REG-96 version 2 Requirements for the Submission of Mock-ups

This Guideline supersedes guideline REG-96 version 1 as of 1 July 2025 and is applicable to all submissions containing mock-ups.

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This Guideline has been issued in order to facilitate navigation in the area of medicinal product packaging graphic design submissions (hereinafter referred to as "mock-ups") and the rules governing their assessment with regard to public health protection, patient safety, and legislative requirements.

The Guideline is issued by the State Institute for Drug Control (hereinafter referred to as the "Institute" or "SÚKL") in compliance with the below-listed legal regulations.

The Guideline is of recommendatory in nature.

Nevertheless, its content is based, *inter alia,* upon the requirements stipulated by legislation and EMA guidance, which are legally binding.

The Institute reserves the right to adjust the assessment practice based on experience or newly established safety concerns.

The objective of mock-up assessment, as adjusted, is to safeguard straightforward and unequivocal identification of the medicinal product by anyone who will be using or handling the medicinal product. Straightforward and unequivocal identification is, *inter alia*, important for the elimination of potential medication errors and confusion in the use of the medicinal product.

This Guideline applies to all medicinal products authorised via the national and MR/DC procedures, regardless of their classification for supply. It is also applicable to the mock-ups of parallel imported medicinal products.

The assessment of mock-ups is considered a matter of national assessment and it is not possible to refer to assessments performed by other Member States.

This Guideline shall not apply to mock-ups of medicinal products authorised via the centralised procedure (the submission of these mock-ups is governed by guideline EMA/305821/2006).

This Guideline shall not apply to mock-ups of individually imported batches of medicinal products placed on the market with texts on labelling in a language other than Czech (in compliance with Section 3(6)(b) of the Marketing Authorisation Decree).

Please note that food supplements, medical devices, and medicinal products are governed by various legislation, and therefore the requirements for the efficacy, purity and quality of starting materials as well as finished products differ across those product categories. For this reason, mock-ups proposed for medicinal products should always significantly differ from other products from other categories of the same manufacturer/holder.

This Guideline does not set forth rules for the submission of medicinal product samples.

Package leaflet mock-ups are generally not required. The package leaflet should only contain the approved text, without any other graphic elements (except for non-specific graphic elements or graphic elements approved in the PL text, such as instructions for use, as applicable).
The layout, font size, colour and type are up to the holder. General recommendations and requirements are outlined in the Guideline on Readability.

1. Legal Regulations and Associated Sources

- Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended (hereinafter referred to as the “Act on Pharmaceuticals”)
- Decree No 228/2008 Coll., on Marketing Authorisation of Medicinal Products, as amended (hereinafter referred to as the “Marketing Authorisation Decree”)
- Directive 2001/83/EC, on the Community code relating to medicinal products for human use (hereinafter referred to as “Directive 2001/83/EC”)
- Guideline on the readability of the labelling and package leaflet of medicinal products for human use (ENTR/F/2/SF/jr (2009)D/869) (hereinafter referred to as the “Guideline on Readability”)
- QRD template
- Appendix IV to QRD template - terms/abbreviations for “batch number” and “expiry date” to be used on the labelling of human medicinal products (hereinafter referred to as “Appendix IV to QRD template”)
- CMDh position paper on the use of mobile scanning and other technologies to be included in labelling and PL in order to provide information about the medicinal product (CMDh/313/2014)
- Commission Delegated Regulation (EU) 2016/161 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (hereinafter referred to as “Commission Regulation 2016/161”)
- Implementation plan for the introduction of the safety features on the packaging of nationally authorised medicinal products for human use (CMDh/345/2016) (hereinafter referred to as the “CMDh Implementation Plan”)

- Implementation plan for the introduction of the safety features on the packaging of centrally authorised medicinal products for human use (EMA/785582/2014) (hereinafter referred to as the "EMA Implementation Plan")
- Safety features for medicinal products for human use – Questions and Answers (hereinafter referred to as the "EC Safety Feature FAQ Document")
- SÚKL information on safety features: https://sukl.gov.cz/prumysl/leciva/ochranne-prvky/
- Národní organizace pro ověřování pravosti léčiv (NOOL; the National Medicines Authentication Organisation): https://czmvo.cz/cs/
- Checking process of mock-ups and specimens of outer/immediate labelling and package leaflets of human medicinal products in the centralised procedure (EMA/305821/2006)
- Act No 477/2001 Coll., on Packaging and on Amendments to Some Acts, as amended (hereinafter referred to as the "Act on Packaging")
- Act No 441/2003 Coll., on Trademarks and the Amendments to Act No. 6/2002 Coll. on Courts, Judges, Lay Judges and State Court Administration and on the Amendments to Certain Other Acts (Act on Courts and Judges), as amended (hereinafter referred to as the "Act on Trademarks")
- Guideline on Excipients in the labelling and package leaflet of medicinal products for human use (EMA/CHMP/302620/2017) (hereinafter referred to as the "Guideline on Excipients")
- Guideline on the packaging information of medicinal products for human use authorised by the Union (hereinafter referred to as the "Guideline on the packaging")
- Compilation of QRD decisions on stylistic matters in product information (hereinafter referred to as the "QRD Stylistic Matters Guideline")
- CMDh guideline "Blue-Box" requirements (CMDh/258/2012)
- UST-29: Administrative Fees, Reimbursements of Costs of Expert Activities, Reimbursements of Activities Associated with the Provision of Information and Reimbursements of Other Activities (Code O-002) (hereinafter referred to as "UST-29")

