, and where INN is already in the name, omission of the INN after the product name, strength and pharmaceutical form may be agreed. See QRD stylistic matters for further details. Such an approach could be further communicated to healthcare professionals and patients in the SmPC or PL as necessary.

l. The readability of the resulting package must not be significantly compromised when two or more languages are added to the package. For example, as per Commission Guideline on the Readability of labelling and leaflet of medicinal products for human use, the minimum font sizes should be respected. However, a minimum font size of 8 points can be accepted for the multilingual patient leaflet, if it is justified that this has been shown to be satisfactory in company user testing of the house style.

Package leaflet

m. It may be useful in the package leaflet, to provide an indication of which language is intended for which MS, in case of different blue box issues arising in particular member states.

n. Multiple PLs in a carton are not prohibited if necessary for technical reasons, however their use must be carefully implemented to ensure ease of identification and use for patients.

The above guidance will be elaborated as further experience is gained.

5. References

A list of references to relevant multilingual guidance published in MSs is included in the accompanying table: **Annex 1-Published guidance and list of national requirements.**

These links can be consulted for a general approach to national requirements for example, for mock-ups review and national exemptions allowed for "hospital-only vials".

The contact points as listed on the CMDh website or as outlined in national guidance can be used in case of further queries. Please quote MRP number in any case related requests.

The following references are also relevant to the preparation of multilingual packaging, as further noted in the examples in **Annex 2**

EDQM patient friendly terms

See EDQM Standard terms database

https://www.edqm.eu/en/standard-terms-database

QRD decisions on stylistic matters

Compilation of QRD decisions on stylistic matters in product information

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/compilation-quality-review-documents-stylistic-matters-product-information_en.pdf

Abbreviations for routes of administration:

QRD annotated template references list of agreed non-standard abbreviations
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/tables-non-standard-abbreviations-be-used-summary-product-characteristics_en.pdf

Expiry date and Lot number:

QRD Appendix IV provides further details of MS expectations regarding the display of Lot and Exp on the labelling of human medicinal products:

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/qrd-appendix-iv-terms-abbreviations-batch-number-expiry-date-be-used-labelling-human-medicinal_en.pdf

Ultrashort terms

A list of further pharmaceutical form abbreviations may be used in Nordic member states (DK, FI, IS, NO, SE) on national mockups as outlined in the reference below:

https://www.lakemedelsverket.se/492d3d/globalassets/dokument/tillstand-godkannande-och-kontroll/forsaljningstillstand/produktinformation/guideline-on-nordic-packages.pdf

Use of these ultrashort terms should follow the notice in the Questions & Answers-Medicinal products-Human and veterinary (labelling and package leaflet), available in
https://www.lakemedelsverket.se/492d2a/globalassets/dokument/tillstand-godkannande-och-kontroll/forsaljningstillstand/produktinformation/qna-nordic-packages.pdf

Annex 1: List of links to national guidance per MS

Published guidance on labelling

AT: https://www.basg.gv.at/fuer-unternehmen/zulassung-life-cycle/faq-zulassung-life-cycle/mock-ups

BE: https://www.famhp.be/sites/default/files/content/POST/MAH/163-en-labelling_of_medicinal_products.pdf

CZ: http://www.sukl.cz/leciva/reg-96-verze-1

DK: https://laegemiddelstyrelsen.dk/en/licensing/licensing-of-medicines/spcs,-package-leaflets-and-labelling/ *and*

Guideline on Nordic packages (including contact points):

https://lakemedelsverket.se/english/product/Medicinal-products/Applications-for-new-authorisations-variations-and-renewals/

EE: http://www.ravimiamet.ee/en/baltic-package-procedure-0 (Baltic packages)

ES: https://www.aemps.gob.es/industria-farmaceutica/etiquetado-y-prospecto

FI: https://www.lakemedelsverket.se/492d3d/globalassets/dokument/tillstand-godkannande-och-kontroll/forsaljningstillstand/produktinformation/guideline-on-nordic-packages.pdf
and

https://www.lakemedelsverket.se/492d2a/globalassets/dokument/tillstand-godkannande-och-kontroll/forsaljningstillstand/produktinformation/qna-nordic-packages.pdf

HR: http://www.halmed.hr/en/Lijekovi/Upute-za-podnositelje-zahtjeva/Nacrt-mock-up-pakiranja-lijeka/

HU: https://ogyei.gov.hu/kiseroirat_ertekeles

IE: HPRA Guide to labels and leaflets of Human Medicines (including section 5.3 on multi-lingual packaging https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/aut-g0034-guide-to-labels-and-leaflets-of-human-medicines-v21.pdf?sfvrsn=60

