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## Change history

| Version | Valid and binding as of | Description, comments (by author) | Author's initials |
|---|---|---|---|
| 3.1 | 02.03.2020 | Section 6.8.1: Information on further excipients;<br>Section 6.14: EXP / LOT indications and arrow indicating corresponding information (date)/(number) on the other side of the folding carton are permitted;<br>Section 7.4: "Happy tooth" symbol for medicinal products whose use entails prolonged contact with the teeth;<br>Section 11.2: Inclusion or deletion of ® or ™<br>Section 11.3: Deletion of information resulting from inclusion of a data matrix | sab |
| **3.0** | **18.10.2019** | **Reformulation of instruction in the chapter 6.4:**<br>▪ **Statement of the active substance is optional for CHM. No INN is issued for substances or preparations of plant origin, and it is therefore recommended to state a short form of the active substance name for herbal remedies (in two official Swiss languages, e.g. Baldrianextrakt or extrait de valériane (for valerian extract), Baldriantinktur or teinture de valériane (for valerian tincture)).** | **rin** |
| **2.0** | **06.09.2019** | **Section 6.23: Reformulation of instruction "Please read the package leaflet"; Section 6.6: Clarification of information regarding dosage strength for parenterals in freeze-dried form; Addition to section 9.3: Hospital packaging;**<br>**Addition to section 11.3.1: Application type A.100, type IA$_{IN}$.** | **sab** |
| 1.4 | 27.05.2019 | Section 6.14: Specification of month and exp. / lot.;<br>Section 6.15: Addition of company-specific barcode section;<br>Section 8.1: Specification of opened blisters;<br>Section 11.2: Addition on switching around two sides and rotating the printing, deletion +/- 10% for changes in size. | sab |
| 1.3 | 12.03.2019 | Chapter 6.2 and 6.22.1: Explanation to brief description (brief claim) for complementary medicinal products. | zim |
| 1.2 | 05.03.2019 | Addition to section 6.7: Information on number of medical devices included in the pack; Addition to section 6.14: EXP/Lot notice and corresponding information on the same side. | sab |
| 1.1 | 01.01.2019 | New section 10: Specific requirements for sample packs | sab |
| **1.0** | **01.01.2019** | **Implementation of TPO4** | **dts** |

# 1 Definitions, terms, abbreviations

## 1.1 Definitions and terms

### 1.1.1 Name of the medicinal product

The name of the medicinal product is the proprietary name of the medicinal product

### 1.1.2 Packaging

Packaging refers to the container / pack in which the product (goods) is packed. It refers to both the primary and secondary packaging.



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### 1.1.3 Container, primary packaging

Primary packages / primary packaging materials are packaging materials that are, or potentially may be, in direct contact with the dosage form. Instead of primary packaging, the term container (e.g. bottle, blister, ampoule, pre-filled syringe, can, tube) is also used.

### 1.1.4 Folding carton, secondary packaging

Secondary packages/secondary packaging materials are outer packages that are not in direct contact with the object to be packed and that usually have a protective and control function. The folding carton is a secondary package for a medicinal product.

### 1.1.5 Multipack

A multipack is a package consisting of several individual packs (individual packaging materials). The individual packs are either combined in an appropriate manner (e.g. with a cellophane wrapping or plastic strips), where a label is affixed to the multipack, or the individual packs are packed in a large folding carton with the corresponding information.

### 1.1.6 Combination pack

Combination packs (combi-packs) are packages containing various, separately arranged medicinal products, which are intended to be used together for the same use.

### 1.1.7 Medicinal product information, medicinal product information texts

These refer to the Information for healthcare professionals and Patient information as a whole.

### 1.1.8 Package leaflet

The package leaflet is generally the Patient information.
For prescription-only medicines that are predominantly used in hospitals, the package leaflet can also be the Information for healthcare professionals.

### 1.1.9 Packaging texts

These refer to the texts and other information, including graphic elements, on the packaging (primary and secondary packaging).

