Austrian
Federal Office for
Safety in Health Care
BASG

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Institute LCM
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Guidance on the presentation (mock-up) of medicinal products

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1. ABBREVIATIONS

AMG	Arzneimittelgesetz (Austrian Medicines Act)
CMD(v)	Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary
CMS	Concerned Member State
DCP	Decentralised Procedure
MRP	Mutual Recognition Procedure
MAH	Marketing Authorisation Holder
PIL	Package Leaflet
RMS	Reference Member State
SmPC	Summary of Product Characteristics
QRD	Quality Revieved Documents

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2. INTRODUCTION

The outer and immediate packaging of a medicinal product has to comprise certain information specified in the Austrian Regulation on labelling of medicinal products (so called „Kennzeichnungsverordnung"). Not only the text, but also the layout of the packaging is an important carrier of information. The layout comprises all kinds of pictures, text and colour of the outer and immediate packaging, as it is marketed. A two-dimensional model of the layout of outer and immediate packaging is called Mock-up.

This guidance deals with the requirements of the BASG/AGES MEA on mock-ups and therewith on the design of the outer and immediate packaging for medicinal products for human and veterinary use.

Rules and recommendations for the sales presentations are listed, which shall guarantee the safe use of a medicinal product.

The guidance applies to all medicinal products for human or veterinary use, which have been or are to be approved/registered nationally or via a European authorisation procedure (DCP/MRP).

3. LEGAL BASIS AND DEFINITIONS FOR THE PRESENTATION OF A MEDICINAL PRODUCT

3.1. What is a mock-up of the labelling?

In this context, a mock-up is a true-to-scale, two-dimensional model of the outer and immediate packaging in the intended colouring (incl. Braille if applicable). After cutting and folding, the mock-up provides a replica of the outer and immediate packaging in a three-dimensional presentation of the labelling text.

3.2. Requirements according to the Austrian Medicines Act as amended

- According to § 9a (1) and § 11 (3) mock-ups of the outer and the immediate packaging of a medicinal product shall be submitted with the marketing authorisation/registration application.

  § 17 and § 17a describe the information which has to be given on the outer and the immediate packaging (see also the Regulation on labelling of medicinal products as amended).
- According to § 6 the sales presentation of a medicinal product is not allowed to be misleading in reference to the active substance, effect or efficacy. It must be ensured that the artwork design does not lead to any confusion:
  - It is not allowed to bring to market medicinal products or active substances, which do contain wrong information or which are misleading because of their names or presentation.
  - It is not allowed, in connection with the placing on the market of medicinal products or active substances, to provide information that is inaccurate or likely to mislead the public.
  - Misleading shall be deemed to exist in particular if:

- the medicinal products are considered to have an efficacy or the active substances are considered to have a property which according to the current state of scientific knowledge/practical experience is not sufficiently documented, or
- the impression is wrongly created that
  - a success is to be expected with certainty
  - after the intended use/long-term-use no harmful effects are to be expected, or
- the name or presentation is likely to cause confusion.

According to the comment on the Austrian Medicines Act on § 6 by *Mayer/Michtner/Schober*, the provisions of § 6 serve the protection of health and the safety of medicinal products. The consumers of medicinal products are to a large extent laypersons who have the need for special protection against deception, misleading, overreaching and most of all they have the need for protection against health damage.

3.3. Requirements according to the Austrian Regulation on labelling of medicinal products (as amended)

The Austrian Regulation on labelling specifies in detail which information has to shown on the labelling and how it has to be represented.

According to § 2. (1) the labelling has to be printed clearly visible and legible, clearly arranged and permanently on the immediate and outer packaging. German language, block letters of the Latin alphabet and Arabic numbers have to be used, unless the use of measuring units or scientific terms requires a different language or characters. The use of customary foreign-language designations is allowed.

The font size (height of the capital letters) has to be in any case at least 1.8 mm (equivalent to 8 points) for information in accordance with § 3. For all further information not stated in §3 the font size should be at least 1.8 mm, where space permits.

According to § 11 (3), Method and Route(s) of Administration, space shall be provided for the prescribed dose to be indicated.

Please note that this is only an excerpt of the relevant legal texts. The entire, consolidated version of the Austrian Medicines Products Act and the Austrian Regulation on labelling of medicinal products in the currently valid version can be found in the legal information system of the Republic of Austria.

