EXEMPTIONS: PROCEDURE TO BE FOLLOWED FOR MEDICINES FOR HUMAN USE

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Introduction

The packaging is the first thing that the person who is going to take or give the medicine will see. So it is important that all relevant information necessary for the correct use of the medicine, found on the packaging is clear and legible.

Each mock-up should be approved by the famph. This can be done at registration, renewal or with a variation that has impact on the packaging or through a notification (MRP: art.61.3 of the Directive 2001/83/EC and NP: art.34§4 of RD 14/12/2006.)

In view of the quantity of information that has to be present on the packaging and the legal obligation to put everything in the 3 national languages it is possible to ask for exemptions to the statutory information so that the legibility of the packaging can be improved and guaranteed.

Some specific deviations are also possible for SPC and PIL.

This document is not directly applicable to homeopathic medicinal products. These derogation requests are always assessed case-by-case. For the application of these derogations use may be made of the template and the proposed categorization.

The possible exemptions are divided into 4 categories in this document and are covered category by category. At the end the main information is summarised in a table.

Category 1. Deviations from the primary and secondary (harmonised) packaging for which an exemption does not need to be requested and which are accepted irrespective of the size of the packaging.

- Active substances and excipients: not required in the 3 national languages, as INN (English) or in Latin is sufficient. For herbal medicines this is only applicable for the excipients. For the active substances of these medicines see category 3.

- Route of administration: generally accepted abbreviations such as IV, IM, SC, are acceptable.

- Saline forms: generally accepted chemical abbreviations such as HCl are acceptable.

- If the route and method of administration are identical this only needs to be mentioned once on the packaging.

- If the pharmaceutical form appears at least once in full text on the secondary (primary) packaging this can be replaced by a pictogram elsewhere on the secondary (primary) packaging. The pictogram should be an exact copy of the pharmaceutical form (e.g. for a scored tablet: the scoring in the pictogram must be clearly visible).

- The note « Read the package leaflet before use » only has to be mentioned once on the packaging.

Category 2. Deviations from the primary and secondary (harmonised) packaging which need to be requested and which are acceptable provided the lack of space can be proven.

- If the name of the medicine consists of the INN/the active substance + the name of the MAH and the strength corresponds with the INN/active substance in the name, the active substance does not need to be repeated separately.

- If the name of the medicine consists of the INN/the active substance + the name of the MAH then, on the primary packaging, the MAH does not need to be repeated separately.

- The « Patient friendly (formerly short)Terms » of the pharmaceutical form shown in the EDQM is accepted. Linguistic abbreviations that are generally accepted can also be used provided the abbreviation is clear enough and cannot lead to confusion. E.g. ‘drinkbare oplossing’ becomes ‘drinkbare opl’. Or ‘solution buvable’ becomes ‘sol buvable’.

- Other possible abbreviations such as those approved in the QRD reference documents (*non-standard abbreviations, names of days on calenderised blisters, ...)* are accepted.

Note: as far as the indication of the days is concerned we also accept abbreviations in Dutch that consist of only 2 letters.
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000254.jsp&mid=WC0b01ac058008c34c

This category of exemptions can be requested when submitting the file or when sending the documents necessary to close the file. The lack of space should be proven by a mock-up or specimen.

Category 3. Deviations from the primary and secondary (harmonised) packaging for which an exemption needs to be requested.

The third category of exemptions can be used if the mock-up is still not legible in spite of applying categories 1 and 2. In this case a request for exemption should specifically be requested. The exemption will be explicitly mentioned on the Marketing Authorisation after approval.

Type of exemption	Legal basis	Acceptability	When to submit the request
Certain information is not shown on the primary and/or secondary packaging (if a lack of space and/or limited legibility can be proven) : o "Read the package leaflet before use" o "storage conditions" (if standard ambient temperature) o Address of the MAH o …	Art. 6 septies, paragraph 7 of the law dated 25th March 1964	Case by case evaluation	NP & MRP/DCP : request when submitting file

The minimal information conforms to - the QRD template for containers – "minimum particulars to appear on small immediate packaging units" - the QRD template for blister packs – "minimum particulars to appear on blisters or strips".	Art. 6 septies, paragraph 7 of the law dated 25th March 1964	Can be accepted for primary packaging for the following size of recipients: o **≤100ml,** for containers (of tablets), for bottles (for injections) and for vials o **≤50 ml** or g for tubes, o **≤ 36 cm^2** for pouches and patches.	NP & MRP/DCP: request when submitting file
The primary and/or secondary packaging is not submitted in the 3 national languages.	Art. 6 septies, paragraph 7 of the law dated 25th March 1964	- Only accepted for medicines for export. - In the case of radiopharmaceuticals it is acceptable for the primary packaging only to show the necessary information in English provided the secondary packaging contains the necessary data in the 3 national languages.	NP : request when submitting file & MRP/DCP : at the time of closure
Braille is not shown on the outer packaging (and, if that is lacking, then on the primary packaging).	Art. 6 septies, paragraph 7 of the law dated 25th March 1964	- Only accepted for medicines for use in hospitals or administered by healthcare professionals and for prefabricated medicines.	NP & MRP/DCP : request when submitting the file
For herbal medicines : to reproduce the declaration of the active substance in line	Art. 6 septies, paragraph 7 of the law dated	- Case by case evaluation	NP & MRP/DCP : request when submitting the file

with the *Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products /traditional of the* EMA	25th March 1964		

Category 4. Deviations from the SPC and the leaflet for which an exemption must be requested.

The exemption will be specifically mentioned on the MA when the medicine is approved.

Type of exemption	Legal basis	Acceptability	When to submit the request
Some information is not on the leaflet.	Art. 6 septies, paragraph 7 of the law dated 25th March 1964	- Only for NP, - Case-by-case evaluation	→ when submitting the file
SPC = leaflet, part of the SPC covered again in the leaflet	Art. 6 septies, paragraph 7 of the law dated 25th March 1964	- Only for NP - Only accepted for medicines for use in hospitals	→ when submitting the file
The leaflet is not submitted in the 3 national languages.	Art. 6 septies, paragraph 7 of the law dated 25th March 1964	- MRP/DCP/NP - Accepted only for medicines for export	→ when submitting the file

Summary table of the 4 categories

	Mentioned on the MA after approval	Request	When to submit the request
Category 1	No	No	NA
Category 2	No	Yes, during the ongoing file	At any time
Category 3	Yes	Yes, request an exemption	When submitting the file
Category 4	Yes	Yes, request an exemption	When submitting the file

Submitting the request:

A request for exemption for categories 2, 3 and 4 should be made using the template ‘’Requesting an exemption’’ and should be mentioned in the cover letter. The completed template is put in the “additional data” folder with a proposed label including the exemptions (by track changes). The label text itself can be written in English. For category 2 it is enough to justify that it is a small packaging by means of the mock-up or specimen.

The request can be made when submitting **a request** for a new Marketing Authorisation or a **renewal**. In case of a **clinical Type II variation or a type IB variation** a request can only be made when the submitted variation has an impact on the document to which the exemption applies. In all other variations (analytical or when the concerned document is not impacted by the variation) it is not possible to submit a derogation.

An exemption can also be requested **independently** of another file via a **notification procedure** submitted on the national level (art 34 §4 of the royal decree dated 14.12.06).