Instructions for preparing a mock-up of medicinal product packaging
(Version 1.3, 29 January 2026)

These instructions are intended for applicants/marketing authorisation holders as a guide on how to prepare a high-quality mock-up of medicinal product packaging in accordance with legislation, and to make best use of the available packaging space to place the mandatory labelling information required by legislation, for the purpose of correct and unambiguous identification of the medicinal product and its safe use. The instructions explain the provisions referred to in legislation for the labelling of the medicinal product and set out more detailed requirements on how to prepare a high-quality and consistent presentation of information on the mock-up of the packaging, which must be clear and legible in order to prevent confusion among healthcare professionals/users of the medicinal product and the possibility of a medication error.

1. Regulatory procedures in which a mock-up of medicinal product packaging must be submitted

1.1. Granting of marketing authorisation

In the procedure for granting marketing authorisation, the applicant shall submit to HALMED one or more mock-ups of the outer and the immediate packaging of the medicinal product, in accordance with Article 26, paragraph 3 point o) of the Medicinal Products Act (Official Gazette, Nos. 76/13, 90/14, 100/18 and 136/25 hereinafter: MPA) and Article 11 of the Ordinance on Granting Marketing Authorisations for Medicinal Products (Official Gazette, No. 83/13, 28/20 and 32/21 hereinafter: Ordinance).

1.2. Renewal of marketing authorisation

In the procedure for renewal of marketing authorisation, during the assessment of the application HALMED may request submission of a mock-up, if a mock-up is necessary to evaluate unambiguous identification and the safe use of the medicinal product. In the procedure for renewal of marketing authorisation of the medicinal product with classification “not subject to medical prescription”, the applicant/marketing authorisation holder shall submit to HALMED the mock-ups of the outer and the immediate packaging of the medicinal product.

1.3. Variation of marketing authorisation

In the procedure for variation of marketing authorisation in line with Articles 33 and 34 of the Ordinance, the applicant/marketing authorisation holder shall submit the mock-ups of the outer and the immediate packaging of the medicinal product.
In the procedure for variation of marketing authorisation in line with Article 36 of the Ordinance (corresponds to Article 61 paragraph 3 of Directive 2001/83/EC), the applicant/marketing authorisation holder shall submit the mock-up of the outer and/or the immediate packaging of the medicinal product, if the variation affects the content of the labelling text which is considered critical information for appropriate and safe use of the medicinal product, and/or change of the design/graphical elements on the mock-up (with or without changes to the content of the text) which can affect the identification of the medicinal product and the legibility of mandatory information on the outer and/or the immediate packaging of the medicinal product. During the assessment of the application HALMED may request submission of the mock-up if it deems this necessary to evaluate unambiguous identification and safe use of the medicinal product.

2. Mock-up of medicinal product packaging

A mock-up is a three-dimensional presentation as a flat design in full colour and actual size of all sides of packaging, outer (box or label for outer box) and the immediate packaging (label or foil for the container), that will be printed on the packaging intended for the market.

The mock-up includes:

- Labelling text in a font type, font size and layout as to be printed on the packaging,
- Design, and
- Layout of all graphical elements for printing on the particular sides of the packaging.

The labelling text for the outer and the immediate packaging of the medicinal product must contain all mandatory elements as referred to in Articles 92, 93 and 94 of the MPA. Applicants/marketing authorisation holders when preparing a proposal of the labelling text of the medicinal product shall use the Instructions on content and templates for submission of product information of the medicinal product in national procedure (abbreviated: national QRD) and CMDh annotated QRD template for MRP/DCP, whereas for herbal/traditional herbal medicinal product the templates from the Addendum to the Quality Review of Documents templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures specific for (Traditional) Herbal Medicinal Products ((T)HMPs).

