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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 countries should be included in the main text.

The establishment of multilingual packaging is an important mechanism for maintaining products in EU markets, particularly smaller markets. This document serves to assist applicants in creating multilingual packages. There are successful initiatives already in place to facilitate multilingual packages e.g. the Nordic, Baltic or BE procedures (see Annex 1 below), therefore the following guidance is proposed where these procedures are not appropriate for the countries involved in developing the multilingual package.

In the May 2019 CMDh plenary, during the joint industry/member states discussion, the willingness of member states to facilitate multilingual packaging, which is seen as helpful to maintain availability of medicines, for example in the context of Brexit, was highlighted. Industry were requested to share their experiences of developing and using multilingual labelling, for consideration when developing guidance in this area. This guidance has therefore been prepared incorporating the recommendations from industry and member states, for use as an information resource to applicants.

2. Scope

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

3. Requesting multilingual labelling- procedural aspects

The following points relate to the approach applicants should take in requesting multilingual packages:

The need for multilingual packaging should be considered at the beginning of an application for a product authorisation, in order to achieve multilingual packaging in a timely and efficient manner. Applicants must inform the MS's involved in the future multilingual packaging at the earliest stage possible in the MR/DCP or national procedure (for example in the cover letter), of their intention to propose multilingual packaging for their market, and of who the other proposed MS on their packaging would be. It should be noted that some MS do not routinely assess mockups but still permit multilingual packaging for their market, therefore those MS should be informed for information only as they will not participate in the discussion of mockups. The applicant should carefully consider national and stylistic requirements as stated in published guidance (Annex 1) in establishing such groupings.

In situations where multilingual packaging would be advantageous, the level of detail proposed in the harmonised text should be carefully considered by the applicant in preparing their MR/DCP submission and throughout the EU assessment phase, to resolve potential barriers to achieving multilingual packages, while retaining information required by current QRD guidelines and Directive 2001/83/EC. 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. The EU harmonised text is assessed and agreed during the EU assessment phase of the application procedure, before the mock-up review process and does not change during mock-up review. 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.

After the end of the European phase of the procedure (EOP), multilingual packaging mock-ups, using the final translated texts for the involved MS, are assessed 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 a separate national Article 61.3 notification at a later date. Where national phase mockups or separate Art 61.3 notifications are submitted to the proposed MS for multilingual packages, the applicant needs to keep the involved MS informed, submit the mockups in a similar timeframe and co-ordinate the contemporaneous review by MS of the mockups. MS should indicate when the mock-ups are considered acceptable, in order for the review to be concluded and so other MS can nationally issue the case.

4. Key principles

Multilingual packaging is possible for products authorised through the MRP, DCP 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
1. The following must be taken into consideration to ensure that the proposed mock-ups are in an acceptable format:
 - a. The approved harmonised text must be adhered to.
 - b. As multiple member states are likely to be involved in the assessment of the mock-ups, the applicant must coordinate comments from different MS and address queries in a timely manner and work with MS to resolve any issues arising.

2. The applicant should consider how translations will be handled in a timely manner.
3. Additional stylistic recommendations to be taken into consideration for multilingual packaging:
 - a. Information in each language should be blocked together where possible.
 - b. Where a number of countries share a common pack, 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.
 - c. It may be useful in the package leaflet, to provide an indication of which language is intended for which country, in case of different blue box issues arising in particular member states.
 - 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. The readability of the resulting package must not be significantly compromised when two or more languages are added to the pack. 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.
 - f. Space constraints e.g. whether it is possible to include the translations of days in calendar packs for the involved MS should be carefully considered.

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

5. References

A list of references to relevant multilingual guidance published in MS is included in Annex 1. The contact point as listed on the CMDh website can be used (specific contact point for multilingual labelling may be applicable). Please quote MRP number in any case related requests.

Annex 1

Member state and contact point	Published guidance
BE	Belgian packages: https://www.famhp.be/sites/default/files/content/POST/MAH/155-en-exemptions.pdf
DK/FI/IS/ NO/SE	Guideline on Nordic packages (including contact points): https://www.lakemedelsverket.se/globalassets/dokument/forsaljningstillstand/produktinformation/guideline-on-nordic-packages.pdf Q&A Nordic packages: https://www.lakemedelsverket.se/globalassets/dokument/forsaljningstillstand/produktinformation/gna-nordic-packages.pdf
EE/LV/LT	Baltic packages: http://www.ravimiamet.ee/en/baltic-package-procedure-0
IE	HPRA Guide to labels and leaflets of Human Medicines (including section 5.3 on multi-lingual

Member state and contact point	Published guidance
info@hpra.ie	packaging) https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/aut-q0034-guide-to-labels-and-leaflets-of-human-medicines-v19.pdf?sfvrsn=48
NL	MEB policy document on labelling of pharmaceutical products: https://english.cbg-meb.nl/topics/mah-policy-documents/documents/policy-documents/2019/01/01/meb-6-labelling-of-pharmaceutical-products