General Legislative Requirements Governing the Provision of Information on Labelling:

- Section 26(5)(n) of the Act on Pharmaceuticals: the application for marketing authorisation must be accompanied, *inter alia,* by **mock-ups of outer and immediate packaging** of the medicinal product;
- Section 37(1) of the Act on Pharmaceuticals: data shown on the packaging of medicinal products must be **consistent with the approved Summary of Product Characteristics**, they must be **easily legible, comprehensible, and indelible.** Medicinal product packaging **must not bear any elements of promotional nature. The name in Braille must be provided on the outer packaging** of the medicinal product, unless specified otherwise by the Marketing Authorisation**;**
- Section 37(1) of the Act on Pharmaceuticals: the implementing legal regulation stipulates the scope of data to be provided on the packaging of medicinal products as well as the conditions for the provision of data for the identification of the medicinal product by an **internationally recognised identification standard serving for electronic processing and compliant with the requirements of the standard coding system**, unless a unique identifier is concerned (as these are stipulated by Commission Regulation 2016/161), and the specification of classification for supply of the medicinal product, if applicable;
- Section 37(1) of the Act on Pharmaceuticals: the packaging of medicinal products for human use **must bear the code allocated as per Section 32(5)**;
- Section 37(5) of the Act on Pharmaceuticals: data on the packaging of the medicinal product and in the package leaflet must be provided in the Czech language; **if they are provided in several languages, their content must be identical;**
- Section 38 of the Act on Pharmaceuticals: if the medicinal product is not intended to be provided directly to the patient or if there are serious problems with the availability of the medicinal product, the Institute or the Veterinary Institute may, in the Marketing Authorisation, provide for the possibility not to show certain data on the labelling and in the package leaflet; the concerned Institute may also

allow that parts of or the complete **texts on the labelling and the package leaflet were not in the Czech language**. The implementing legal regulation (i.e., Section 3(6)(a) of the Marketing Authorisation Decree) lists the cases when it is possible to provide the texts on labelling in a language other than Czech;

- Section 6(5) of the Marketing Authorisation Decree: along with the application for marketing authorisation, or, where applicable, prior to the issue of the Marketing Authorisation, specimens of any outer and immediate packaging in which the medicinal product for human use is to be placed on the market, shall be submitted;
- Annex 5(A)(1)(o) to the Marketing Authorisation Decree: unless the identification of the medicinal product is provided by means of a unique identifier as part of its safety features, the outer packaging of the product, or the immediate packaging of the product, where there is no outer packaging shall show an internationally recognised identification standard;
- Annex 5(A)(6) to the Marketing Authorisation Decree: **symbols or pictograms explaining certain data** provided on the packaging of the product or in the package leaflet **or other data that are useful for the patient** may form part of the labelling on the outer packaging of the product. **Such data must be consistent with the Summary of Product Characteristics and must not contain elements of promotional nature**;
- Annex 5(A)(7) to the Marketing Authorisation Decree: the outer packaging of the product, or the immediate packaging of the product, where there is no outer packaging shall show **the code allocated by the Institute** as per Section 32(5) of the Act on Pharmaceuticals*;*
- Annex 5(A)(10) to the Marketing Authorisation Decree: the **name of the product shall be shown on the outer packaging also in Braille**, unless specified otherwise by the Marketing Authorisation;
- Section 33(3)(a) of the Act on Pharmaceuticals: **the marketing authorisation holder shall be obliged to ensure that the properties of an authorised medicinal product and the current product documentation**, including the Summary of Product Characteristics, Package Leaflet, texts on the labelling and documentation concerning the product classification for supply were consistent with the current data and documentation forming the basis for the issuance of the Marketing Authorisation, as amended;
- Section 3(5) of the Marketing Authorisation Decree: In case of applications falling within mutual recognition by Member States, the Czech drafts of the Summary of Product Characteristics, texts on labelling, package leaflet, and **all specimens of immediate and outer packaging** in which the product is to be placed on the market, **including graphic design in colour**, shall be submitted no later than within 5 days after the conclusion of the procedure.

For further recommendations on the presentation of data on the packaging, please refer to Guideline on Readability, which, in compliance with Art. 65(c) of Directive 2001/83/EC, further details the requirements on how data on the packaging of medicinal products are to be presented.

2. Medicinal Product Mock-ups – Definitions and General Principles

2.1. Mock-up Definition:

Mock-up is the proposed graphic design of the outer and immediate packaging in full colour, which clearly shows the three-dimensional leyout of texts on the packaging.

2.2. When Should Mock-ups Be Submitted?

2.2.1. New Marketing Authorisation

National Procedure:

In the case of applications for new marketing authorisation (hereinafter referred to as "MA"), Czech mock-ups form part of the submitted documentation (module 1.3.2). It is also acceptable to commit to submitting the mock-ups in the course of the assessment phase of the procedure in which they are to be assessed as part of scientific assessment of the documentation.

If the submitted mock-ups are not accepted, the comments are included in the assessment report as an annex to the remedy the deficiencies in the application.