During the procedure HALMED assesses the submitted proposal of the labelling text (Word document) and approves the labelling text. The marketing authorisation holder is responsible for printing accurately approved labelling text on the packaging and has to ensure compliance of the approved labelling text with the text drawn on the final mock-up of the outer and the immediate packaging which will be printed on the packaging material of the medicinal product intended for the market.

HALMED reviews the legibility of text on the mock-up in terms of the quality and consistency of presented information, with an emphasis on identification of the medicinal product and information considered critical for appropriate and safe use of the medicinal product, as well as acceptability of the design and layout of graphical elements in terms of their impact on the legibility of the labelling text.

2.1. Requirements for mock-up

For preparing/drawing the mock-up applicants/marketing authorisation holders must use these instructions along with the *"Guideline on the readability of the labelling and package leaflet of medicinal products for human use"*. The Ordinance (Article 11, paragraph 3) lays down:
"The mock-up of the outer and the immediate packaging may not:

- create confusion concerning the dosage and use of the medicinal product,
- create confusion concerning the composition of the medicinal product,
- create confusion concerning the safety and efficacy of the medicinal product,
- contain messages of a promotional character,
- create confusion due to the similarity of appearance with another medicinal product."

From the above mentioned conditions it follows that the mock-ups for various strengths and pharmaceutical forms of the same medicinal product or for different medicinal products must be clearly differentiated to prevent the risk of mixing up and medication error.

To fulfil the conditions laid down, the mock-up of the outer and the immediate packaging must be prepared/drawn in accordance with the following requirements for:

1. **Format of the mock-up**

   - Submitted in electronic form as a PDF document.
   - Submitted in colour and actual size.

2. Several packaging sizes of the same strength and same pharmaceutical form of the medicinal product

- Submitted only for the smallest packaging size if the labelling text is the same for all packaging sizes except different information on the packaging size/number of dose units. For other packaging sizes the same design and layout should be retained (including the horizontal or vertical orientation) and the same font type and font size (characters may be the same or larger) and pack dimensions for other packaging sizes may be the same or larger.
- It is recommended to differentiate by design only the information for the particular packaging size (i.e. different colour or size of the characters, bold or by other graphic elements such as framing, contrast between the text and the background, etc.),
- It is not recommended that mock-ups of various packaging sizes differ significantly in terms of design/colour scheme, because it may lead to confusion, except if various (or same) packaging sizes have different classification of the medicinal products as "subject to medical prescription" or "not subject to medical prescription", then the design of the packaging size of the medicinal product which is "subject to medical prescription" must be differentiated from the size which is "not subject to medical prescription", in line with section 3.1 of these instructions.
- Submitted for other packaging sizes if the mock-ups for various packaging sizes differ in the design (e.g. the use of different colours) and layout (different orientation horizontal or vertical).
- If several mock-ups are submitted for various packaging sizes of the same strength and same pharmaceutical form, all should be submitted in a single PDF document.

3. Several strengths of the same pharmaceutical form

- Submitted for each strength as a separate PDF document.
- Different strengths of the medicinal product need to be differentiated by design, use of various colours and/or graphical elements on the mock-up or by indicating dosage in the name of the medicinal product with different font colours for different dosages of the same pharmaceutical form.
- The mock-up of a previously approved medicinal product must be submitted if another strength of the same medicinal product has been approved, for the purpose of comparison (in case of "line extension").

4. Several pharmaceutical forms of the medicinal product

- Submitted for each pharmaceutical form as a separate PDF document.
- Mock-ups of various pharmaceutical forms need to be differentiated by design or by indicating dosage in the name of the medicinal product with different font colours for different pharmaceutical forms of the same medicinal product.
- The mock-up of a previously approved medicinal product must be submitted if another pharmaceutical form of the same medicinal product has been approved, for the purpose of comparison (in case of line extension).