4. REQUIREMENTS OF THE BASG/AGES MEA REGARDING MOCK-UPs

- In general illustrations on the packaging have to be truthful and meaningful for the safe use of the medicinal product.

- The presentation of promotional content, which claims unproven effects or efficacy, is prohibited.

- The text must correspond to the approved labelling text. It is neither allowed to delete parts of the approved labelling text nor to add non-approved text passages.
  Exceptions are the prefixes for the expiry date and the batch number as well as product code and serial number, which can only be imprinted during the production process.

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An amendment to the labelling text can only be submitted via an Art. 61 (3) Notification or it may be submitted together with another variation, aimed to change the Product Information (with a corresponding note in the cover letter).

- The legally required content must be prominently visible. They must not be pushed into the background by the other design of the packaging (e.g. by graphic elements).
- The text must be easily legible. Among other things, font, font size (in accordance with the Austrian Regulation on labelling of medicinal products), colouring and contrast have to be taken into account.
- In the case of line breaks the text should always continue on the same side of the outer packaging.
- At least once the full name of the medicinal product in the correct order (name - strength - pharmaceutical form) has to be presented in the same field of view in order to be recognized as a unit.
- If a Braille lettering has to be embossed on the outer packaging, its placement must be recognizable on the Mock-up. If Braille is affixed in form of an adhesive label, no other information must be covered.
- There must be sufficient space for the dosage information (§ 11 (3) Austrian Regulation on labelling of medicinal products).
- The name, expiry date and batch number must be visible on blisters until the last dose is removed. The expiry date and batch number can be embossed at the edge of each blisters to meet this requirement.
- Within a product range, teach strengths must be displayed sufficiently different, e.g. via the colouring.
- In general, the Austrian national mock-up has to be submitted. During an ongoing European procedure, the mock-up may be submitted in English. It must be true to scale, in colour and with sufficient space for blue box requirements. The applicant has to ensure that the design is transferred to the Austrian mock-ups. Once the European procedure has been completed, the Austrian mock-up has to be submitted during the national implementation phase.
- The following applies to illustrations:
    - They must not be misleading (e.g. with regard to ingredients, indication, effect, use, etc.).
    - It must be obvious that it is a medicinal product.
    - The legibility of the labelling text must not be impaired.
    - The following applies to pictograms:
        - From the point of view of the BASG/AGES MEA, pictograms generally bear a high risk of being misleading according to § 6 of the Austrian medicines act and should therefore be viewed very critically in terms of patient safety.

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- The meaning of the pictogram must be explained in words in the package leaflet and/or the labelling text.
- Derogation for veterinary products:

For veterinary products, instead of text, only the standardised pictograms approved by CMDv and the QRD Group Veterinary are permitted for the target species on labels of small immediate packaging units, ampoules or blisters.

Examples of generally permitted illustrations:

- The illustration of the pharmaceutical form.
- In the case of herbal medicinal products, an illustration of the medicinal herb(s) contained.
- The illustration of the company logo.
- The imprint of the calendar days in order to facilitate the regular intake/use.
- Examples of generally not permitted illustrations:
- The exact illustration of a medicinal plant, if the product contains only synthetically produced ingredients of the medicinal plant.
- Children's toys or other images that look tempting to children.
- Illustrations with a promotional character.

Whether an illustration is permissible or not, can only be decided on a case-by-case basis.

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5. DECISION TREE FOR MOCK-UPS

The assessment of mock-ups by the BASG/AGES MEA is based on the following decision tree. This decision tree has to be taken into account when the mock-up is prepared by the applicant.