MR/DC Procedure:

In the case of applications for new marketing authorisation, common mock-ups form part of the submitted documentation (module 1.3.2). It is also acceptable to commit to submitting the common mock-ups in the course of the assessment phase of the procedure.

Mock-ups for the Czech market in line with the relevant translations of texts on the labelling should be submitted no later than 7 days after the end of procedure (EoP) along with Czech translations of product information. It is also acceptable to submit the mock-ups later in the national phase of the procedure in which they are to be assessed, but prior to the issue of the Marketing Authorisation.

If no mock-ups for the Czech market are available in the national phase of the procedure, the submitted mock-ups will be considered to be the common ones, which, in this case, would be assessed only in the national (rather than the European) phase of the procedure. Nevertheless, upon the subsequent placement of the product on the market, the marketing authorisation holder (hereinafter referred to as the "MAH") shall be obliged to place the product on the market only in packaging which is fully identical to these common mock-ups in terms of graphic features (graphic design, size, type and layout of the text) with texts corresponding to the relevant approved texts on the labelling (i.e., in the Czech language). Such mock-ups for the Czech market should also be sent by e-mail to mock-upy@sukl.gov.cz no later than 3 months prior to the placement on the market.

In case a (common or Czech) mock-up of a medicinal product is approved for a new marketing authorisation and thereafter, the MAH plans to place the product on the market in another mock-up, it is necessary to submit an application for variation to marketing authorisation (see "Change to Mock-up Design" below).

2.2.2. Variations to Marketing Authorisation

If a mock-up (module 1.3.2) is being submitted with the documentation upon any variation to MA (incl. P variations), its submission must be ticked in the relevant part of the application form.

Change to Mock-up Design:

Application for variation to MA is required when the design of the packaging changes from the previously approved version (e.g., change in colour, change in font size, addition/removal of symbols and pictograms, adjustments in text layout, etc.). In case of minor changes to mock-ups which do not adversely affect readability (such as larger font size, minor change in colour of the font to enhance contrast, small shifts of text or graphic element positions), it is not necessary to submit the variation to MA.

A change to mock-up design shall be submitted via national variation to labelling or package leaflet not associated with the SmPC, so-called **type P variation**, submitted on the REG-90 application form (also for products authorised via the MR/DC procedure). Applications for type P variations shall be submitted for each medicinal product (i.e., MA Number) individually. It is also acceptable to submit the change to mock-up design as an application for type IB variation of the relevant classification.

In addition to the newly proposed version of the mock-ups (so called "proposed version") it is recommended to include in the documentation also the previously approved version of the mock-ups (so called "present version"), if available.

The timelines for the submission of these variations are the responsibility of the MAH, with regard to statutory timelines for the processing of the concerned application for variation. The concerned application for variation, however, has to be approved prior to the placement of the product in the concerned mock-up version on the Czech market.

In case of doubts as to whether a change to design requiring the submission of a variation to MA is concerned, it is possible to send an enquiry to e-mail address mock-upy@sukl.gov.cz with the mock-up (i.e., the present and proposed version) attached.

Change to Mock-ups Resulting from Other MA Variations:

More extensive changes to the texts on labelling may result in change to the layout of data on the mock-ups, impacting their readability.

Where such change has an impact on the data on the mock-ups, e.g., when the classification for supply of the product has changed, a warning box is added on the packaging, or the full product name and its presentation significantly changes, etc., along with the application for such variation, the MAH shall submit also the mock-up with the proposed new text layout. In case the MAH does not submit the mock-ups and, in the course of assessment of the variation in question it is found out that mock-up submission is necessary, the MAH may be **invited by the Institute to submit them within the relevant MA variation procedure**.

Change or Addition of a New Container

The proposed mock-up must be also submitted with applications for MA variations concerning change to the container or addition of a new container (e.g. addition of a bottle as an alternative type of immediate packaging of a medicinal product previously authorised only in blister).

2.2.3. Transfer of Marketing Authorisation

In the case of MA transfer to another MAH, mock-ups should form part of the submitted documentation (module 1.3.2). If no mock-ups are submitted in the MA transfer procedure, the new MAH is deemed to intend to keep the currently approved mock-ups (see point (a) below).

If no mock-ups for the Czech market are available upon MA transfer, the new MAH shall be obliged to submit such mock-ups to the Institute for assessment no later than 3 months prior to placement on the market, and do so either:

a) by sending them to e-mail address mock-upy@sukl.gov.cz – only in case the graphic design and text presentation (i.e., size, type and position of the text) of the mock-ups placed on the market remain unchanged, i.e., they are identical to the originally approved mock-ups of the previous MAH and there is only a text amendment (change to the name and address of the MAH); or
b) by submitting a change to the mock-up design (see section 2.2.2.) – in case the mock-ups placed on the market are not identical in terms of graphic design with the originally approved mock-ups of the previous MAH.

2.2.4. Renewal of Marketing Authorisation

The submission of mock-ups as part of applications for MA renewal of nationally authorised medicinal products is not required. If mock-ups are attached to the submitted documentation, they will be subject to standard assessment. If, in the course of assessment of the concerned MA renewal, it turns out that mock-up submission is needed, the MAH may be invited by the Institute to submit them within the scope of the concerned procedure. Within the scope of an application for MA renewal, it is, however, possible to change

the mock-up design, to introduce multilingual packaging, change the number of languages in which data on the labelling are provided, or introduce foreign-language labelling.