5. Legibility of the labelling text

- The labelling text on the mock-up should be printed in a font size of at least 7 points in Times New Roman, leaving at least 3 mm between lines. Another font may be used provided the mock-up specifies the font and size used (the height of the lowercase letter must be at least 1.4 mm). This applies to marketing authorisation applications submitted after the publication of these instructions and for marketing authorisation applications which are pending at the time of publication of these instructions. In the variation/renewal procedures in which the marketing authorisation holder must submit a mock-up, it is also required to use the above stated font size. In exceptional cases for very small packaging (e.g. 1 ml ampule), smaller font size may be used and legibility of the chosen font size will be assessed by HALMED during the procedure.
- Larger font size than the minimum size required above should be used on mock-ups whenever the packaging space allows it, due to better legibility of text.
- The legibility of text should not be disrupted by design. Do not use gloss or reflecting surfaces nor print text in colours with a metal effect, as it may negatively impact legibility. Background colours that negatively affect the legibility of text should not be used, and selected colours should ensure good contrast between the text and the background in order to provide optimal legibility of information.
- In the packaging design, along with text (selection of font type and font size) and colours, other graphical elements (e.g. stripes, arches, circles, pictograms etc.) may be used if the packaging space allows it and does not negatively affect the legibility of the mandatory labelling text or distract the user's attention from the mandatory text. Graphical elements that are not the labelling text should not be larger than 1/3 of the space of the packaging side on which they are displayed.

6. Name of the medicinal product and the active substance

- Not recommended to use different font colours, nor mix various font types or uppercase and lowercase letters to highlight one part of the name of the medicinal product (name is one of the elements of "the full name" of the medicinal product, according to the National QRD, section 1 of the SmPC), as it may lead to an error in identification of the medicinal product due to possible wrong reading of the name.
- "The full name" of the medicinal product (full name: name + strength + pharmaceutical form, as written in section 1 of the SmPC) should be placed in the same line if the space allows. If that is not possible, then "the full name" of the medicinal product can be placed in several lines but should be drawn an integrated graphic entity which is not separated with other text or graphic element.
- The name of the active substance should be placed immediately under "the full name" of the medicinal product using a smaller font size than for "the full name" of the medicinal product.
- "The full name" of the medicinal product and the name of the active substance on the mock-up must be set as an integrated textual graphic entity which is not separated by other text or a graphic element, using a larger font (than on the other sides) on the front side of the packaging as much as space allows.
- "The full name" of the medicinal product and the name of the active substance should be placed on at least three non-opposite sides of the packaging (on the front side, at least on one lateral side and the upper side (flap) of the packaging). It is very important for the pharmacist for correct identification of the medicinal product when dispensing the medicinal product, because the information drawn in this way is visible regardless of how the pack is placed on the shelf/in a tray/drawer.

- For a medicinal product in a liquid pharmaceutical form in a bottle, for which packaging is kept vertically, "the full name" of the medicinal product and the name of the active substance should be placed on at least three sides as well, on two vertical sides (may be the opposite sides) and one top side (flap), so that the medicinal product can be identified when it is on a shelf (front or back side view) or in a tray/drawer (top side/flap view).
- The packaging size should be placed on the packaging sides where "the full name" of the medicinal product and the name of the active substance are placed, if space on those sides allows it (except on these three sides packaging size may be placed also on the other sides of the packaging).
- On the mock-up of the outer packaging an empty space on one side must be provided, onto which a pharmacist will indicate the prescribed dose, in accordance with Article 92, paragraph 1, point e) of the MPA.

7. Multilingual packaging

- A multilingual mock-up of the packaging is acceptable only if the packaging space allows it, under the condition that the labelling text in the other language has no negative impact on the legibility of the mandatory labelling text in the Croatian language, and the texts in the other languages must be clearly separated. The content of information in non-Croatian language must be identical to the content of information in the Croatian language (according to Article 94 paragraph 3 of the MPA), and the marketing authorisation holder is responsible for the equivalence of the text in various languages on the mock-up.

