BEST PRACTICE GUIDE ON THE SUBMISSION OF HIGH QUALITY NATIONAL TRANSLATIONS

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1. Introduction and Scope

The *Best Practice Guide for Decentralised and Mutual Recognition Procedures* of the Co-ordination Group for Mutual Recognition and Decentralized Procedures (CMDh) states that the National Competent Authority (NCA) of each MS shall adopt, for new applications, extensions and renewals, a national decision 30 days after the RMS closes the procedure, subject to submission of acceptable translations. The *CMDh Best Practice Guide for the submission and processing of variations in the mutual recognition procedure*, states that for type IA and IB variations that affect the SmPC and/or labelling or package leaflet, both the English texts and the national translations should be submitted at the start of the procedure, for type II variations and, if applicable, the MAH should send the national translations within seven days of the procedure ending.

The Applicant must submit high quality national translations of the SmPC, PL and labelling and mock-ups, in accordance with the timelines described in the Best Practice Guides mentioned above. MSs may only introduce linguistic changes to the SmPC, PL and labelling and must ensure their national version of the product information is a faithful translation of the final harmonised position (this guidance document does not cover the blue box requirements for each MS).

The Applicant should also be aware that translating does not equal a word-to-word translation from one language to another. It is therefore of crucial importance, that the translation is made by a person who has professional knowledge of the field and whose mother tongue should preferably be the target language (avoiding the use of machine translations).

This document aims to improve the quality of translations of the agreed product information submitted during the national implementation phase of the procedures. It provides information about criteria defined to ensure the high quality, clarity, consistency and coherence of the SmPC, PL and Labelling translations.

This document also intends to ensure and facilitate the compliance with the timelines by all parties involved to comply with the established legal timeframe for the national phase and to avoid delay in the market access of the medicinal products.

This guidance must be read together with the

- CMDh Best Practice Guide for the Decentralised and the Mutual Recognition Procedure,
- CMDh Best Practice Guide for the submission and processing of variations in the mutual recognition procedure,
- EC Guideline on the Readability of the labelling and Package Leaflet of Medicinal Products for Human use, Revision 1, 12 January 2009
- National guidance on language specific conditions

2. Criteria taken into account for the linguistic review of the Product Information

In accordance with the guidance established in the *CMDh Best Practice Guide for Decentralised and Mutual Recognition Procedures and CMDh Best Practice Guide for the submission and processing of variations in the mutual recognition procedure*, the Applicant must submit high quality translations of the final agreed versions of the product information.

To guarantee the quality of the product information translation, the Applicant should check all crucial issues ensuring their compliance, namely a complete national translation with **clear wording** and taking into account the **target group**. Specific attention should be given to spelling, punctuation and other grammatical aspects taking also into account the extent of editorial and stylistic changes, particularly with the rephrasing of the texts ensuring that the meaning of the information is clear and comprehensible and in agreement with the final harmonised product information.

A correct patient friendly translation of the user tested PL is just as important as a high quality medically correct translation of the SmPC. This will often not be achieved by a literal translation of the English text.

The proposed Product Information should take into account the following points:

a) Compliance of the translation with the final agreed English product information;
b) Use of QRD template, country specific national language version;
c) Compliance with specific national requirements regarding specific style sheet of the texts of the texts;
d) Use of the appropriate scientific terminology;
e) Consistency of terminology with other medicinal products (innovator, generic or class-similar medicinal products) already approved by the NCA;
f) User-friendly terms (for PL).
g) National Blue Box requirements.

a) Compliance of the translation with the final agreed product information

The Applicant must ensure a faithful translation of the final agreed product information approved at the end of the European phase of the procedure, avoiding omissions and/or addition of sentences, terms or paragraphs. This is in particularly important when the translation is updated concurrently with the assessment done during the procedure.

All manufacturer(s) responsible for batch release that are listed in the final English PL should be included in the national translation (regarding the requirements for the printed package leaflet see **http://www.hma.eu/126.html.**

b) Use of QRD template, country specific national language version

The submitted translations must ensure that the latest approved QRD template version (as completed by the RMS) and its appendixes are used. Therefore, the Applicant should not use different titles, subtitles and sentences from those stated on current QRD template and its appendixes.