In case of application for standard MA renewal of products authorised via the MR/DC procedures, it is not possible to submit or change mock-ups.

2.3. How to Submit Mock-ups?

The submission of mock-ups is governed by the following requirements:

- As a standard, mock-ups should be submitted in the **pdf. format**, although other formats (such as .jpg; .doc) are also acceptable.
- The submitted mock-up design shall **clearly demonstrate the real size of the final packaging and used fonts** – it is advisable to incorporate also a drawing scale or data about dimensions; the used font sizes may be also directly specified.
- The mock-up shall be submitted **for each MA Number** of the medicinal product, specifically **for the smallest pack size** which will be marketed. If a smaller pack size than the one for which the mock-up has been approved is to be placed on the market, it is necessary to submit an application for type P variation only in case the readability of the text on the labelling is affected. Where larger pack sizes are subsequently placed on the market, no mock-ups need to be submitted. An exception to the rule are products for which the individual pack sizes are graphically different (especially in terms of colour), or products where the strength is expressed as concentration, but individual packs differ in the total amount of the active substance (and, at the same time, the entire volume is typically administered *en bloc*). For such products, it is necessary to submit a mock-up **for each pack size** to be marketed.
- Mock-ups shall be submitted for **each approved type of packaging and container** to be marketed (i.e., outer packaging including multipacks and all types of immediate packaging if the individual types of immediate packaging graphically differ from each other).

3. Mock-up Assessment Criteria

Each mock-up is assessed individually on the basis of all of the below-listed criteria. The conclusions of the overall assessment of a mock-up or the assessment of individual aspects cannot be directly applied to the mock-up of another medicinal product. The essential principles according to which a mock-up should be submitted and on the basis of which the Institute assesses mock-ups, are detailed below.

Any data shown on the mock-up must be fully consistent with the relevant currently approved text on the labelling (see section 3.6. below).

3.1. Presentation of the "Full Product Name"

So called "full product name" is important for straightforward and unequivocal identification of the medicinal product and its proper and safe use. For this reason, it has to be given a prominent position on the mock-ups (i.e., a position where such name will be clearly visible).

The full product name contains the following data:

- **Name of the medicinal product** (common/invented), incl. any qualifiers, if applicable
- **Strength,** incl. units, if applicable
- **Pharmaceutical form**

For the purposes of unequivocal identification of the medicinal product, these data should be shown on the mock-ups **in sufficiently large size, more distinctly than other data, all in one field of vision, in the same spatial orientation and in order consistent with the full product name, i.e., name + strength with units + pharmaceutical form. In every occurrence on the packaging, the name of the medicinal product shall be followed by the strength and the pharmaceutical form (if relevant). The full product name does not have to be presented on one line on the mock-ups.**

- Graphic elements and other text must not interfere with these data and affect their visibility or readability and must not separate them visually.
- Highlighting some of the letters of the name with large font or font in another colour is generally not appropriate, as it may hinder readability. Such presentation could be also considered an element of promotional nature. Exceptions may be granted where such highlighting facilitates safer use of the product.
- The name of the medicinal product on the mock-up may be shown in upper case (MEDICIN), with first capital letter only (Medicin), or all in lower case (medicin).
- In respect of medicinal products placed on the market in a box, it is recommended to position the full product name on the outer packaging at least on three non-opposite sides of the box, where practicable.
- Trademark symbols ® and ™ may be placed on mock-ups (and hence also on the product packaging placed on the market), nevertheless, the placement of these symbols is the responsibility and competence of the applicant/MAH. These data shall not be included in the texts on labelling.

3.2. Other Important Data

- **Active substance –** if the name of the product is an invented name, the active substance shall be shown at least once on the front side of the mock-up, immediately next to the full product name. If the name of the product is a common name (i.e., INN + MAH), the active substance may be shown in any position on the mock-up.

  The active substance does not have to follow every full product name occurrence on the mock-up.
- **Total pack content** – particularly for products where the strength is expressed as concentration, but individual packs differ in the total content of the active substance, it is advisable – for safety reasons – to clearly distinguish also individual pack sizes given by the total amount of the active substance (e.g., the product strength is expressed as 10 mg/ml and pack sizes are 5 ml, 10 ml, etc.).
- **Essential safety precautions/information** – such information on the packaging should always be sufficiently distinguished from other data.
- **Distinguishing a product with new excipient composition affecting the organism** – where the composition of the medical product changes in terms of its excipients affecting the organism (listed under the Guideline on Excipients), the Institute recommends to reflect this fact on the packaging so as to be able to easily and unequivocally distinguish between the packaging of the medicinal product in the original and new composition at first sight (e.g., by highlighting the presence of the newly added excipient). The Institute recommends maintaining such highlighting for the full period when the medicinal product in the original and new composition is marketed in parallel, i.e., until the expiry of the product in the original composition.

3.3. Font Size and Readability

The font size should be at least 7 points, or such where the letter “x” is at least 1.4 mm high.

Nevertheless, whenever there is enough space on the packaging, bigger font sizes than the minimum permissible one should be used.

At the same time, however, the mock-up of the outer packaging, or of the immediate packaging where there is no outer packaging, must provide sufficient space where a clearly legible record of the prescribed dosage will be made.

