June 2024
CMDh/413/2019/Rev. 5

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. While the primary focus of this guide is on MR (Mutual recognition)/DC (Decentralised) procedure products, many of the recommendations are useful in preparing joint packs for purely national products. Currently, there are successful initiatives in place to facilitate multilingual packages e.g., the Nordic, Baltic or BE procedures (see Annex 1). 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.

Additional ongoing initiatives, for example electronic package leaflet (ePIL) projects, are also complementary to multilingual packaging to ensure availability of medicines. Information on these initiatives is available on national websites.

In order to further facilitate multilingual packaging with the aim of improving the availability of medicines in MSs, CMDh encourages applicants 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 approach are outlined in Section 3.2 below. This approach applies to labelling text only; package leaflets are not included.

2. Scope

This guidance covers the preparation of multilingual packages for MR/DC products. 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 MSs. It should be noted that the guidance may not be applicable in all aspects for all MSs, 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 multilingual packaging should be considered at the beginning of an application for a marketing authorisation, in order to achieve a multilingual packaging in a timely and efficient manner. In situations where 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 MR/DC submission and throughout the EU assessment phase. The EU harmonised text is assessed and agreed during the EU assessment phase of the application procedure.

The applicant should aim to resolve potential barriers to achieving 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 or 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 a multilingual packaging.

The applicant should highlight in the cover letter for MR/DC applications, whether they intend to prepare 'EU full/reduced harmonised labelling text' (see Section 3.2 below). The applicant should also highlight that they propose to apply a multilingual packaging and list the MSs involved in the cluster. A cluster is considered to be the group of MSs which will share a mock-up (a multilingual packaging). This information on proposed clusters will facilitate communication between clustered MSs, preferably by e-mail, but also for example by focused *telecom* calls to aid finalisation of a shared product name or reduced harmonised labelling text proposal 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 (see sections 3.2.2 - 3.2.6 for further possibilities) 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. Preparation of EU reduced harmonised labelling text

The applicant may agree an EU reduced harmonised labelling text **during an MR/DC procedure** if the preparation of a multilingual packaging in future is foreseen. Although alternative approaches to agreeing a multilingual package are possible, the preparation of EU reduced harmonised text during the procedure is recommended in order to better facilitate agreement of such packages. The approach is currently limited to applications for prescription-only products.

The process is described further below (please see also the flow chart in Annex 3).

3.2.1. New Marketing Authorisation (MA) applications

EU phase

When a new MA application is submitted, the applicant should clearly state in the cover letter their intention to agree 'EU full/reduced harmonised labelling text' during the procedure and indicate the MSs involved in a cluster (see Templates of the cover letter 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 (example is provided in the Annex 3 below). 'Dark grey shaded italics' indicate that this text will be omitted from the final labelling for a multilingual packaging, thus creating the 'reduced' text;

   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.

   One set of reduced labelling text will be agreed, not a set per cluster.

b) Exceptionally with the agreement of the RMS, the applicant can submit the proposed 'EU full/reduced harmonised labelling text' and a completed cover letter later in the procedure within the **response documentation:**

   - at Day 106 or at Day 160 at the latest for DC procedure
   - at Day 40 at the latest for MR procedure

c) The applicant should ensure the *'EU full/reduced harmonised labelling text'* template supplied at each stage of the procedure includes a list of the proposed MS clusters for multilingual packaging in the heading, however this does not preclude the formation of further clusters based on the 'EU full/reduced harmonised labelling text' *(see Annex II for the example)*.

MR procedure

The **CMSs** involved in a cluster actively comment where *EU reduced harmonised labelling text* is proposed on Day 30 of the procedure. However, this does not preclude other interested CMSs from commenting as they may be involved in a future cluster using the reduced text, if the marketing plans of the marketing

authorisation holder (MAH) are changed. A MS involved in a cluster which cannot accept the reduced labelling text on their market following their scientific evaluation of the reduced text proposal, is advised to let both the applicant and RMS know, at their earliest opportunity before EoP, that the multilingual packaging for that MS can only be prepared with the full harmonised labelling text.

The RMS can comment and provide opinion on Day 48 or Day 68 of the procedure if it does not agree with the applicant's proposals or the CMSs' agreement/remarks on the reductions in the EU reduced harmonised labelling text.