8. Trademark/logo

- A trademark (registered trademark may be word/personal name, image, letters, numbers, shape, colours or combination of all the above indicated signs, according to Article 6 of the Trademarks Act) or logo (image/graphic sign which is distinctive for the company and is a part of a registered trademark) of the marketing authorisation holder (exceptionally of the local representative of the marketing authorisation in the Republic of Croatia) can be placed on the mock-up, under the condition that the trademark/logo due to its position (not be placed too close to the mandatory text so as not to distract attention from the text) or size (not be dominant) does not negatively affect the legibility of the mandatory information on the packaging.
- If the trademark/logo will be placed on the packaging it has to be indicated in the proposal of the labelling text according to the National QRD, as described in "Labelling" under section 11 "PARTICULARS TO APPEAR ON <THE OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>.
- If the design or position of the trademark/logo placed on the packaging is changed but the change does not negatively affect the legibility of the mandatory information due to position or size of the new trademark/logo, it is not necessary to submit a variation according to Article 36 of the Ordinance.
- The trademark/logo of the manufacturer of the medicinal product (including the importer or the licensor) may not be stated on the outer and immediate packaging due to the possibility of causing confusion about who is responsible for the medicinal product.

9. Immediate packaging of the medicinal product

- Submitted mock-up of the label for the immediate packaging or packaging foil on which all labelling elements are directly printed.

- The mock-up of the immediate packaging for blister/strip must show the number and scheme of dose units in the blister/strip and must contain the mandatory text of the labelling in accordance with paragraph 2 of Article 93 of MPA ("the full name" of the medicinal product, expiry date, batch number, and the name of the marketing authorisation holder → abbreviated name as trademark/logo may be placed if space is limited).

- The mock-up of "perforated unit dose blisters/strips" containing several unit dose blisters (see definition for "unit dose blister" in the EDQM database of standard terms at https://standardterms.edqm.eu/) which can be easily separated along the perforation into single units, must clearly show that it is "perforated unit dose blisters/strips". The information laid down in paragraph 2 of Article 93 of the MPA for labelling of the "standard" blister/strip must appear on the mock-up for each single "unit dose blister/strip" of "perforated unit dose blisters/strips", due to the traceability of labelling information on each "unit dose blister" when it is separated from the original perforated blisters/strips. In the product information (in section 6.5 of the SmPC, also corresponding part of PL and labelling) it should be clearly described that it is "perforated unit dose blisters/strips" and how many "unit dose blister/strip" it consists of, in accordance with the example described in the EMA's document "Compilation of QRD decisions on stylistic matters in product information" in the section that refers to <"Unit dose" pack sizes>.

2.2. Pictograms/symbols

A pictogram (Latin, *pictus*: pictured or painted) is a simplified illustration/image or graphic sign used as an element of visual communication, and is read/understood as a symbol. The pictogram clearly and unambiguously visually presents the meaning of a particular term or information, and as a form of communication is superior to words in certain cases. The standardised pictogram or agreed sign that has a generally accepted meaning for a certain term or information is called a symbol.

The use of the pictogram/symbol on the mock-up of medicinal product packaging is possible in accordance with Article 95 of the MPA only if the pictogram/symbol meets all of the provisions of the Article and the following conditions:

- It additionally clarifies the mandatory labelling text and does not replace the mandatory text,
- Has an unambiguous meaning and provides clear visual information,
- Is not contradictory to information given in the summary of product characteristics, package leaflet and labelling of the medicinal product,
- Does not lead to confusion on the efficacy of the medicinal product (e.g. may not suggest a broader therapeutic indication than it is authorised or only some (narrow) of authorised therapeutic indications or emphasis over-efficacy of a medicinal product),
- Does not have a promotional nature.
- Does not lead to confusion as to the nature of the product (e.g. may not be associated with a food or cosmetic product),
- It is not complicated and is understandable for the average user,
- Its size, position and design does not dominate with respect to the labelling text and do not negatively affect legibility of the mandatory labelling text.