IS: https://www.ima.is/licences/marketing_authorisations/labelling_national_requirements/

LT: http://www.ravimiamet.ee/en/baltic-package-procedure-0

LV: http://www.ravimiamet.ee/en/baltic-package-procedure-0

MT: http://www.medicinesauthority.gov.mt/registration

NL: MEB policy document on labelling of pharmaceutical products: https://english.cbg-meb.nl/topics/mah-policy-documents/documents/policy-documents/2021/01/01/meb-6-labelling-of-pharmaceutical-products

NO: Norwegian guideline: https://legemiddelverket.no/Documents/Godkjenning/Godkjenning%20av%20legemidler/Maler%20og%20veiledninger%20for%20produktinformasjon/Guideline_packaging%20Norway_v%201.4_19.2.2021.pdf *and*

Common Nordic Guideline

https://www.lakemedelsverket.se/492d2a/globalassets/dokument/tillstand-godkannande-och-kontroll/forsaljningstillstand/produktinformation/qna-nordic-packages.pdf

PL: http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU20150001109/O/D20151109.pdf

RO: https://www.anm.ro/medicamente-de-uz-uman/legislatie/legi-ordonante-si-hotarari-de-guvern/ *and*

http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU20180001626/O/D20181626.pdf *and*

http://www.urpl.gov.pl/sites/default/files/Komunikaty/Druki/1.%20Komunikat%20w%20sprawie%20zalece%C5%84%20dotycz%C4%85cych%20projekt%C3%B3w%20graficznych%20oznakowa%C5%84%20opakowa%C5%84.pdf

SE: Swedish guideline:
https://www.lakemedelsverket.se/48f3f5/globalassets/dokument/lagar-och-regler/vagledningar/vagledning-lvfs-2005-11-engelsk.pdf
Guideline on Nordic packages:
https://www.lakemedelsverket.se/492d3d/globalassets/dokument/tillstand-godkannande-och-kontroll/forsaljningstillstand/produktinformation/guideline-on-nordic-packages.pdf
Q&A Nordic packages:
https://www.lakemedelsverket.se/492d2a/globalassets/dokument/tillstand-godkannande-och-kontroll/forsaljningstillstand/produktinformation/qna-nordic-packages.pdf

SK: https://www.sukl.sk/buxus/docs/Registracie/Pokyny/MP_140-2021_Metodicky_pokyn_na_predkladanie_navrhu_obalu_lieku_-_mock-up.pdf

Annex 2: Practical guidance

Approaches to preparing harmonised text in case of a multilingual packaging

The following is a range of options which may be considered by applicants, in the preparation of harmonised templates where a multilingual packaging is likely. They may be proposed in the EU harmonised full or reduced templates (for both outer and immediate package) prior to EOP, for the agreement of MSs. It should be noted however that the complexity of the product may have a bearing on the likelihood of a successful multilingual package.

Examples of reductions in text

The following are examples used in existing multilingual packages, which could be considered by the applicant in the preparation of the harmonised text (full or reduced template), to avoid proposing inessential information. The information remaining must however allow safe use of the product. These examples are illustrative only, the RMS decision will take precedence.

Labelling - outer:

Referring to sections in the QRD template

1. NAME:

[PRODUCT NAME] 90 mg film-coated tablets

Active substance

2. ACTIVE SUBSTANCES:

Each ~~film-coated~~ tablet contains 90 mg xxx.

3. EXCIPIENTS:

Contains lactose

If more excipients, then **do not use** ‘and‘ but rather use a comma between the substances

Do not write ‘See package leaflet for further information‘. This is already a standard sentence referring the patient to the leaflet ‘Read the package leaflet before use‘ (section 5 of the QRD labelling document).

The E number alone may be used for an excipient on the labelling, provided that the full name and the E number are stated in the package leaflet.

Excipients in the Excipient guideline e.g. sodium, need not be stated if their quantity is below the threshold of the guideline (unless injectable/topical/eye preparation as all excipients need to be listed for such)

“Contains lactose” could be used instead of “Contains lactose monohydrate” to omit all unnecessary information on the labelling.

4. FORM AND CONTENT:

30 ~~film-coated~~ tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION:

Read the package leaflet before use.

The route of administration could be omitted where it is explicitly included in the pharmaceutical form in the product name, for example:

~~Oral use~~ (omitted for tablets and capsules) and e.g. ~~nasal use~~ (omitted for nasal sprays). However the route is required for parenteral products

Use the correct Standard Terms name, e.g. 'Intravenous use' (not e.g. 'For intravenous use').