At Day 60 or 90 for MRP (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 assessment is reflected, and it is clear for future procedures.

DC procedure

The **RMS**:

a) Assesses the 'EU full/reduced harmonised labelling text' proposal, focusing on safety issues (i.e., can the requested text be removed without significantly affecting the 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) Lets CMSs know that the 'EU full/reduced harmonised labelling text' has been proposed by stating this in Day 70 AR (or Day 120 AR or Day 180 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) RMS circulates the 'EU full/reduced harmonised labelling text' at Day 70 (or Day 120 or Day 180) for DCP for CMSs to comment along with the AR, the full PL and SmPC.

The **CMSs** involved in a cluster actively comment where *EU reduced harmonised labelling text* is proposed. However, this does not preclude other interested CMSs from commenting as they may be involved in a future cluster using the reduced text, if the marketing plans of the MAH are changed. A MS involved in a cluster which cannot accept the reduced labelling text on their market following their scientific evaluation of the reduced text proposal, is advised to let both the applicant and RMS know, at their earliest opportunity before EoP, that the multilingual packaging for that MS can only be prepared with the full harmonised labelling text.

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 assessment 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 MR or DC procedure, including both the full text and reduced text, where applicable, 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 60 or 90 for MRP or Day 210 for DCP (EoP) 'EU full/reduced harmonised labelling text'. The submission of the translations and mock-ups is done 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. This may include for example, approval only of the translation of the product information (full and reduced), review of mock-ups during the national phase, request to submit national Article 61.3 notification/national variation at time of launch, or no review required for mock-ups.

Recommendations

The following points should be taken into account during the 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 labelling text* is used where space permits on a multilingual packaging. However, in case of space constraints *EU reduced harmonised labelling text* may be used by the applicant.
- *EU reduced harmonised labelling text* is only applicable for a multilingual packaging. When a monolingual package is prepared, the agreed full harmonised labelling text must be used.
- **As 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 labelling text are then envisaged during mock-up preparation (after finalization of EU phase). 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.

3.2.2. Repeat-use procedures

During a Repeat Use Procedure, no changes to the previously agreed labelling text are possible (this could either be a full labelling text only or a 'EU full/reduced harmonised labelling text'). If the applicant would like to introduce or amend an 'EU reduced harmonised labelling text', a MR Article 61.3 notification should be submitted after finalization of the RUP.

3.2.3. Line extension procedures

An 'EU full/reduced harmonised labelling text' template can be created for a line extension where none exists for the original application. The applicant should proceed in line with requirements and recommendations mentioned in Section 3.2.1 per procedure – either for DCP or MRP. This request could only pertain to the line extension. If the MAH would like to introduce 'EU full/reduced harmonised labelling text' for the original applications as well, the MR Article 61.3 notification should be submitted.

3.2.4. Change to MS clusters where the 'EU reduced harmonised text' is already approved - communication to relevant MS

When agreed, the approved set of 'EU reduced harmonised labelling text' may be used to develop further multilingual packages with different MSs.

When changes are made to the **MSs in a particular cluster** (addition or deletion), or formation of a new cluster are proposed, this can be done in different ways:

- In those MSs that routinely review mock-ups, via appropriate national procedure e.g. Article 61.3 notification or variation (see also Section 3.4);
- In MSs that do not routinely review mock-ups, via a national notification (courtesy email);
- Via MR variation procedures affecting product information.

All MSs involved in the cluster (including those added, deleted or involved in a new cluster) should be clearly indicated e.g. in the cover letter/background section of the application form or in the courtesy e-mail, so MS can add this to their records as required, and to allow for communication as necessary between relevant MSs.

MAH should also update the clusters in the heading of '*EU full/reduced harmonised labelling text'* template (see Annex II for example) with first post-authorisation MR procedure affecting product information to reflect the latest clusters, for the awareness **of all MSs**. No separate application is required to update the information in the heading when new clusters are formed.

3.2.5. Existing (authorised) medicinal products and preparation of 'EU reduced harmonised labelling text'

A MAH may propose the preparation of an 'EU reduced harmonised labelling text' for existing products by submission of an MR Article 61.3 notification to the RMS and CMSs, indicating the proposed clusters in the cover letter, and describing the request to reduce text.