The overall readability is affected also by other factors that may require a bigger font size or adoption of other measures to maintain readability – this concerns, in particular, a difficult-to-read font, insufficient contrast (such as light font on light background), unsuitable material or background effects (e.g. glossy, metallic or reflex background), etc. The applicant/MAH should take such factors into consideration when preparing the mock-ups. **The selected font must be always well readable and contrast with the background.**

3.4. Distinction of Strengths, Pharmaceutical Forms, and Pack Sizes

If several strengths of a medicinal product have been authorised, the mock-ups of individual strengths have to be clearly distinguished from each other in order to reduce the risk of confusion of individual medicinal products (ideally by colour-coding or by showing the strength in a significantly bigger font size).

Likewise, in some cases, it is desirable to distinguish various pharmaceutical forms (particularly those that are similar – such as nasal drops/nasal spray), or even pack sizes, if relevant (particularly for injection and infusion products, where the strength is expressed as concentration, but individual packs differ in the total content of the active substance).

Distinction by colour may assume the form of application of colour directly on the concerned distinguishing information [expression of strength/pharmaceutical form/pack size (total content of the active substance)], showing the distinguishing information in fields of various colours, or selecting a particular colour scheme for the entire mock-up. The chosen colours (or hues of one colour) should sufficiently differ from each other and should be used consistently for all types of containers for the same strength and pharmaceutical form (if relevant).

Pack size should be shown in sufficiently big and distinct font and visually separated from other data. In respect of pack size, it is possible to highlight only the numeral in the text (e.g. by employing a bigger font).

For medicinal products placed on the market in cartons, the Institute recommends to show the pack size on the outer packaging on at least three non-opposite sides, if practicable.

Graphic presentation of a numeral without unit is not acceptable on mock-ups and it is not consistent with the texts on labelling. This applies particularly to the strength of the medicinal product, which must be always shown with the unit, and to pack size.

3.5. Graphic Elements, Symbols, and Pictograms

Product labelling may incorporate symbols or pictograms intended as an explanation of particular data provided on the product labelling or in the package leaflet, as well as other data that may be useful for the patient. **Such data must be consistent with the Summary of Product Characteristics and must not contain elements of promotional nature.**

Symbols and pictograms without any relation to the product information, those that are not useful for the patient, serve primarily for marketing purposes (are of promotional nature), are presented in an inappropriate or appealing manner (such as indications or other information expressed in the form of a

drawing intended to attract attention), or that are misleading, incomprehensible or confusing shall be considered unacceptable graphic elements.

All graphic elements on the packaging of medicinal products must be positioned in a manner which does not hinder the visibility and readability of mandatory data, in particular, the full product name. This applies also to their overall size, distinction, and colour.

Each graphic element is assessed individually with regard to the specific properties of the concerned medicinal product mentioned in the product information taking into account the type, size, and presentation of the graphic element under review.

This Guideline is without prejudice to the obligation to show other symbols as required by effective legislation (such as labelling with the international radioactivity symbol).

Some Examples of Acceptable Graphic Elements on Medicinal Product Packaging:

- **Representation of the pharmaceutical form/administration aid, etc.**

A graphic representation of the pharmaceutical form or administration aid may be useful for easy identification of the medicinal product; **the representation of the pharmaceutical form must correspond to the product information** (particularly the product description in section 3 of the SmPC) **and the representation of an administration aid must correspond to the actual appearance;** schematic representation of such a graphic element (contours only) is also acceptable.

A mock-up may show only such application aids that form part of the medicinal product package.

A mock-up may show the type of immediate packaging, such as a bottle, prefilled pen, sachet, etc.

- **Instructions for Correct and Safe Use of the Product**

Graphic instructions for correct use of the product (such as taking tablets out of blisters or other handling of the medicinal product) are generally acceptable **provided that they are completely unequivocal and comprehensible.** Where such instructions for use form an integral part of the labelling texts, they shall be provided on the mock-ups in identical representation.

- **Indication/Application Site Illustrations**

Graphic representation of the indication/administration site may be useful for the patient, nevertheless, it **must be strictly consistent with the product information, unequivocal, and comprehensible.**

In the case of multiple indications or administration sites of the product, it is not acceptable to provide a graphic representation of only some of them.

- **Medicinal Product Flavour**

Graphic representation of the product flavour must be consistent with the SmPC or with the product name, if applicable.

- **Administration Time Symbols**

For some products, it is acceptable to provide a representation of the product administration time (e.g. symbols for the morning/noon/evening). These symbols, however, must be consistent with the data provided in the SmPC and must be applicable to all patient groups for whom the product is indicated.

- **Recycling Symbols**

The use of symbols on the packaging is governed by the Act on Packaging. The packaging of medicinal products may show recycling symbols except for the "figure with the waste basket", as it could mislead the patient to throw the packaging and the unused product into municipal waste.

- **MAH's Logo**

The logo of the MAH or of the parent business group to which the MAH belongs may be placed on the mock-up as long as it corresponds to the actual MAH, it is of adequate size, it does not hinder the visibility and readability of other data, does not give a misleading impression, and cannot be confused with the product name. MAH's logo is acceptable on the mock-ups of both outer and immediate packaging, without the necessity of including the words "MAH Logo" in the texts.

Under the same conditions, it is possible to place also the logo of the local representative of the MAH on the mock-up. Its placement is governed by EMA Guideline on the packaging.
No other logos (e.g., distributor's logo) may be shown on the mock-up.