Important information e.g. 'Do not swallow' etc. should be stated, however it is noted that the package leaflet contains further information.

6. SPECIAL WARNING ETC.:

Do not use the sentence 'Any unused medicinal product or waste material should be disposed of in accordance with local requirements' unless this is stated in section 6.6 and fulfils the criteria in the annotated QRD template, e.g. cytostatic products.

7. OTHER SPECIAL WARNINGS(S), IF NECESSARY:

Only necessary warning to be stated here. Other warnings may be in the package leaflet.

Important information would be e.g.: 'Cytotoxic: Handle with caution' or 'May cause birth defects'.

8. EXPIRY DATE

Proposed to use 'EXP' as it is acceptable for most member states. QRD Appendix IV provides further details of MS expectations regarding the printing of Lot and Exp on the labelling of human medicinal products (see Section 5)

9. SPECIAL STORAGE CONDITIONS

Annex to the QRD template to be followed, e.g. 'Store in a refrigerator' but not 'Store in a refrigerator (2°C – 8°C)'

10. SPECIAL PRECAUTIONS

Only precautions stated in section 6.6 or 12, e.g. cytostatics, radiopharmaceuticals

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

To be filled out, the applicant should consider whether the address can be reduced while still remaining a valid contact point

12. MARKETING AUTHORISATION NUMBER

To be filled out

13. BATCH NUMBER

Proposed to use 'Lot' as it is acceptable for most member states. Refer to QRD Appendix IV.

14. GENERAL CLASSIFICATION FOR SUPPLY

Do not fill in prescription status here (keep the section empty or add 'to be filled in nationally'). It is part of the Blue-Box and may be on carton.

15. INSTRUCTIONS FOR USE

Only for OTC text

16. BRAILLE

Name of the product, and strength if several in range.

Do not state pharmaceutical form unless it is necessary

'Justification for not including Braille accepted' could be included when relevant.

17. Add standard statement to template as per QRD, however 2D barcode will be only printed on carton for products where required by legislation

18. Add standard statements to template as per QRD however PC: SN:,NN will be printed on carton for products where required by legislation

Labelling – small immediate packaging

Referring to sections in the QRD template

1. NAME :

[PRODUCT NAME] 90 mg ~~film-coated~~ tablets

or

[PRODUCT NAME] 5 mg/ml ~~solution for injection or for infusion~~ injection/infusion

Patient friendly term may be used here, e.g. tablets, capsules , injection/infusion (if included in SmPC).

{active substance(s)}

If INN as used in the name (INN+MAH format) and the following active substance would be the same, delete active substance.

In the case of multi-pocket blisters the product name and/or strength and/or pharmaceutical form and/or INN/active substance could alternate in the language of different member states.

2. METHOD OF ADMINISTRATION

Important information e.g. 'Do not swallow' etc. should be stated. The package leaflet contains further information.

3. EXPIRY DATE

Proposed to use 'EXP ' as it is acceptable for most member states. Refer to QRD Appendix IV as above.

4. BATCH NUMBER

Proposed to use 'Lot' as it is acceptable for most member states Refer to QRD Appendix IV as above.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

To be filled in

6. OTHER

Annex 3

Flow chart – new applications - Pilot

The following is a flow chart to illustrate the process for a new DCP procedure for the preparation of EU reduced harmonized text which may be used by all the MLP clusters

Applicant indicates request for MLP cluster and participation in pilot in cover letter and proposes a reduced text for MLP during initial submission (*dark grey shading italics* of full text). A common EU full and reduced harmonised text is to be prepared by the applicant, i.e. one document, no separate "reduced harmonised text" document should be prepared.

⇩

RMS reviews full and reduced labelling texts and provides comments in D70 AR (or at D120)

⇩

CMS involved in MLP clusters provide comments on reduced text proposal and feedback on any RMS queries raised at D100 (or D145), focusing on issues of safety

⇩

Applicants can provide mock-ups for MLP as part of D106 responses that account for RMS and CMS comments on EU full and reduced harmonised text

⇩

The RMS can request a MLP breakout session in clockstop (or D195) in exceptional cases if issues remain

⇩

EU full and reduced harmonised text is agreed by EOP

⇩

Applicant provides mockups where required in accordance with national requirements to involved MSs, based on the agreed EU full or reduced (for MLP cluster) harmonized text, either during national phase or register prior to marketing according to national requirements