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

3.2.6. Change to the approved 'EU full/reduced harmonised labelling text'

An MR Article 61.3 notification is also required if the MAH proposes a modification/further reduction of the already agreed 'EU full/reduced harmonised labelling text' template, and therefore the RMS and all CMSs would need to be included. National translations are provided as described in Section 3.2.1.

3.3. Product names

Applicants and MSs are requested to discuss product names (especially proposed invented names) early in MR/DC submissions if a multilingual packaging is proposed, aiming to agree the name within the clock stop. 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. The existing national and EU published guidance on choosing names should be

consulted. The following recommendations which are particularly relevant to multilingual packaging should be considered:

- 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, thus this may require extra coordination by the MAH to agree the name early in the procedure;
- 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 inclusion of company styles such as B.V., D.A.C. in the name should be carefully considered as it may impact on the possibility for preparation of a multilingual pack where these differ between member states and may be superfluous;
- Minor linguistic revisions in the name of the MAH may be accepted in the product name on the label, with regard to special characters that are not used in other member states, and this may also avoid repetition e.g. the use of accents. In principle, however the name of the MAH within the product name should correspond to all or part of the official name of the MAH as presented in the proof of establishment of the applicant/MAH;
- The invented name of a medicinal product should not be comprised wholly of initial letters (acronyms) or code numbers nor include punctuation marks (e.g., hyphen);
- Applicants should avoid using qualifiers/abbreviations by letters as part of the invented name when preparing the multilingual packaging.

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 coordinate agreement of 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 approach to preparation of 'EU harmonised full/reduced labelling text' templates as outlined in Section 3.2, for MRP or DCP products or purely national products, according to agreed practice and procedures in MSs following the approaches outlined below.

The following procedural stages provide opportunities to expedite final agreement of multilingual mock-ups whether 'EU harmonised full/reduced labelling text' templates are prepared or not:

European phase of the procedure

Mock-ups for a multilingual packaging may be submitted during the new MA procedure or MR 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 labelling text is available. It is emphasized that the RMS is not responsible for assessing the multilingual mock-ups design, layout or space considerations on behalf of other MSs. 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/DC new applications/variations or separate national Article 61.3 notification or national variation at a later date.

Communication and coordination to expedite the national phase and agreement of mock-ups *MS:* 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.

In case of MSs 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 and indicate when the mock-ups are considered acceptable by them, 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 MSs if requested.

Applicant/MAH: To progress efficiently, where national phase mock-ups and/or separate national Article 61.3 notification/national variation 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 labelling 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.

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 MSs, 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 product 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 pharmaceutical form, or grouping information relating to the strength and pharmaceutical 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 the 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 EDQM 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 MLPs. 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 guidance on stylistic matters (see Section 5 below). Such an approach could be further communicated to healthcare professionals 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 allowed. See QRD guidance on 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.

m. The readability of multilingual labelling can be impaired due to space limitation on the packaging. To overcome these difficulties and to improve the readability of multilingual labelling, the use of INNs in English or Latin for active substances or excipients is allowed for some Members States as per table *Use of EN or Latin Translation of INNs in Product Information Annexes* in Compilation of QRD decisions on stylistic matters in product information.

Package leaflet

n. 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 state.

o. 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 MR/DC procedure 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

Compilation of Quality Review of Documents stylistic matters in product information (europa.eu)

Abbreviations for routes of administration

QRD annotated template references list of agreed non-standard abbreviations

Tables of non-standard abbreviations to be used in the summary of product characteristics (europa.eu)

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:

Appendix IV (europa.eu)

Ultrashort terms

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

https://www.lakemedelsverket.se/49323d/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/4930bd/globalassets/dokument/tillstand-godkannande-och-kontroll/forsaljningstillstand/produktinformation/qna-nordic-packages.pdf*