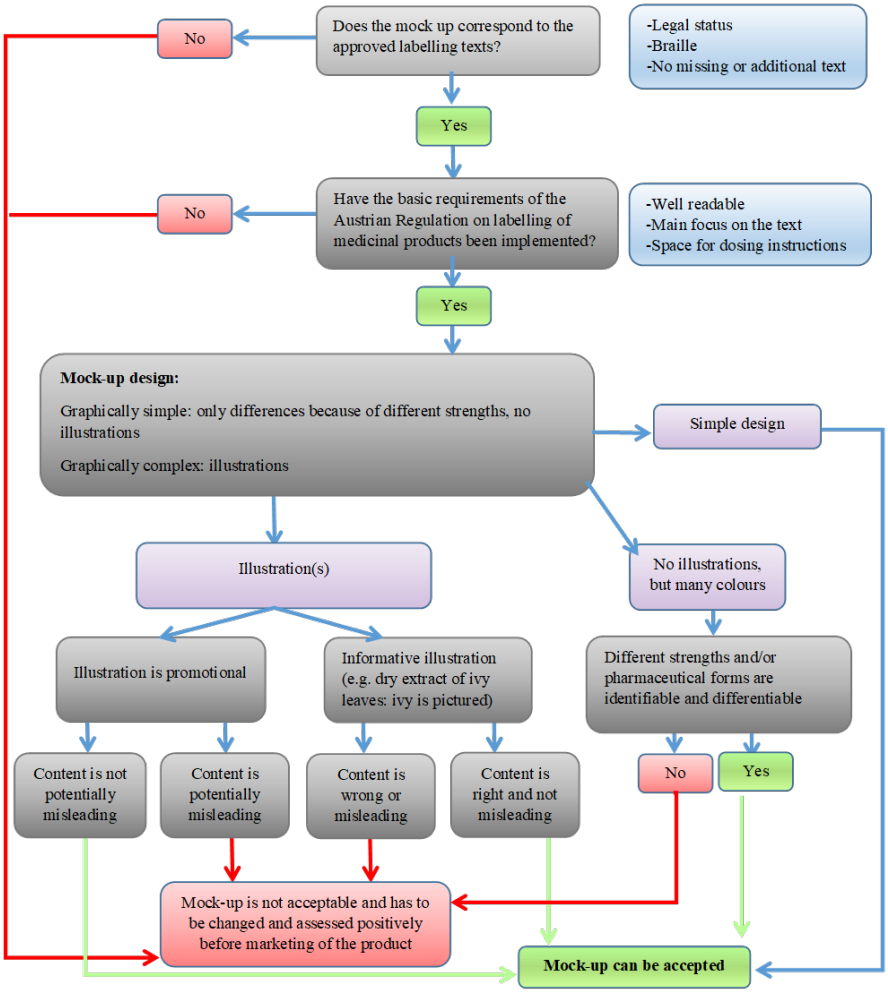

Figure 1: Decision tree

6. SUBMISSION OF THE MOCK-UP

6.1. When has a mock-up of the labelling to be submitted to BASG/AGES MEA?

A mock-up has to be submitted:

a) At the time of submission of an application for marketing authorisation or registration (the submission of draft-Mock-ups or English common Mock-ups is possible)

b) For Marketing authorisations/registrations: When submitting the German translated product information in the national implementation phase after finalisation of the MRP/DCP or during the final text discussion in the national procedure, if the medicinal product is to be marketed immediately

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c) Renewal: During the national implementation phase or during the final text discussion in the national procedure, if the medicinal product is marketed

d) In case of a transfer of the marketing authorisation holder

e) Before marketing, if it has not already been submitted according to b) or c)

f) At any time on request by the competent authority (for products on the market)

In the case of marketing authorisation or registration procedures as well as in the case of a renewal, the mock-up shall be deemed as approved as soon as the administrative decision is issued; in the case of transfers, on receipt of the corresponding notification.

Changes to existing mock-ups that do not affect the content of the labelling must meet the criteria set out in this guidance. An approval procedure is not foreseen.

6.2. What to submit?

The following has to be submitted:

- Mock-ups of the immediate and outer packaging, true to scale and in original colour.

- Mock-ups for the smallest package size of all strengths/pharmaceutical forms/containers marketed in Austria.

6.3. How should mock-ups be submitted?

If possible, mock-ups should be submitted as part of the dossier.

If texts are submitted via the eService portal, the mock-up should be uploaded as well. Otherwise, the submission should be made together with the product information via e-mail.

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7. FURTHER DOCUMENTS

Legal information system of the Republic of Austria: https://www.ris.bka.gv.at/

- Austrian Medicines Act (Arzneimittelgesetz, AMG)
- Regulation on labelling of medicinal products (Kennzeichnungsverordnung)

European Commission/Eudralex: http://ec.europa.eu/health/documents/eudralex_en

- Directive 2001/83/EC
- Regulation (EC) No 726/2004
- Regulation (EU) 2019/6

Compilation of QRD decisions on stylistic matters in product information

Checking process of mock-ups and specimens in the CP

Blue – Box requirements

Piktogramme for veterinary medicinal products

8. CONTACT ADRESSES FOR QUESTIONS CONCERNING MOCK-UPS

medicinal products national: nat@basg.gv.at
medicinal products AT=CMS: basg-cms@basg.gv.at
medicinal products AT=RMS: rms@basg.gv.at