### 1.1.10 Dosage form

Dosage form refers to the delivery form (e.g. metered dose spray) including the pharmaceutical form (e.g. suspension). The description of the dosage forms must conform to the EDQM Standard Terms.

### 1.1.11 Route of administration

The route of administration is the manner in which the product is administered. The description of the route of administration should conform to the EDQM Standard Terms.

## 1.2 Abbreviations

| | |
|---|---|
| AD | Authorisation document |
| Ann. | Annex |
| CHM | Complementary and Herbal Medicines |
| DCI | Denominatio Communis Internationalis, international generic name of active pharmaceutical ingredients |
| EDQM | European Directorate for the Quality of Medicine & Healthcare |
| FC | Folding carton (secondary packaging) |
| FOPH | Federal Office of Public Health |
| GMFO | FDHA Ordinance of 23 November 2005 on Genetically Modified Foodstuffs (SR 817.022.51) |
| GMO | Genetically modified organism |
| HMP | Human Medicinal Products |
| IHC/PI | Information for healthcare professionals / Patient information |



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| | |
|---|---|
| INN | International Nonproprietary Name |
| IU | International units |
| Known API | Medicine with known active pharmaceutical ingredient |
| LS | List of pharmaceutical specialities |
| MAH | Marketing authorisation holderNarcCO Ordinance of 25 May 2011 on Narcotics Control (SR 812.121.1) |
| MPI | Medicinal product information (Information for healthcare professionals and Patient information) |
| NarcLO-FDHA | FDHA Ordinance of 30 May 2011 on the Lists of Narcotics, Psychotropic Substances, Precursors and Auxiliary Chemicals (SR 812.121.11) |
| OP | Original print |
| OTC | Over the counter (non-prescription medicines) |
| pt | Point (unit for font size) |
| TPA | Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21) |
| TPAO | Ordinance of 17 October 2001 on the Advertising of Therapeutic Products (SR 812.212.5) |
| TPLRO | Ordinance of the Swiss Agency for Therapeutic Products of 9. November 2001 on the Licensing Requirements for Therapeutic Products (SR 812.212.22) |
| TPO | Ordinance of 21. September 2018 on Therapeutic Products (Therapeutic Products Ordinance, TPO) (SR 812.212.21 |

# 2 Introduction and purpose

This guidance document explains how primary and secondary packaging (packages) for human medicinal products must be labelled and how it may be designed.
Swissmedic uses the document as a resource for implementing the legal provisions on requirements pertaining to packaging texts in a uniform and equitable manner. The guidance document is intended to clarify the specific requirements that must be fulfilled so that corresponding applications can be processed as quickly and efficiently as possible.

# 3 Scope

This guidance document is valid for the Authorisation division of Swissmedic and is applicable to the labelling and design of packaging for human medicinal products. Unless the guidance document *Authorisation of individual teas, cough and throat lozenges and pastilles in the notification procedure HMV4* contains more detailed or different regulations, medicinal products whose authorisation is described in that document are also governed by this guidance document.
For homeopathic or anthroposophic medicinal products with no indication that are authorised by the notification procedure or with a reduced dossier, the requirements stipulated in Annex 1a TPLRO shall as a rule apply. Asian medicinal products authorised by the notification procedure are subject to the requirements stated in Annex 1b TPLRO. Unless these Annexes of the TPLRO contain more detailed or different regulations, the corresponding medicinal products with no indication are subject to the requirements of this guidance document.

# 4 Legal framework

The TPA, the TPO and the TPLRO constitute the legal basis. For provisions on the labelling of narcotics, the NarcCO and the NarcLO-FDHA also apply.

# 5 Assessment principles

## 5.1 General principles

In accordance with the general provisions of Art. 1 TPA, approval is not granted for packaging that jeopardises drug safety, misleads patients, leads to inappropriate or excessive use or distorts information about the medicinal product.



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As a general rule, the packaging may only display information that is useful, necessary, clear and not misleading (Art. 12 para. 1 TPLRO).
For ease of readability, text on the packaging must have a minimum font size of 7 pt. (Ann. 1 no. 1. para. 1 TPLRO).

