CBG MEB

MEDICINES EVALUATION BOARD

Policy document
MEB policy concerning marketing authorisations without Dutch translations of the product information and/or mock-ups

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1 INTRODUCTION

The MEB is aware of the fact that medicinal products are not always marketed immediately after authorisation. Following the European decentralised or mutual recognition procedures (DCP/MRP), it is possible that medicinal products are authorised but subsequently not released on the Dutch market. There are various reasons for this, such as copy procedures with NL as RMS or a delayed market introduction due to patents.
In addition, as a result of Review 2001, starting in 2013 it should be taken into consideration that medicinal products submitted and authorised 8 years after the innovator will only be marketed after 10 years. Taking these above-mentioned facts into consideration, the Medicines Evaluation Board (MEB) has decided to allow the following exceptions:

1) The option of awarding a marketing authorisation in the Netherlands for a product accepted via an MRP or DCP without having to submit Dutch translations of the product information and mock-ups. The MEB will register medicinal products from the MRP/DCP procedure that will not be released on the Dutch market with only the European (English) confirmed product information.

2) The option of submitting a request for a marketing authorisation with further conditions for medicinal products with Dutch product information that have already been registered, but have not been introduced on the market yet.

3) The option of awarding a marketing authorisation in the Netherlands for a product accepted via an MRP or DCP with a Dutch translation of the product information or accepted via a national recognition procedure without submitting mock-ups.

The obligation to keep the Dutch product information up-to-date remains for medicinal products for which the Dutch product information has already been approved and that have already been introduced on the market.

Mock-ups:
In general, a mock-up is required before a medicine can be registered. If the application involves several strengths and/or pharmaceutical forms, then a mock-up must be submitted for all strengths and/or pharmaceutical forms. If there are various packaging forms, then a mock-up is also required for each packaging form. It is not necessary to submit a mock-up for all packaging sizes, provided the layout of the mock-ups does not differ significantly for the various packaging sizes.

The definition of a mock-up is stated in the 2nd footnote of the Readability Guideline (Guideline on the readability of the labelling and package leaflet of medicinal products for human use, Revision 1, 12 January 2009[1]):

> 'A mock-up is a copy of the flat artwork design in full colour, presented so that, following cutting and folding where necessary, it provides a replica of both the outer and immediate packaging so that the three dimensional presentation of the labelling text is clear. This mock-up is generally referred to as a paper copy and not necessarily in the material of the sales presentation. A specimen is a sample of the actual printed out outer and immediate packaging materials and package leaflet (i.e. the sales presentation).'

[1] http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf

A derived mock-up is defined as: “a mock-up that is not an exact representation of the final packaging, but does give a good impression of the final packaging.” There are various examples of derived mock-ups:

1. Mock-ups based on an English mock-up
   If a product
   - has been authorised via a mutual recognition procedure (MRP or DCP), and
   - mock-ups are available in English, and
   - there is no difference in the three-dimensional presentation of the text, and
   - there is no difference in colour scheme, and
   - there is no difference in logos, signs, images or icons

   then it is permitted to submit these mock-ups with a statement that there will be no difference in the three-dimensional presentation of the texts and colour scheme and an explanation of which English text will be replaced with the relevant Dutch text.

2. Mock-ups with sticky notes
   For products that will not be marketed in the Netherlands, but for which a Dutch mock-up is submitted, the mock-up of another product from the same series may be used, provided that the differences are clearly marked. This can be done using sticky notes in PDFs of mock-ups. Differences in the presentation of the text or differences in colours compared to the final packaging cannot be indicated in this manner. Experience has shown that a mock-up containing a lot of sticky notes and a lot of text in a small font size is difficult to assess. If a mock-up with sticky notes cannot be properly assessed, the MEB can still request the submission of a completely new mock-up (in other words without sticky notes).
   The rest of this document refers to mock-ups as defined in the Readability Guideline and a derived mock-up.

This document does not include any instructions for the packaging requirements. These are provided in policy document “Labelling of pharmaceutical medicinal products (MEB 6)” and the explanation.