Together with these instructions, it is recommended to use the *„Guideline on readability of the label and package leaflet of medicinal products for human use"*.

It should be avoided to use combinations of several pictograms/symbols which are clear and acceptable when each is used separately, but when used together may be unclear and lead to confusion.

Explanations for pictograms/symbols used should be stated textually beside them on the packaging or, exceptionally if the space of the packaging does not permit, in the package leaflet. The pictogram,

together with the appropriate explanation, must be stated in the proposed labelling of the medicinal product (if the explanation is stated in the package leaflet, it should be stated in the proposed text of the package leaflet).

It is permitted to place a pictogram/picture on the mock-up of the packaging, if it meets the above mentioned provisions/conditions for the pictogram and also the following additional requirements for the cases below:

- pharmaceutical form:
  - It must clearly and unambiguously show the pharmaceutical form of the medicinal product.
  - The details must correspond to the particular pharmaceutical form (e.g. if the tablet has a score line, the line must be shown or not shown if the tablet has not score line).
  - Showing the number of tablets/capsules is only permitted if in line with the recommended dose stated in section 4.2 of the SmPC, because showing several tablets/capsules may lead to confusion regarding the recommended dose of the medicinal product (e.g. displaying two or more tablets on the package may be associated with the need to take multiple tablets at once, whereas it is prescribed to take only one).
  - It is recommended to place a realistic picture (photograph) of the pharmaceutical form (e.g. capsule/tablet) on the mock-up rather than a pictogram, as it provides clearer visual information.

- medical device:
  - Only if a medical device is an integral part of the medicinal product pack, as it is necessary for use of the medicinal product (e.g. spoon, syringe, and similar).

- target population:
  - Only for the purpose of clearly identifying a target population and not leading to confusion with respect to the population for whom the medicinal product is intended (e.g. for medicinal products intended for use in several age populations, adults, adolescents and children, it is not permitted to display only one of these populations as it may lead to confusion as to which age population the medicinal product is intended).
  - Indicated a child/children must be consistent with the age subgroup of the paediatric population for which the medicinal product is intended and should not in any way suggest a different age subgroup than the one for which the medicinal product is intended (e.g. not to display a picture of a small child if the medicinal product is intended for children older than 12 years of age), and the information on the children's age must be explicitly stated by the text in or near the pictogram/symbol.

- route of administration:
  - Permitted only if the medicinal product has only one site where it can be administered.
  - Any pictogram/symbol used for the part of the body must unambiguously indicate the site where the medicinal product is to be administered (e.g. an ear on the packaging of the medicinal product intended for use in the ear, or a nose on the packaging of the medicinal product intended for use in the nose, etc.).

- indication(s):
  - Only if a pictogram/symbol of part(s) of the body gives clear and complete visual information related to **all** authorised indications for the medicinal product, e.g. for analgesics it is not permitted to show only one indication (e.g. headache) if the medicinal product is authorised for several indications (e.g. back pain, toothache and menstrual pain).
  - Visual information shall not be too complex and confusing.

- fruits or parts of the plant:
  - Only if the herbal substance or preparation from the fruit or part of the plant drawn on the packaging is in the composition of the medicinal product (e.g. if the medicinal product contains ivy leaf extract, a picture of an ivy leaf may be placed on the mock-up).

2.3. Other graphical elements (e.g. stripes, arches, circles)

Only if the space of the packaging allows it and the elements have no negative impact on the legibility of the mandatory labelling text, and do not draw the user's attention from the mandatory text.