### 5.2 Language

According to Art. 26 para. 1 TPO, the information on the packaging must be drafted in at least two of Switzerland's official languages (official languages are German, French and Italian).
The marketing authorisation holder may also include other languages (e.g. EU languages, Arabic, etc.) provided the mandatory information in the required languages is clearly legible and meets the requirements for font size.
Swissmedic approves the packaging texts in the correspondence language; the marketing authorisation holder is responsible for ensuring that the information in other languages is correct. Swissmedic does not check this.
The composition of the medicinal product can be stated in the official Swiss languages along with internationally customary short forms such as the International Nonproprietary Name (INN) of the World Health Organisation or in Latin (Art. 26 para. 3 TPO).
Packaging texts for medicinal products that are intended exclusively for use in hospitals or by defined medical specialists can be drafted only in one official Swiss language or in English (Art. 26 para. 4 TPO).

## 6 Packaging texts

### 6.1 Overview of the information on the primary packaging

The following information on the primary packaging, i.e. the container intended for dispensing, is required in all cases:

| Information | Requirements |
|---|---|
| ▪ **Name of the medicinal product** | mandatory, if necessary stating the dosage strength, dosage form and quantitative content of the individual pack (primary container) |
| ▪ **Batch number** | mandatory |
| ▪ **Expiry date** | mandatory |

The following information is also required on the primary packaging, although this can be **omitted**, subject to authorisation by Swissmedic, if its inclusion does not appear to be possible for technical reasons (e.g. very small primary containers):

| Information | Requirements |
|---|---|
| ▪ **Active substances** | up to 3 active substances (up to 2 for parenteral products), by type and quantity, concentration in internationally recognised units; optional for CHM, recommended for herbal medicines (short form) |
| ▪ **Additional designation of the type of medicinal product (e.g. homeopathic medicinal product)** | mandatory for CHM |
| ▪ **Dosage strength** | mandatory if several dosage strengths exist |
| ▪ **Route of administration** | mandatory for parenteral products |
| ▪ **Use-by period after the pack is opened** | if applicable |
| ▪ **Storage instruction** | mandatory for parenteral products if different from RT |
| ▪ **Warning regarding children: "keep out of the reach of children"** | |
| ▪ **Marketing authorisation holder** | |



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| | |
|---|---|
| ▪ **Note on package leaflet – "Please heed the package leaflet"** | can be omitted on products used exclusively in hospitals |
| ▪ **EAN code / authorisation number** | Can be omitted for a secondary container |

If, for technical reasons, all of the information cannot be presented on the container intended for dispensing to patients, secondary packaging displaying all the information stated in the following chapter "Overview of information on the secondary packaging" must be provided.



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## 6.2 Overview of the information on the secondary packaging

The following information usually appears on the secondary packaging:

| Information | Requirements |
|---|---|
| ▪ **Name of the medicinal product** | mandatory |
| ▪ **Active substances** | mandatory for up to 3 active substances (up to 2 for parenteral products), which must be stated directly under the name (or in front of the name, in the case of KAS without innovation for which an application for inclusion on the LS as a generic has been submitted to the FOPH); optional for CHM, recommended for herbal medicines (short form) |
| ▪ **Additional designation of the type of medicinal product (e.g. homeopathic medicinal product)** | mandatory for CHM |
| ▪ **Composition** | mandatory |
| ▪ **Dosage strength** | mandatory if several dosage strengths exist |
| ▪ **Dosage form** | mandatory |
| ▪ **Route of administration** | mandatory for parenteral products |
| ▪ **Brief description** | optional |
| ▪ **Quantity with dosage form (number of tablets, ampoules, etc.)** | mandatory |
| ▪ **Use-by period after the pack is opened** | mandatory if applicable |
| ▪ **Storage instruction** | mandatory |
| ▪ **Warning regarding children: "keep out of the reach of children"** | mandatory |
| ▪ **Marketing authorisation holder** | mandatory |
| ▪ **Manufacturer** | optional |
| ▪ **Note on package leaflet – "Please heed the package leaflet"** | mandatory (can be omitted on products used exclusively in hospitals) |
| ▪ **Swissmedic licence symbol / dispensing category** | mandatory |
| ▪ **EAN code / authorisation number** | mandatory |
| ▪ **Batch number** | mandatory |
| ▪ **Expiry date** | mandatory |