The current QRD template is available at:
http://www.hma.eu/126.html
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&mid=WC0b01ac0580022c59&jsenabled=true

c) Compliance with specific national requirements regarding specific style sheet of the texts

The Applicant must ensure that the national requirements are met for specific style sheet of the texts (type and font size, paragraphs, tabs, header and footer, etc.) of the product information. Specific information on this should be checked in the national websites. If not stated otherwise, the requirements of the Readability Guideline should be followed: http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf
No changes to the wording of the agreed product information are allowed.

d) Use of the appropriate scientific terminology

The scientific terms used in the translation of the product information should be carefully checked. Therefore, the Applicant should use appropriate scientific terminology and take into account that if a standard statement is used in the English text, a standard translation should be used, namely:

1) In all sections where reference is made to the pharmaceutical form, the standard term according to the EDQM should be used (current version of the *Standard Terms* – European Pharmacopoeia)*;*
2) The information in the SmPC, Section 4.6 'Fertility, pregnancy and lactation' should comply with "Statement for use in Section 4.6 'Pregnancy and lactation' of SmPC" (available in Appendix I of the QRD template)
3) The information in the SmPC, Section 4.8 "Undesirable effects" should comply with the MedDRA terminology (available in Appendix II of the QRD template);
4) The information in the SmPC, Section 6.4 "Special precautions for storage" should comply with the Storage condition statements (available in Appendix III of the QRD template);
5) The information regarding Batch number and Expiry date should comply with Appendix IV of the QRD template

6) With regard to the active substances and excipients, their naming should always be that used for national designation according to the [National] Pharmacopoeia or other relevant standard published by NCA, where applicable;
7) The warning statements relating to the presence of certain excipients in medicinal products should comply with the country specific national language version of the Guideline "Excipients in the label and package leaflet of medicinal products for human use.
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000254.jsp&mid=WC0b01ac058008c34c&jsenabled=true
8) In all sections where reference is made to the routes of administration and primary packages, the standard terms in accordance with the EDQM should be used (current version of the *Standard Terms* – European Pharmacopoeia);
9) The applicant must ensure that country specific guidance regarding Braille implementation is taken into account.

e) Consistency of terminology with other medicinal products (innovator, generic or class-similar medicinal products) already approved

The Applicant should take into account the terminology already approved by the NCA for the reference medicinal product or a medicinal product with the same active substance or from the same therapeutic class. National translations of the PhVWP recommendation or the texts agreed for Art. 45/46 Paediatric worksharing published on the NCA website should be used for translations, if available.

Additionally, it should be noted that for generic applications to Centrally Authorised Products the applicant should preferably use the national wording from the centrally approved product in all relevant sections of the SmPC and PL.
Furthermore, generics implementing the wording of an article 30 Commission Decision for the innovator product should comply with the national translation published in the Community Register:
http://ec.europa.eu/health/documents/community-register/html/refh_others.htm

Where the existence of usage patent(s) leads to differences in the product information compared to the reference medicinal product, this should be indicated accordingly when submitting the national translations.

f) User-friendly terms (for PL)

It is recommended that the package leaflet should be written in a language understandable by the patient and should reflect the terminology the patient is likely to be familiar with.
Additionally, it should be kept in mind that the PL is user tested and the Applicant should ensure that the terminology used in the national translations of the user tested PL is user-friendly and appropriate to the target patient groups.

g) National Blue Box requirements

The Applicant must ensure that all national blue box requirements are taken into account.

3. Process of reviewing the translations

The Applicant must submit, to all MS involved in the procedure, high quality national translations of the SmPC, PL and Labelling and mock-ups, if necessary, according to the *CMDh Best Practice Guide for the Decentralised and the Mutual Recognition Procedure* and the *CMDh Best Practice Guide for the submission and processing of variations in the mutual recognition procedure*. Final English texts circulated by the RMS and not the texts from the earlier phases of the procedure must be used for the national translations.

Marketing Authorisation Applicants or Marketing Authorisation Holders are advised to take into account the criteria defined above in Section 2. Any deviation to the principles identified should be avoided.
When planning a multilingual package, Applicants should carefully consider the translation, particularly concerning labelling and PL, taking into account the need to harmonise the relevant translations for a multilingual package.

The NCA should review the received national translations and grant national marketing authorisation within 30 days after the receipt, if no inaccuracies are found.

In case the quality of the national translations is not acceptable, the NCA will inform the Applicant of the identified deficiencies and request the Applicant to address these and resubmit updated national translations. No tracked change version by the NCA will be prepared in this case.

Alternatively, the NCA will review the translations submitted and notify the Applicant of necessary corrections in a tracked-change version.
The Applicant should accept the tracked changes or justify the non-acceptance, and submit to the NCA the final versions of the product information. Within this reviewing process, the Applicants should meet their deadlines for the agreement on the product information in accordance with each NCA guidance.

The legal timeframe for the finalisation of the procedure in the national phase is suspended whenever a request for resubmission of the product information is made and whenever the Applicant is requested to address the inaccuracies found.

4. Multiple applications

Specific national guidance on finalisation of multiple applications should be followed. Some MS advice the Applicant to provide a single contact for the simultaneous submission of the product information translations and of all relevent documentation to the finalisation of multiple applications, in order to streamline the revision of the texts as well as the granting of the MA. The granting of a duplicate MA, in this case, should occur simultaneously in order to make all the resources involved more efficient and ensure equity on MA granting for every duplicate applications.