Product names

The general criteria which are applied by the MSs when reviewing the acceptability of proposed (invented) names are available on the competent authorities' national web sites, also under the section 4 of the document

https://www.ema.europa.eu/en/guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure

and

INNA - tool for evaluation of invented names for medicinal products developed by Estonian Agency

https://inna.ravimiamet.ee

Annex 1: List of links to published national guidance on labelling per MS

MS	Links to published national guidance	Notes
AT	https://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	
BG	https://www.bda.bg/images/stories/documents/regulations/naredbi/naredba38.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	
	https://www.lakemedelsverket.se/49323d/globalassets/dokument/tillstand-godkannande-och-kontroll/forsaljningstillstand/produktinformation/guideline-on-nordic-packages.pdf	Guideline on Nordic packages
EE	https://www.ravimiamet.ee/en/human-medicines/marketing-authorisation-and-fees/baltic-package-procedure	
ES	https://www.aemps.gob.es/industria-farmaceutica/etiquetado-y-prospecto	
FI	https://www.lakemedelsverket.se/49323d/globalassets/dokument/tillstand-godkannande-och-kontroll/forsaljningstillstand/produktinformation/guideline-on-nordic-packages.pdf	Guideline on Nordic packages
HR	https://www.halmed.hr/en/Lijekovi/Upute-za-podnositelje-zahtjeva/Nacrt-mock-up-pakiranja-lijeka/	
HU	https://ogyei.gov.hu/kiseroirat_ertekeles	
IE	https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/aut-g0034-guide-to-labels-and-leaflets-of-human-medicines-v23.pdf?sfvrsn=74	HPRA Guide to labels and leaflets of Human Medicines (including section 6.3 on multi- lingual packaging
IS	https://www.ima.is/licences/marketing-authorisations/labelling-mock-ups/	
LT	https://www.ravimiamet.ee/en/human-medicines/marketing-authorisation-and-fees/baltic-package-procedure	
LU	https://sante.public.lu/fr/espace-professionnel/domaines/pharmacies-et-medicaments/medicaments-humains/autorisation-mise-sur-le-marche.html	

LV	https://www.zva.gov.lv/en/industry/marketing-authorisation-holders/post-authorisation/multilingual-packaging	
MT	http://www.medicinesauthority.gov.mt/registration	
NL	https://english.cbg-meb.nl/topics/mah-labelling/documents/policy-documents/2023/01/01/meb-6-labelling-of-pharmaceutical-products	MEB policy document on labelling of pharmaceutical products
NO	https://www.dmp.no/globalassets/documents/godkjenning/godkjenning-av-legemidler/maler-og-veiledninger-for-produktinformasjon/merkingsveiledningen-versjon-2.3-12_2022-_01-24.pdf	Norwegian packaging guideline
	and	
	https://www.lakemedelsverket.se/49323d/globalassets/dokument/tillstand-godkannande-och-kontroll/forsaljningstillstand/produktinformation/guideline-on-nordic-packages.pdf	Guideline on Nordic packages
PL	https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20200001847	
RO	https://www.anm.ro/medicamente-de-uz-uman/legislatie/legi-ordonante-si-hotarari-de-guvern/	
SE	Guideline on Labelling, Package Leaflets and naming of Human Medicinal Products (lakemedelsverket.se)	Swedish guideline
	and	
	Guideline on nordic packages (lakemedelsverket.se)	Guideline on Nordic packages
	and	
	Guideline on Nordic packages - Questions & Answers (lakemedelsverket.se)	Q&A Nordic packages
SI	Navodilo za označevanje_V2.0_objava_julij_2023.pdf (jazmp.si)	
SK	https://www.sukl.sk/buxus/docs/rozhodnutia/MP_140-2021_Metodicky_pokyn_na_predkladanie_navrhu_obalu_lieku_-_moc....pdf	

Annex 2: Practical guidance

Approaches to preparing harmonised text in case of a multilingual packaging

The following is a range of options to omit redundant text and simplify text which may be considered by applicants, in the preparation of harmonised reduced templates. 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 reduced text 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):

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
OUTER CARTON – EU full/*reduced* harmonised labelling text

<MS clusters e.g. Cluster 1 (XX/YY/ZZ), Cluster 2 (AA/BB)>

1. NAME:

[PRODUCT NAME] 90 mg film-coated tablets

Active substance

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

2. ACTIVE SUBSTANCES:

Each *film coated* tablet contains 90 mg <active substance>.

The pharmaceutical form could be shortened to save space, for example unit of presentation or patient friendly term may be used here, e.g. tablets, capsules, injection/infusion.

3. EXCIPIENTS:

Contains lactose *monohydrate. See package leaflet for further information*

Where several excipients must be listed, they should appear in all national languages or alternatively one common language may be accepted - Latin or English (depends on the MS), or alternatively Latin and English may be accepted. *Where several excipients must be listed 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:

Film-coated tablet

The pharmaceutical form can be omitted if it is already mentioned in section 1 (Name).