## 6.3 Name of the medicinal product

The following notations are permitted in the packaging texts for the name of the medicinal product:

- Multilingual version of the product name
- Lower case, upper case or a mixture of upper and lower case
- Alternating upper and lower case letters in the medicinal product name, known as "tall man letters". The tall man letters must also appear on the labels or blisters.
- Different colouring or different font for name components
- Different font size for name components: the name suffix or prefix must be at least half the font size of the main name, and the main name must be the largest part of the name. The name of the medicinal product should be identifiable as a unit.
- The registered trademark symbol ® or ™. On the other hand, it is not permitted to state "*(name of the medicinal product) is a trademark of (company name)*" (or *license of….*).
- Handwritten name of medicinal product, provided this is additionally stated as printed lettering.
- Name in "quotation marks".
- Printed on two lines, provided the name of the medicinal product remains identifiable as a unit, i.e. the name sections are close together so that it is clear that they belong together.



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- Name of the medicinal product embossed in Braille. The authorisation holder is responsible for the correct implementation of the Braille, which is not checked.
- Symbols in the name of the medicinal product, if these are part of the registered trademark logo.
- For names with abbreviations, the abbreviation should consist of at least three letters. This sequence of letters must not have a separate meaning, potentially leading to misunderstandings.

## 6.4 Active substance

- The WHO, which is responsible for issuing INN, publishes these in Latin, English, French (and also Spanish, Arabic, Chinese and Russian). Therefore, the active substance should be stated in Latin, French or English. In line with current practice, stating the name in the other official Swiss languages (German and Italian) is also acceptable.
- Statement of the active substance is optional for CHM.
  No INN is issued for substances or preparations of plant origin, and it is therefore recommended to state a short form of the active substance name for herbal remedies (in two official Swiss languages, e.g. Baldrianextrakt or extrait de valériane (for valerian extract), Baldriantinktur or teinture de valériane (for valerian tincture)).
- Abbreviations are not permitted, not even for active substance combinations.
- As a rule, the active substance must be stated in its commonly used form. While this can be both the free base/acid and the salt, it must correspond with the stated dosage strength.
- Stating the active substance on the main side of the secondary packaging is sufficient. If the name of the medicinal product is stated in two languages, the active substance should also be stated in both languages.
- The active substance should be stated in a font size that is at least half as large as that used for the name of the medicinal product. For the name of the medicinal product in a font size of up to 24 pt, the font ratio of 1 to 2 should be observed. If a larger font size is used for the name of the medicinal product, a font size of 12 pt for the active substance is sufficient.
- The names of the active substances should appear **directly below** the name of the medicinal product (see example in Fig. 1).

Main side of the folding carton (sample presentation, layout can differ for CHM)

