Luxembourg – Multilingual/multi-country packaging

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1. Introduction

This page provides information on LU requirements for multilingual/multi-country packaging and links on where to find further information.

Multilingual/multi-country packs are medicinal products that are labelled to allow their placing on the market in several Member States with the same packaging. This aim is to improve the availability of medicinal products in Luxembourg.

Multilingual/multi-country packaging can be used for medicinal products authorized through the MRP, DCP and national-only procedures. In Luxembourg is it required that at least one of the three official languages is on the product information (French, German **or** Luxembourgish), which mean that companies can market medicines in Luxembourg without adding a new language on the packaging (multi-country packaging e.g. BE/LU, BENELUX, DE/LU, etc.).

Note: This guidance does not apply to CP medicinal products, as Luxembourg does not require any additional labelling information (EU MA number is sufficient).

Please also consult the CMDh Best Practice Guide on Multilingual Packaging.

2. Guidance

2.1. A multilingual/multi-country package must fulfil the following criteria:

- The name and the strength of the medicinal product is the same.
- The product information is exactly the same in all MS
- The information that appears on the labelling and the package leaflet is consistent with the information in the SmPC (Summary of Product Characteristics).
- The readability must not be compromised.
- The legal status (POM/OTC) must be the same in all countries involved.
- The additional labelling information ("blue box") is fulfilled.

2.2. Applying for multilingual/multi-country packs

Applicants/MAH can request multilingual/multi-country packaging during a new application procedure, or post authorisation via an editorial change during a variation affecting the product information or via an Article 61(3) notification or a type IA variation C.I.z. depending on the MAH assessment and the following recommendations.

During a new application procedure, applicants should:

- Identify the member states where multilingual/multi-country packs will be required early in the procedure.
- If applicable, provide sufficient justification for any label flexibility.
- Coordinate assessments across member states and share their comments so that assessments can be concluded in a similar timeframe.

For post authorisation, MAH should:

- Identify the member states where multilingual/multi-country packs will be implemented.

- If applicable, provide sufficient justification for any label flexibility.
- Coordinate assessments across member states and share their comments.

2.3. Agreement of mock-ups

Mock-ups for a multilingual/multi-country packaging may be submitted during the new MA procedure (as part of the national phase) or Article 61.3 procedure for layout and design review, for comment by MSs.

LU do not routinely assess mock-ups, but other MS could routinely assess them, such as Belgium. This may impact the process of application for multilingual/multi-country packs.

2.4. LU product information requirement

Luxembourg does not have national requirement other that what is specified in the QRD template, i.e.:

- The marketing authorisation (MA) number and/or national number(s) (NN) according to the QRD template below.
- The paragraph on the reporting of adverse reactions, according to the latest version of the reporting ADR details. Please consult the appendix V of the QRD template on EMA website.

QRD template - Luxembourg

Following some requests, a lighter version has been agreed. The addition of the national number is optional and therefore does not need to be removed in already approved product information which contain the NN. The same is true if the national number is present on the labelling.

Bracketing convention:
- {text}: Information to be filled in
- *: Information can be replaced by "X" if the applicant/MAH does not have the LU specific information yet and replace before printing by the LU number.

Version	Product information	LU specifics
V3	SmPC	**4.8 Undesirable effects** […] **Reporting of suspected adverse reactions** {See QRD Template Appendix V} […] **8. MARKETING AUTHORISATION NUMBER(S)** {LU: MA number (10 digits)*}
V3	Labelling	**12. MARKETING AUTHORISATION NUMBER(S)** {LU: MA number (10 digits)*}

Flexibility

For All packaging:

- Sections 9 and 10 of the SmPC and the respective section in the PIL could be identical as the other MS.
- Exemption for inner/small packaging are possible without applying for a derogation in Luxembourg, as follows [1]:
    - When contained in an outer packaging conforming to the requirements of Article 10, **blister** must include at least the following particulars:
        - the name of the medicinal product,
        - the name of the marketing authorisation holder,
        - the expiry date,
        - the batch number.
    - **Small primary packaging** on which it is impossible to include the particulars provided for in Article 10 at least the following information must be mentioned:
        - the name of the medicinal product,
        - the method of administration,
        - the expiry date,
        - the manufacturing batch number,
        - the contents by weight, volume or units.
    - Exemption upon request
- As the MA number(s) and national number(s) will be provided by the DPM after the national expert commission ("Commission d'experts"), the MAH can submit the PI without the exact number and replace it with "X", e.g. LUXXXXXXX.

Medicines not marketed in Luxembourg:

- For medicinal products not currently marketed in Luxembourg, the submission of a multilingual/multi-country packaging is not mandatory but recommended.

For BE-LU/BENELUX packaging:

- LU specific information may not be in the Dutch documentation as this is not a national language in Luxembourg.