- **Non-specific Graphic Elements**

Design elements that serve for the distinction of medicinal products from each other and that are of no specific meaning (such as colour stripes, fields, geometric shapes, ornaments, patterns, etc.) are acceptable on mock-ups as long as they do not adversely affect the visibility and readability of text data. Such graphic elements may also serve for the distinction of individual strengths, pharmaceutical forms or pack sizes, where the total content of active substance differs.

3.6. Consistency with Texts on Labelling

The texts stated on mock-ups must be fully consistent with the currently approved texts on labelling, which is entirely the responsibility of the MAH.
Text data associated with graphic elements which do not form part of the approved texts on labelling, such as 12 H (short for "12 hours") cannot be placed on mock-ups.

Furthermore, a mock-up must or may include other data which, however, do not form part of the texts on labelling under approval:

Mandatory:

- **SÚKL code** (in compliance with Section 37(1) of the Act on Pharmaceuticals and Annex 5(A)(7) to the Marketing Authorisation Decree).
- **An internationally recognised identification standard** (in compliance with Section 37(1) of the Act on Pharmaceuticals and Annex 5(A)(1)(o) to the Marketing Authorisation Decree).
  (See section 3.9. below - Internationally recognised identification standard, SÚKL code, QR code/other scanning technologies and safety features)

Acceptable:

- Trademark symbols ® and ™. Please note that, in the assessment of mock-ups, the Institute disregards intellectual property and registered trademark aspects.

- Other text information about trademarks/licences/etc. – the MAHs may print this information themselves, provided they comply with the national legislation governing this area (Act on Trademarks).

Headings of individual sections of the QRD template are not normally placed on mock-ups. Should the applicant/MAH plan to place them on the mock-up, it is necessary to use the QRD template heading in its entirety – unabbreviated (e.g., "List of excipients" rather than just "Excipients"). In case an abbreviated heading is used on the mock up (such as "Excipients"), this text must be also provided directly in the relevant section of Labelling.

3.7. Introductory Terms for Expiry Date and Batch Number

Annex IV to QRD template stipulates specific introductory terms for individual EEA countries, which must be placed next to the expiry date and batch number data, and, where applicable, it sets forth further specific particulars.

Introductory terms must be positioned together with the specific data so as to clearly indicate which data they refer to.

For the Czech Republic, Annex IV to the QRD template stipulates that the introductory terms must be always used, even on small immediate packaging or blisters.

Acceptable introductory terms pursuant to the currently effective version of this Annex are as follows:
For expiry date: "**EXP**" or "**Použitelné do:**"
For batch number: "**Lot**" (possibly "**LOT**"); "**č.š.:**" or "**Č. šarže**"

In case the introductory terms are added to the packaging only during manufacture along with the expiry date and batch number (e.g., printed or embossed), the mock-ups must clearly indicate **where the data will be located and the exact wording to be used**.

3.8. Braille

The name of the medicinal product in Braille must be shown on the product packaging, unless the Marketing Authorisation stipulates otherwise. The specific text data which must be provided in Braille are set forth by the relevant section of Labelling.

To ensure the data in Braille are comprehensible and well readable for blind or partially sighted Czech patients, **the Czech version of Braille must be used** on mock-ups intended for the Czech market.

The mock-up shall display the position and the specific Braille symbols.

Where it is necessary to provide the name in Braille on more than one side of the outer packaging (e.g., due to lack of space), the Institute recommends to use two opposite sides in order to facilitate orientation for blind or partially sighted patients. Furthermore, the Institute recommends to avoid placing the record in Braille in a manner interfering with the field for the record of prescribed dosage.

3.9. Internationally Recognised Identification Standard, SÚKL Code, QR Code/Other Scanning Technologies and Safety Features

Internationally Recognised Identification Standard:

The outer packaging of a product must show an internationally recognised identification standard, such as the European Article Number (hereinafter referred to as the "EAN code") or a two-dimensional barcode (hereinafter referred to as the "2D code"). In terms of mock-ups, it is sufficient to display only the position of the concerned standard.

In respect of products, for which it is mandatory to provide a unique identifier in the form of the 2D code after 9 February 2019, the EAN code may continue to be shown on the packaging unless it hinders the readability of other data.

For EAN codes, it is recommended not to use other lines in its vicinity (e.g., to put the code in a frame), as for some types of EAN code readers, this may cause problems with readability.

SÚKL Code:

The outer packaging, or the immediate packaging where there is no outer packaging, must show the code allocated by the Institute (SÚKL code); it is not necessary to put this detail on the mock-up. The Institute recommends introducing

the numeric code with the words "SÚKL code" for easier orientation. Neither this code nor its introductory words are provided in the Labelling. SÚKL code should not form part of the unique identifier (UI) or data in human-readable format associated with the UI.

QR Codes and Other Scanning Technologies, Including Separate URL Address:

A QR code (Quick Response Code) is a two-dimensional barcode which is one of the examples of technologies that may serve patients or healthcare professionals for easy access to information on the particular medicinal product via smartphone or another suitable device.

Guidance concerning the use of these technologies on medicinal product labelling is provided in the "CMDh position paper on the use of Mobile scanning and other technologies to be included in labelling and PL in order to provide information about the medicinal product".