2 The possibility of authorising an MRP/DCP product in the Netherlands without Dutch translations of the product information and mock-ups

Upon conclusion of an MRP or DCP, the automatically generated "start national phase" message will send the following notification to the applicant:

[NL] Geneesmiddelen die niet in Nederland verhandeld zullen worden:
Als een geneesmiddel, geregistreerd via een MRP/DCP, niet in Nederland verhandeld zal worden, wordt u verzocht dit binnen twee weken na het einde van de procedure te melden bij het CBG. In dit geval hoeven er geen Nederlandse vertalingen van de finale productinformatie en mock-ups ingediend te worden.
Als het CBG na twee weken geen Nederlandse vertalingen en geen verdere meldingen dienaangaande ontvangt, gaat het College ervan uit dat het geneesmiddel niet in Nederland verhandeld zal worden. Er zal in beide situaties een handelsvergunning (met een Engelstalige SmPC) worden afgegeven.

[EN] Medicinal products that will not be marketed in the Netherlands:
In case a medicinal product which is registered by means of a MRP/DCP, will not be marketed in the Netherlands, you are requested to inform the MEB hereof within two weeks after the end of the procedure. In this case no Dutch translations of product information and mock-ups need to be submitted.
If the MEB does not receive either Dutch translations or notifications with respect to that within this two-week period, the Board will assume that the medicinal product will not be marketed in the Netherlands. In both situations a marketing authorisation (including an English SmPC) will be granted.

If the applicant decides that the medicinal product will not be marketed in the Netherlands, the MEB will grant a marketing authorisation for the medicinal product without Dutch translations of the SmPC, the package leaflet and packaging and without mock-ups (product information). The MEB will then issue a marketing authorisation subject to certain conditions.

- The following further conditions apply for a marketing authorisation without Dutch translations: This is a marketing authorisation as defined in Art. 1 of the Medicines Act.
- The marketing authorisation states that
  "*The medicinal product may only be marketed in the Netherlands if the Medicines Evaluation Board has approved the Dutch translations of the summary of product characteristics, the package leaflet, the packaging text and the mock-ups.*
- The English SmPC and package leaflet are confirmed during the registration and the following sections will have to be amended – labelling will not have to be amended:
  - section 1: Name of the medicinal product (nationally approved product name)
  - section 7: Marketing authorisation holder for marketing
  - section 8: Marketing authorisation number (RVG number)
  - section 9: Date of first authorisation / renewal of the authorisation
  - - section 10: Date of revision of the text (*if necessary*)

- Dutch translations of the product information and mock-ups do not need to be submitted for variations / renewals, if a marketing authorisation with further conditions has been granted. This must be clearly stated in the submission letter at such a time that the amended texts are expected. The sections listed above (1, 7, 8, 9 and 10) in the English SmPC and package leaflet will also have to be amended.
- The marketing authorisation holder is responsible for amending the SmPC and package leaflet, both for the national implementation of a registration and the subsequent variations / renewals.

- The marketing authorisation is displayed in the Database Human Medicine (GIB) (https://www.geneesmiddeleninformatiebank.nl/), along with the English text of the product information. An explanation concerning the English product information is included in the GIB.
- The marketing authorisation is subject to objection and appeals procedures.
- A medicine with a marketing authorisation with English product information may only be marketed after an addendum of the marketing authorisation has been received with approval of the Dutch product information. The Dutch translations and mock-ups based on the most recently approved English Product Information must be submitted via a national art. 61.3 procedure.
- If an application for the granting of a parallel import marketing authorisation is submitted to the MEB, with a medicinal product that has been authorised without Dutch translations serving as a reference medicinal product, then the MEB will ask the marketing authorisation holder of the reference medicinal product with English product information to submit a high quality Dutch translation of the product information within 1 month. As the medicinal product will not be introduced on the Dutch market, the MEB will not request mock-ups in this case.
- The MEB will continue the current policy concerning the sunset clause. A marketing authorisation will only be withdrawn if the marketing authorisation holder submits a request.
- A marketing authorisation will not be awarded if consensus has not yet been achieved concerning the product name in the Netherlands.
- A marketing authorisation will not be awarded if the dispensing status for the product in the Netherlands has not yet been approved.
- The registration can be transferred to a different marketing authorisation holder both during and after registration under further conditions. The usual documents must be submitted for this.