2.5. Addition of LU number depending of the country with a shared pack

Belgium

The FAMHP and DPM permit the addition of LU requirement as editorial changes when a variation would be submitted with impact on the PI. This is the preferred type of submission.

The change can also be submitted separately as a variation of type IA C.I.z. Please see the Q&A for details on the possible submission types.

[1] Article 11 - Règlement grand-ducal du 15 décembre 1992 tel que modifié relatif à la mise sur le marché des médicaments

Other countries with no mock-up assessment (Other than BE)

Luxembourg accepts the addition of LU requirements to the Luxembourg PI:

- as an editorial change during of the national phase of a variation impacting the PI for MRP and DCP
- as a notification 61.3 for MRP/DCP products if only the MA numbers need to be added (and ADR reporting details are already present) for XX-LU packs
- As a notification 61.3 for NPs for XX-LU packs
- as a type IA C.I.z variation in case of MRP/DCP procedures and in case the ADR reporting details are affected. Please see the Q&A for details on the submission type.

MAH is responsible of the compilation of all PI approved by the others NCA and approved LU PI in the multilingual/multi-country packaging. No common PI will be assessed by Luxembourg or other NCAs.

3. Additional information and links

- CMDh Best Practice Guide on Multilingual Packaging
- CMDh Best Practice Guides Variations
- Directive 2001/83/EC, Article 63
- CMDh Q&A - List for the submission of variations for human medicinal products according to Commission Regulation (EC) 1234/2008 as amended
- Code de la Santé Luxembourg

4. Contact point

maa.hum@ms.etat.lu

5. Q&A

1) **The MAH has already implemented a common BE-LU pack with more information as requested in the current version of the guideline. Do they need to submit a new notification / variation to comply to the current guideline?**

   No, the present guideline details the minimum information to be present on the product information. If more details regarding MA number or the national number is present on the currently approved product information (NN in SmPC or on labelling - allowing a more detailed labelling of the different pack sizes, MA number on patient leaflet), no change need to be implemented.

2) **Is there a timeline when changes need to be implemented or submitted for products currently on the market without a common pack?**

   The presence of the LU specific information like MA numbers and ADR reporting details is a legal obligation and the implementation of changes to currently non-compliant product information need to be performed as soon as possible. There is no deadline until when the changes need to be implemented, but it is the responsibility of the MAH to plan the implementation all while not causing any shortages.

3) **Is there a preferred approach to submit the changes for a multilingual/multi-country pack?**

   The preferred approach is to include the addition of LU MA numbers and/or ADR details as an editorial change in variations that affect the product information, please also see question 3.16 of the CMDh Q&A List for the submission of variations for human medicinal products according to Commission Regulation (EC) 1234/2008 as amended (CMDh/132/2009).

4) **In which case can I submit the changes for a common pack as a 61(3) Notification?**

   The submission of a 61(3) notification for a common pack can be chosen in the following cases:
   - Purely national procedure with 1) a common pack XX-LU other than a BE-LU pack and 2) the mock-ups of a common pack are not assessed by the country of origin.
   - MRP/DCP procedure when 1) only missing LU MA numbers are added to a common pack 2) other than a BE-LU pack and 3) the mock-ups of a common pack are not assessed by the country of origin.

5) **In which case can I submit the changes for a common pack as type IA C.I.z variation (when the submission as editorial change is not possible)? When does the change needs to be submitted?**

   A type IA C.I.z variation always needs to be submitted w
   1) for a common BE-LU pack and

2) for MRP/DCP procedures in case both the LU MA numbers are added, and the the ADR reporting details are changed (by addition of the LU information).

The type IA C.I.z variation can be submitted

a. in the annual update for 1 specific MA for MRP/DCP and NPs
b. as a super-grouping for multiple MAs in MRP/DCP procedures but only if it concerns the same RMS for all MAs
c. as a super-grouping for multiple MAs in NP **and** MRP/DCP procedure but only for procedures with BE as RMS and LU as only CMS.

6) When mock-up is not assessed/submitted, should the MAH submit a common PI to both NCAs?

The PI should be sent only to LU with the LU requirement. Other NCA will not assess the LU information. The MAH is responsible of the compilation of both approved PI.

Summary Table:

		Notification 61(3)	**Editorial Change**	**Type IA C.I.Z Super-Grouping**	**Type IA C.I.Z Annual Update**
Mockup Review	NP	No	Yes	Yes for BE	Yes
	MRP/DCP	No	Yes	Yes if RMS=BE + CMS=LU	Yes
No Mockup review	NP	Yes	Yes*	No	Yes
	MRP/DCP	Yes (without ADR cahnge)	Yes*	Yes, if RMS is the same	Yes

*Submission only in LU as it's impacting only LU PI.