The placement of a QR code or other scanning technologies on the mock-up must not adversely affect the visibility and readability of other data. The mock-up must be submitted already at the time of the application for the addition of this technology and the mock-up must clearly show the actual size and placement of the scanning technology. The scanning technology may be placed also on the inner side of the lid/flap of the packaging.

Along with the QR code proper or other scanning technology, the URL address must also be shown so as to provide access to the information also to those users who do not own a suitable scanning device. According to the aforementioned document, it is possible to place the URL address alone, without scanning technology, on the packaging. The requirements governing readability shall apply also to such URL address.

In case of multilingual labelling it is advisable to use one QR code/scanning technology referring to a website serving as a directory to individual language mutations.

Safety Features:

Safety features consist of a unique identifier and an anti-tampering device, which allow for unequivocal identification of the medicinal product and authentication. Detailed guidance on safety features is provided in Commission Regulation 2016/161. Additional details are available from the EC Safety Feature FAQ Document, CMDh and EMA implementation plans as well as from the websites of SÚKL or NOOL (the National Medicines Authentication Organisation).

For mock-ups, it is sufficient to display **only the position of the safety features** (unique identifier and data in human-readable format). The product code (PC) and serial number (SN) are the data elements of the unique

identifier; these data must be printed on the packaging also in human-readable format so as to allow for the verification of the authenticity of the unique identifier and its decommissioning in case the 2D code is unreadable. The PC and SN data elements do not have to be on the packaging in a human-readable format, as long as the sum of the two longest dimensions of the packaging is less than or equal to 10 cm, nevertheless, their placement is also possible in this case. Data in human-readable format (PC, SN) must be placed next to the 2D code on the packaging, if practicable considering the nature of the packaging. The Act on Pharmaceuticals does not require the introduction of a national reimbursement number or another national number identifying the medicinal product in the NN format on the outer packaging of medicinal products.

The expiry date and batch number are mandatory data to be shown on the packaging of medicinal products, as required by the Marketing Authorisation Decree independently of safety features. The expiry date and batch number do not have to be located in the vicinity of the 2D code.

The order of data in human-readable format is to be decided by the manufacturer and it does not have to follow Art. 4(b) or Art. 7(1) of Commission Regulation 2016/161.

Minimalizing the Number of 1D/2D Codes on the Packaging

The presence of a larger number of two-dimensional barcodes on the packaging could be confusing. For this reason, it is not possible to provide multiple two-dimensional barcodes on the packaging of medicinal products for the purposes of identification and authentication.

Commission Regulation 2016/161 allows for the placement of both a code allowing patients and/or healthcare professionals easy access to information on the particular medicinal product via smartphone or another suitable device and a 2D code with safety features on the packaging of medicinal products. Nevertheless, where technically practicable, it is recommended to use a **single 2D code** incorporating both information from the QR code/other scanning technology and information on safety features.

The outer package of a medicinal product must show an internationally recognised identification standard, which may be, for instance, the EAN code or 2D code. In respect of products, for which it is mandatory to provide a unique identifier in the form of the 2D code after 9 February 2019, the EAN code may continue to be shown on the packaging unless it hinders the readability of other data. If practicable, however, the Institute recommends that only the 2D code be used for these products, and to limit the parallel placement of the EAN code and 2D code to as short a period of time as possible.

3.10. Blisters

The mandatory data on blisters should be printed multiple times and placed irregularly so as to remain readable and available to the patient until the last dose is used.

For single-dose blisters, it is necessary to provide all of the data on each individual section of the blister (incl. expiry date and batch number).

3.11. Multilingual and Foreign-Language Labelling

When using **multilingual labelling**, it is necessary to conceive the overall design and data layout in a manner providing sufficient space for all languages to be displayed clearly and in sufficient size, legibility, and clear distinction of the individual language mutations. The data in all languages must be identical, except for blue-box data stipulated by CMDh guideline “Blue-box requirements”.

The number of languages on the outer packaging, immediate packaging and in the PL does not have to be consistent, i.e., it is possible to have a multilingual immediate packaging and PL in a single-language carton.

Multilingual packaging may be introduced within the scope of new marketing authorisation, renewal of the marketnig authorisation for nationally authorised medicinal products, or variation to existing marketing authorisation. Where a multilingual packaging is introduced after the medicinal product has been authorised, it is necessary to submit the national application for Type P variation.

In respect of nationally authorised products, the Institute, moreover, requires a MAH's declaration stating that the data provided in the SmPC, PL and on the mock-ups are identical in all languages. If the information for nationally authorised products is not identical, the texts need to be harmonized by means of variation prior to the introduction of multilingual labelling.

The submission of the national application for Type P variation is required only where the number of languages, in which the texts on labelling are provided, is being increased.

If the number of languages is being reduced (e.g., from CS/SK to CS), or if the language on a previously approved multilingual packaging is being changed (e.g., from CS/SK to CS/PL), it is sufficient to send this information by e-mail to mock-upy@sukl.gov.cz.

In case there is not enough space to print the active substance(s) in all of the relevant national languages of the multilingual labelling (particularly on small immediate packaging), in compliance with the QRD stylistic matters document, it is possible to provide the name of the active substance(s) in the English language or in Latin. The name of the active substance(s) in the relevant language shall be also provided in the texts on labelling in the QRD template and, in brackets after the Czech name of the active substance(s) in the introductory part of the PL.