30 *film coated* tablets

The pharmaceutical form could be shortened to save space, for example unit of presentation or patient friendly term may be used here, e.g. tablets, capsules, injection/infusion.

5. METHOD AND ROUTE(S) OF ADMINISTRATION:

Oral use. 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' (for tablets and capsules) or 'nasal use' (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.:

Keep out of the sight and reach of children.

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 MSs. Refer to QRD Appendix IV.

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

***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.*

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

12. MARKETING AUTHORISATION NUMBER

As per QRD template

13. BATCH NUMBER

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

14. GENERAL CLASSIFICATION FOR SUPPLY

As per QRD template

15. INSTRUCTIONS FOR USE

As per QRD template

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. & 18. UNIQUE IDENTIFIER – 2D BARCODE and HUMAN READABLE DATA

As per QRD template

Labelling - small immediate packaging (referring to sections in the QRD template):

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING
– EU full/*reduced* harmonised labelling text

<MS clusters e.g. Cluster 1 (XX/YY/ZZ), Cluster 2 (AA/BB)>

1. NAME AND ROUTE(S) OF ADMINISTRATION:

[PRODUCT NAME] 90 mg film coated tablets

or

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

Pharmaceutical form: patient friendly term may be used here, e.g. tablets, capsules, injection/infusion if included in SmPC.

Active substance

If INN used in the name (INN+MAH format) and the following active substance would be the same, the active substance may be deleted. *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 MSs.*

Route of administration

In case of space limitation abbreviation can be used for route of administration. Table of non-standard abbreviations provides further details on these abbreviations.

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 MSs. Refer to QRD Appendix IV.

4. BATCH NUMBER

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

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

As per QRD template.