2.4. Pictures that are not permitted on mock-up:

- Picture of a cup/glass containing a beverage which can be associated with food, as it may lead to confusion on the nature of the product (e.g. it is not acceptable a picture which is associated with a refreshing beverage, tea or juice that can be drunk as desired and which does not need to be dosed),
- Picture of a toy as it may make the medicinal product pack additionally attractive to children and create a wrong perception of the nature of the product (e.g. a picture of a toy on a packaging of tablets may lead the child to associate it with sweets/bonbons, or on a packaging of oral solution may associate with a fruit juice),
- Picture of excessively playful children on a package of a medicinal product that is authorised for indication for which it is recommended to rest during the treatment (e.g. for an antipyretic, a picture of children jumping or playing with a ball) may lead to confusion that children may play and do sport unconstrained instead of resting during the treatment,
- Picture/pictogram of fruit may not be placed on the mock-up if the ingredient from the fruit is not contained in the medicinal product, but the picture/pictogram only suggests a flavour/aroma (e.g. if the medicinal product contains a strawberry aroma, drawing of a strawberry on the package is not permitted). The flavour/aroma may be identified/differentiated in the labelling text by the statement (e.g. "strawberry flavoured") and/or by using various colours in the packaging design of the medicinal products containing different flavours/aromas.

When using a pictogram/symbol/picture on the mock-up, it is important to evaluate whether or not it contributes to a better understanding of the mandatory labelling text. It should be avoided to place any pictogram/symbol/picture that does not have added value for the user/patient in terms of better understanding the information about the medicinal product, in order not to take up the packaging space unnecessarily that is required for the clear and legible printing of the mandatory labelling text which is critical for safe use of the medicinal product.
The acceptability of the pictogram/symbol/picture on a mock-up of medicinal product packaging, along with the appropriate textual explanation, will be assessed by HALMED in the regulatory procedure.

3. Additional requirements for mock-ups of the packaging of the medicinal product "not subject to medical prescription"

When preparing/drawing the mock-up of packaging of the medicinal product "not subject to medical prescription" (abbreviated: "non-prescription") the applicants/marketing authorisation holders must, along with the requirements for the mock-up of packaging of the medicinal product stated under section 2 of these instructions, also meet the following additional requirements:

1. The design of a mock-up of packaging of the "non-prescription" medicinal product must be adequately differentiated from the design of a mock-up of the medicinal product "subject to medical prescription", such that the user can clearly visually recognise and differentiate the "non-prescription" medicinal product from the medicinal product "subject to medical prescription", without any possibility of confusion.

2. In the labelling text under section “PARTICULARS TO APPEAR ON <THE OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>” according to the National QRD), for the “non-prescription" medicinal product additional text under point “15. INSTRUCTIONS ON USE” should be part of the mandatory information for labelling.

   The text under point “15. INSTRUCTIONS ON USE” is critical information necessary for the appropriate and safe use of the “non-prescription” medicinal product during self-medication, and shall be presented on the mock-up in a “high quality” way as follows:

   - As one integrated graphical entity which is not separated by other text or graphical element(s).
   - On one of the main sides of the outer packaging (side which has the largest space), as usual on the back main side of the outer packaging. On the side of packaging on which the text under point 15 appears, it is not necessary to place also the integrated textual entity “full name of the medicinal product + active substance”. If the “full name of the medicinal product + active substance” is placed together on the same side of packaging with text under section 15, “full name of the medicinal product + active substance” should be stated in a smaller font size with respect to the font size used on the front main side, in order to better utilise the space of the back main side for a high quality presentation of the mandatory text under point 15.
   - If necessary, all aproved indications listed under point 15 may also be repeated on the front main side of the packaging
   - Font size must ensure good legibility of the text. It is not recommended to use the smallest font size required in section 2.1 of these instructions if the space of the packaging side, on which the text under point 15 is placed, allows the use of larger font size.
   - A high quality presentation of the text under point 15 on the mock-up should have priority over placing pictogram/picture/graphical elements which do not have added value for the users. The space of the side on which the text under point 15 is placed should be used mostly for that text, instead of placing other design elements on that side.

HALMED will assess the mock-up of the packaging of each “non-prescription” medicinal product on a case by case basis, taking into account the conditions and requirements referred to in these instructions.