In case there is not enough space on the immediate packaging, a simplified ("Patient-Friendly Term") term of the pharmaceutical form may be used (see Table X – Standard names of dosage forms, routes of administration and packaging). In such a case, the simplified name of the pharmaceutical form must be stated also in section 3 of the SmPC and in section 6 of the PL.

If the medicinal product is not intended to be provided directly to the patient or if there are serious problems with the availability of the medicinal product, the Institute may, in the Marketing Authorisation, allow *inter alia* for the texts on labelling to be in a language other than the Czech (so-called **foreign-language labelling**). A foreign-language labelling may be approved in English, German, or Slovak language. The complete conditions governing the use of a foreign-language labelling are stipulated by the Marketing Authorisation Decree.

The applicant/MAH may apply for foreign-language labelling at the time of marketing authorisation of the product, renewal of MA, or separately, via a national application for Type P variation.

4. Preliminary Assessment of Medicinal Product Mock-ups

In case of an application for preliminary assessment of a medicinal product mock-up, the Institute shall issue a written opinion, the costs of which as an expert activity will have to be reimbursed by the applicant as stipulated by Decree No 472/2008 Coll., setting the amounts of reimbursement of costs of expert activities conducted by the State Institute for Drug Control and the Institute for State Control of Veterinary Biologicals and Medicines, as amended (for more details, please refer to UST-29, as last amended, available from the Institute´s website; payment code: O-002).

To allow for the assessment of the design, the applicant shall submit, along with the application for preliminary assessment of the mock-up, the specific mock-up design, present and proposed versions (where relevant), detailed information on the properties of the product, for which the mock-up is intended (envisaged indication, dosage, and method of use of the product, classification for supply, target patient group, composition of the medicinal product; ideally, draft SmPC, PL, and texts on labelling or their currently approved versions if available to the applicant should be submitted) and proof of payment of cost reimbursement. The Institute shall consider applications without the aforementioned particulars invalid and shall request additional information meeting the aforementioned scope. A single application may contain no more than three mock-up designs for a single medicinal product.

It is recommended to send applications for preliminary mock-up assessment electronically to posta@sukl.gov.cz. Thereafter, usually within 30 days, the Institute electronically sends the expert opinion

as to whether the proposed mock-ups are acceptable or not (incl. specific objections) to the applicant. The preliminary assessment always pertains solely to the particular application which has been comprehensive assessment based on all of the required information. No appeal may be lodged against the Institute's opinion.

5. Reporting Medicinal Product Confusion Associated with Similar Packaging

The Institute calls for reporting of medicinal product confusions associated with similarity of their packaging, whether the confusion occurred on the medicinal product supply or use level. Reporting cases where the health of patients could be jeopardised is of special importance. Such reports may be sent by e-mail to mock-upy@sukl.gov.cz.

Note: This is without prejudice to the MAH´s obligation to report any and all adverse drug reactions (incl. medication errors) in compliance with the Act on Pharmaceuticals (pursuant to Section 93a(2)). Healthcare professionals are obliged to report serious or unexpected adverse reactions (incl. medication errors) as stipulated by the Act on Pharmaceuticals; see SÚKL guidelines at sukl.gov.cz/nezadouciucinky.

6. Used Terms and Abbreviations

Alphabetic list of used abbreviations:

- 2D code – two-dimensional barcode
- CMDh – Co-ordination Group for Mutual Recognition and Decentralised procedures - Human
- EAN code – European Article Number
- EC – European Commission
- EEA – European Economic Area
- EMA – European Medicines Agency
- INN – International Non-proprietary name recommended by the World Health Organisation
- MA – Marketing Authorisation
- MAH – Marketing Authorisation Holder
- MR/DC – Mutual recognition/Decentralised procedure
- NOOL – Národní organizace pro ověřování pravosti léčiv (the National Medicines Authentication Organisation)
- PC – product code
- PL – Package Leaflet
- QR code – Quick Response Code
- QRD template – the Quality Review of Documents template for product information
- ® – registered trademark
- SmPC – Summary of Product Characteristics
- SN – serial number
- SÚKL, Institute – State Institute for Drug Control
- ™ – unregistered trademark
- UI – unique identifier
- URL – Uniform Resource Locator, a standardised format for source localisation on the internet (web address)

Used terms:

- MAH – marketing authorisation holder

- Product information – Summary of Product Characteristics, Package Leaflet, and Labelling
- Full product name – name of the medicinal product followed by strength incl. units and pharmaceutical form
- Container – e.g., bottle, blister
- Type of packaging – outer, immediate packaging
- Multipack – multiple container in one pack (aggregate packaging of e.g., two bottles in one packaging, where the single boxes cannot be sold separately)
- Multilingual labelling – data on the labelling of the medicinal product are provided in multiple languages at the same time (incl. the Czech language)
- Foreign-language labelling – data on the labelling are provided in a language other than the Czech
- SÚKL code – code of the medicinal product allocated by the Institute, which identifies the medicinal product, its strength, pharmaceutical form and pack size
- Marketing Authorisation Number – a number allocated by the Institute and specified in the Marketing Authorisation; it identifies each strength and pharmaceutical form of the medicinal product. One Marketing Authorisation Number may have several SÚKL codes (i.e., presentations/pack sizes)
- Pack size – the number of units in one pack (e.g., 30 tablets, 2 vials)