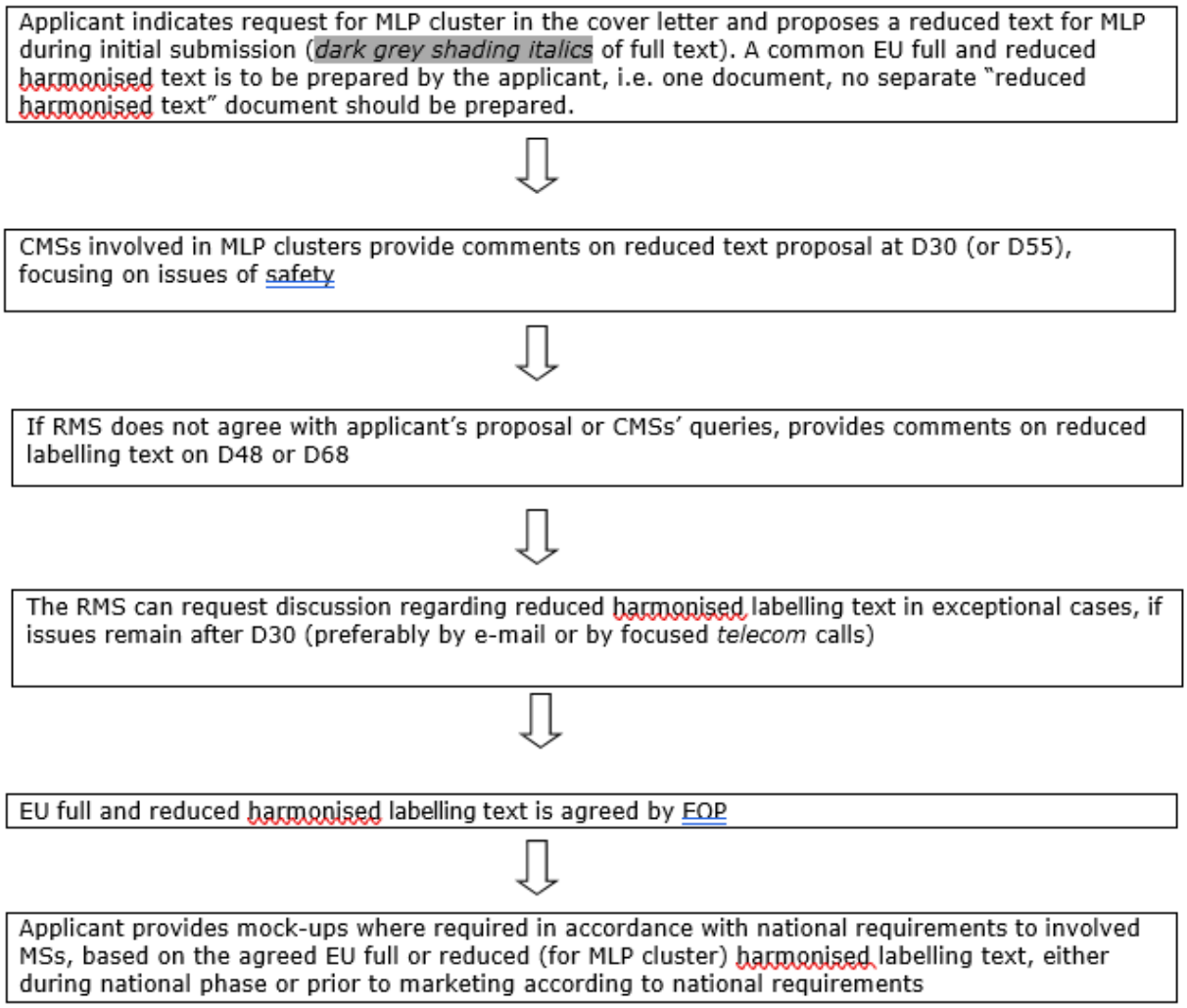
6. OTHER

As per QRD template.

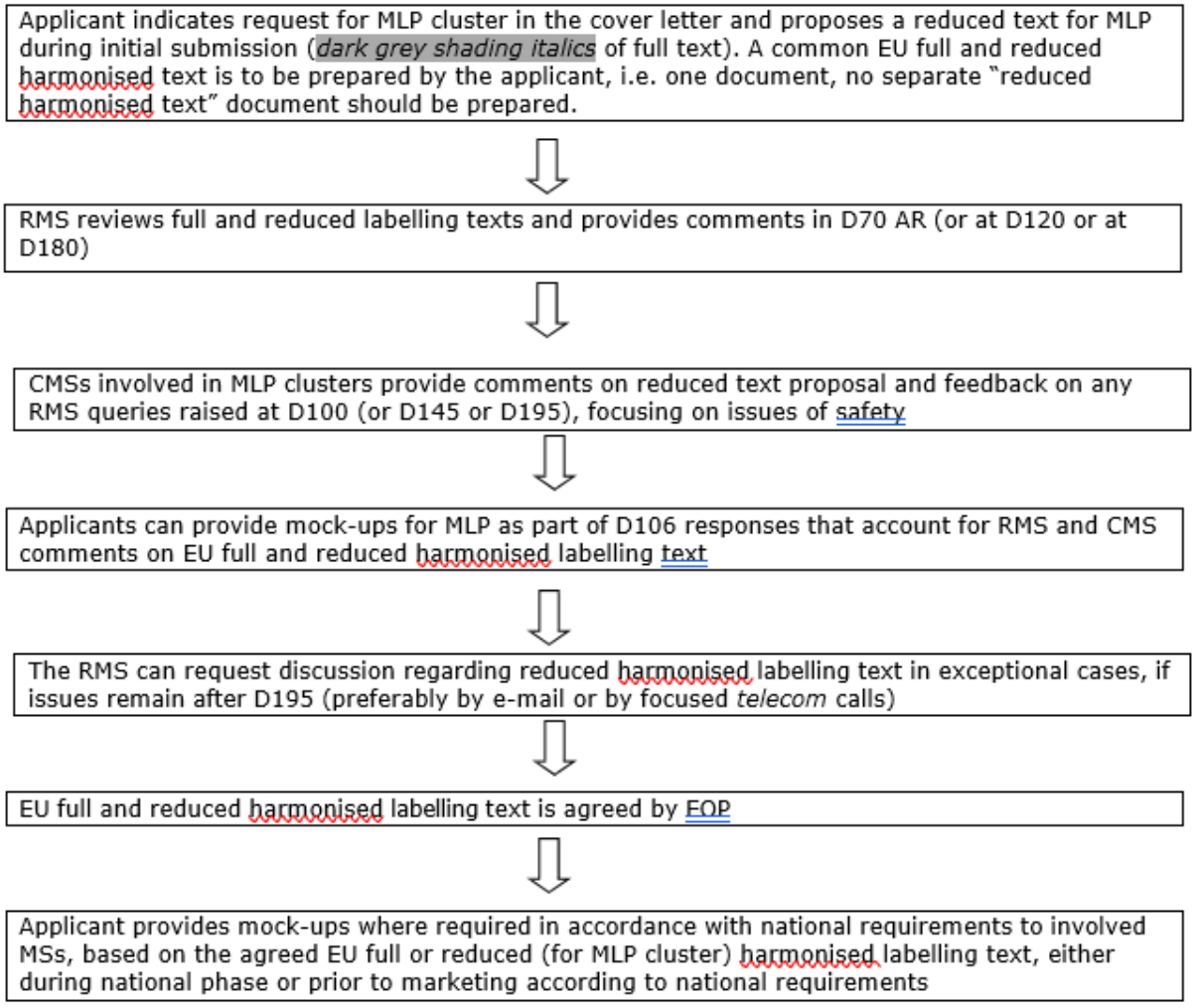
Annex 3: Flow chart – new applications (MRP and DCP)