Submission of the Dutch translations

If a marketing authorisation holder decides to introduce a medicinal product in the Netherlands, a national Article 61.3 procedure must be submitted. This should include the following documents:

a. Dutch product information
b. Mock-ups
c. Last approved EU product information

The product may only be introduced onto the market after the Dutch product information has been formally recorded by the MEB.

Conversion of a previously confirmed marketing authorisation to a marketing authorisation with further conditions

If a medicinal product with Dutch text has already been registered but has not been released on the Dutch market yet, it is possible to convert this authorisation into a marketing authorisation with further conditions. This can be arranged via an Article 61.3 procedure or as part of a variation (type IB and II) of the C category. This conversion must be clearly indicated in the accompanying letter. A declaration must also be present stating that the medicinal product has not previously been released on the Dutch market.

If a registered medicinal product with Dutch text has already been marketed, it is not possible to convert that permission to a marketing authorisation with further conditions. The Dutch summary of product characteristics, package leaflet and label text will therefore have to be kept up to date (i.e. in line with the defined Europe-wide texts). However, there is the possibility of replacing the mock-ups with a declaration in which the authorisation holder undertakes to present the mock-ups to the MEB for approval before the medicinal product is reintroduced on the Dutch market. For more details, see point 3).

3 Possibility of authorising a national/MRP/DCP product in the Netherlands without mock-ups

It is also possible to grant a marketing authorisation for a product without the submission of mock-ups. The MEB will then grant a marketing authorisation with Dutch product information.

- A medicinal product for which a marketing authorisation has been granted, but for which mock-ups have not been approved by the MEB may only be marketed once the mock-ups have been submitted via an art. 61.3 procedure and have been approved by the MEB. This must be confirmed by means of a commitment from the marketing authorisation holder.
- If there are various packaging forms and or strengths, it is possible to submit mock-ups for some of these forms and a commitment can be submitted for the packages that will not be marketed.
- The MEB will continue the current policy concerning the sunset clause. A marketing authorisation will only be withdrawn if the marketing authorisation holder submits a request.

4 Submission of mock-ups

For the various types of procedures listed below, a mock-up must be submitted at a certain phase in the relevant procedure. If the product will not be marketed in the Netherlands, an explanation to this effect must be submitted instead of a mock-up in the same phase of the procedure.

4.1 Request for variation, national procedure

- For a type IA or IB variation that results in a change in the three-dimensional presentation of the text or in the colour of the packaging, the application must include a mock-up, when submitted on day 0.
- For a type II variation that results in a change in the three-dimensional presentation of the text or in the colour of the packaging, the mock-up must be submitted during the second round of the procedure.

4.2 Request for variation, mutual recognition procedure (MRP)

- For a type IA or IB variation that results in a change in the three-dimensional presentation of the text or in the colour of the packaging, the application must include a mock-up, when submitted on day 0.
- For a type II variation that results in a change in the three-dimensional presentation of the text or in the colour of the packaging, the mock-up must be submitted at the start of the national implementation phase.

4.3 Renewal

- A renewed marketing authorisation is granted upon completion of a renewal procedure. To this end, a mock-up must be submitted at the start of the national implementation phase, but only if changes have been made during the renewal procedure. These changes may be indicated using sticky notes (see page 4).

4.4 Change of authorisation holder

A change of authorisation holder usually involves a change in the three-dimensional presentation of the texts or the colours on the packaging, and therefore a mock-up must be submitted at the start of the procedure. If a change in authorisation holder is being submitted for a large number of medicinal products simultaneously, then the Medicines Evaluation Board (MEB) should be consulted in advance (see Questions and Answers document regarding changes in authorisation holder (https://www.cbg-meb.nl/onderwerpen/hv-variaties/documenten). In such cases, by prior agreement, a mock-up can be submitted for several medicinal products and a declaration can be submitted for the other medicinal products stating that the mock-up is the same for these medicinal products with the exception of the product name, strength, number of units, etc. If the applicant does not consult the MEB in advance, the MEB assumes that a mock-up will be submitted for all the medical products.