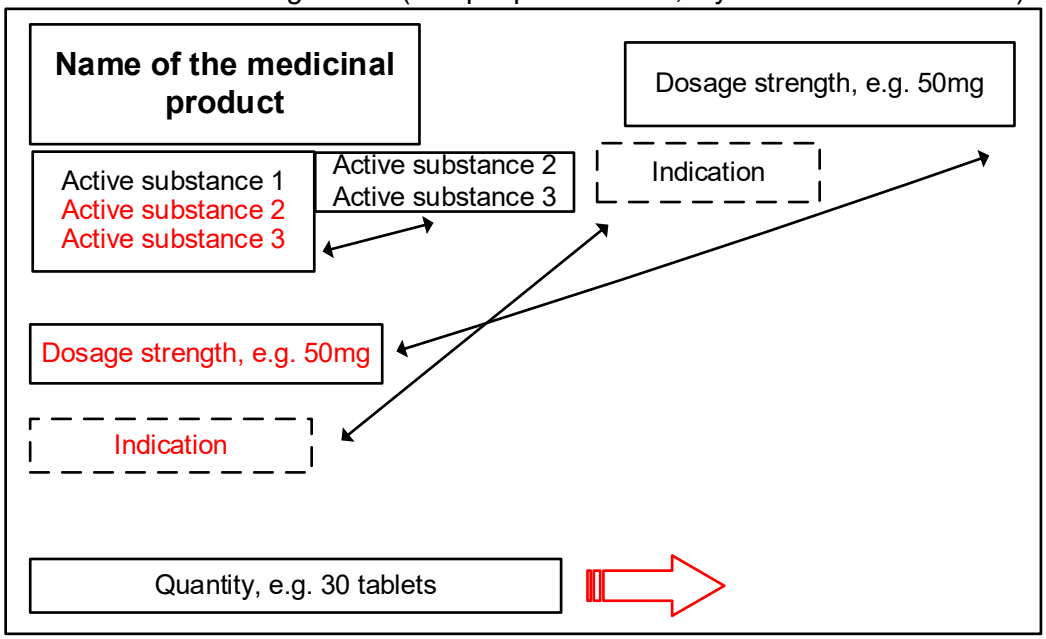


***Figure 1**: Example for medicinal products (solid pharmaceutical form) with up to three active substances*
*Dashed box = optional*
*The variants shown in red are alternative variants. For the dosage strength, the variant shown as appearing on the same line as the name of the medicinal product should preferably be selected.*

On the secondary packaging of KAS products without innovation and containing no more than three active substances, the active substances should be shown **directly in front of** the name of the


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medicinal product if the authorisation holder intends to apply to the FOPH for the product to be included in the SL as a medicinal product that is interchangeable with an original preparation (generic) (Fig. 2).

Main side of the folding carton (sample presentation, layout can differ for CHM)

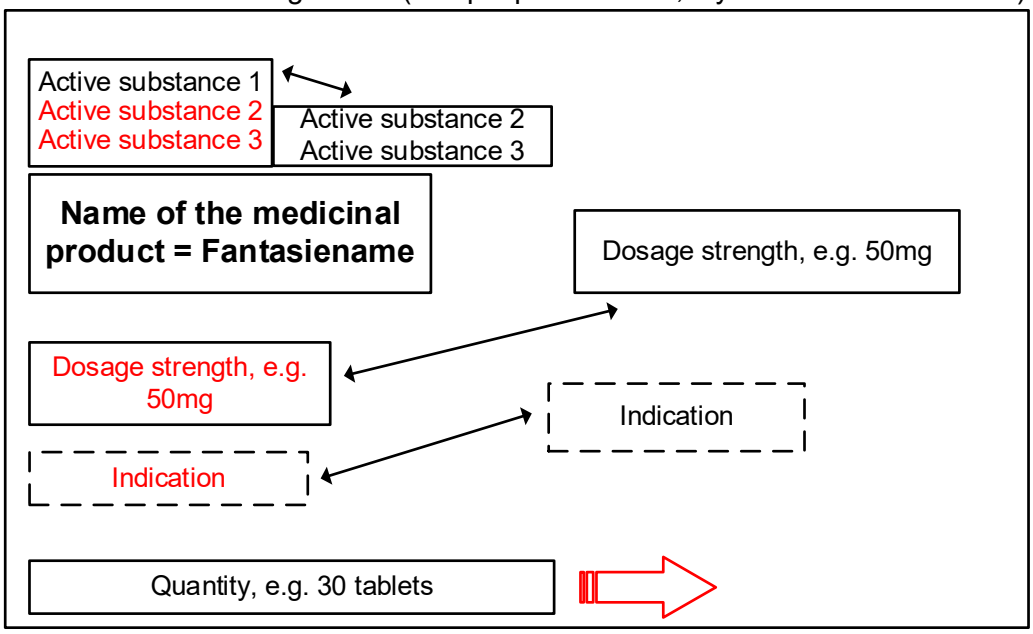


***Figure 2**: Example for KAS without innovation, intended for LS/FOPH with up to three active substances, name of medicinal product = creative name*
*Dashed box = optional*
*The variants shown in red are alternative variants. For the dosage strength, the variant shown as appearing on the same line as the name of the medicinal product should preferably be selected.*
*If sufficient space is available, the active substance name(s) can be shown in front of the proprietary name (creative name) on the same line.*