The following is a flow chart to illustrate the process for a new MR and DC procedure for the preparation of EU reduced harmonised labelling text which may be used by all the MLP clusters.

MRP



DCP


Applicant indicates request for MLP cluster in the 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 or at D180)
CMSs involved in MLP clusters provide comments on reduced text proposal and feedback on any RMS queries raised at D100 (or D145 or D195), 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 labelling text
The RMS can request discussion regarding reduced harmonised labelling text in exceptional cases, if issues remain after D195 (preferably by e-mail or by focused *telecom* calls)
EU full and reduced harmonised labelling text is agreed by EOP
Applicant provides mock-ups where required in accordance with national requirements to involved MSs, based on the agreed EU full or reduced (for MLP cluster) harmonised labelling text, either during national phase or prior to marketing according to national requirements

Annex 4:

Example for requesting preparation of EU harmonised full/*reduced* harmonised labelling text templates

Note in the cover letter template for new applications/in template for Art 61.3 notification:

<'We intend to apply multilingual packaging and the following clusters will apply: <MS clusters e.g. Cluster 1 (XX/YY/ZZ), Cluster 2 (AA/BB)>'.>

<'We want to prepare 'EU harmonised full/reduced harmonised labelling text' as outlined in the BPG on multilingual packaging.'>

<'We intend to use EU full harmonised labelling text (no text reductions required) for a multilingual packaging.'>

Example of the proposed EU full and reduced (for clusters) harmonised labelling text

Illustrating the use of the dark grey italic shading to show what text does not appear on multilingual packs.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON - EU full/*reduced* harmonised labelling text
(Cluster 1 (XX/YY/ZZ), Cluster 2 (AA/BB) etc)

1. NAME OF THE MEDICINAL PRODUCT

[Invented name] 2.5 mg film-coated tablets
[Invented name] 5 mg film-coated tablets
apixaban

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each *film-coated* tablet contains 2.5 mg apixaban.
Each *film-coated* tablet contains 5 mg apixaban.

3. LIST OF EXCIPIENTS

Contains lactose. *See package leaflet for further information.*

4. PHARMACEUTICAL FORM AND CONTENTS

10 film-coated tablets
14 *film-coated* tablets
20 *film-coated* tablets
28 *film-coated* tablets
30 *film-coated* tablets
56 *film-coated* tablets
60 *film-coated* tablets
90 *film-coated* tablets
100 *film-coated* tablets
120 *film-coated* tablets
168 *film-coated* tablets
200 *film-coated* tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

Revision history

Rev.	Summary of changes made	Date
5	The main change to the updated BPG document is to reflect the success of the Multilingual Packaging pilot which took place 2020-2024. To improve the availability of medicinal products in the EU, especially in so called "small markets", the pilot facilitated the preparation of an 'EU full/reduced harmonised labelling text' during the EU procedural timelines to expedite the agreement of multilingual packs in the national phase of procedures. Due to the engagement with the pilot, it has now been agreed to move from a pilot basis to a standard process. Therefore, EU reduced harmonised labelling text can now be prepared on a voluntary basis within new DC/MR procedures, within line extensions, and using MR Art. 61.3 procedures. The cover letter template for new applications in MRP/DCP and the notification form for Art. 61.3 procedures are also updated to reflect this agreement.	June 2024