An exception to this rule can be granted, subject to a corresponding application, for medicinal products that are established with their own brand name. In these cases, the marketing authorisation holder may show the active substance, or substances, directly below the proprietary name.

If the complete (non-abbreviated) INN is included in the name of the medicinal product, the active substance does not need to be stated in addition.

Main side of the folding carton (sample presentation, layout can differ for CHM)

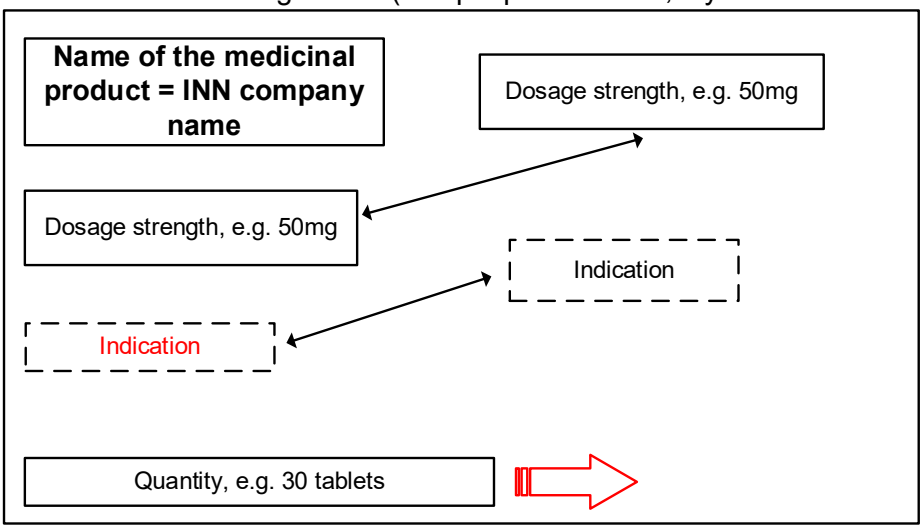


***Figure 3:** Example for KAS without innovation, intended for LS/FOPH with up to three active substances, name of the medicinal product = INN and company name*
*Dashed box = optional*
*The variants shown in red are alternative variants. For the dosage strength, the variant shown as appearing on the same line as the name of the medicinal product should preferably be selected.*



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## 6.5 Dosage form

For capsules, drops, solution for injection, powder for solution for injection and similar dosage forms, the dosage form (= delivery form and pharmaceutical form) must always appear on the packaging elements. If just one pharmaceutical form is authorised under the name of the medicinal product, this can also be stated under Composition.
The description of the dosage forms must conform to the EDQM Standard Terms.

## 6.6 Dosage strength

The dosage strength must be shown on the packaging, particularly if several dosage strengths exist for a medicinal product.
For parenterals, "Total quantity of active substance" and "Total volume" must be stated. (For parenterals in freeze-dried form, the total quantity in mg is sufficient.) For total volumes of less than 1 ml, however, stating the total quantity of active substance per ml is not appropriate and should be omitted.
For parenterals, the concentration must also be stated (if the product contains no more than two active substances). (For parenterals in freeze-dried form, the concentration does not need to be stated). For preparations for which IU are used by default or in the dosage recommendation, this concentration can also be expressed in the form of x IU per ml.
The concentration (mg per ml) does not need to be stated for disposable syringes without graduations and whose full contents are to be administered according to the dosage recommendation.
Main side of the folding carton for parenterals

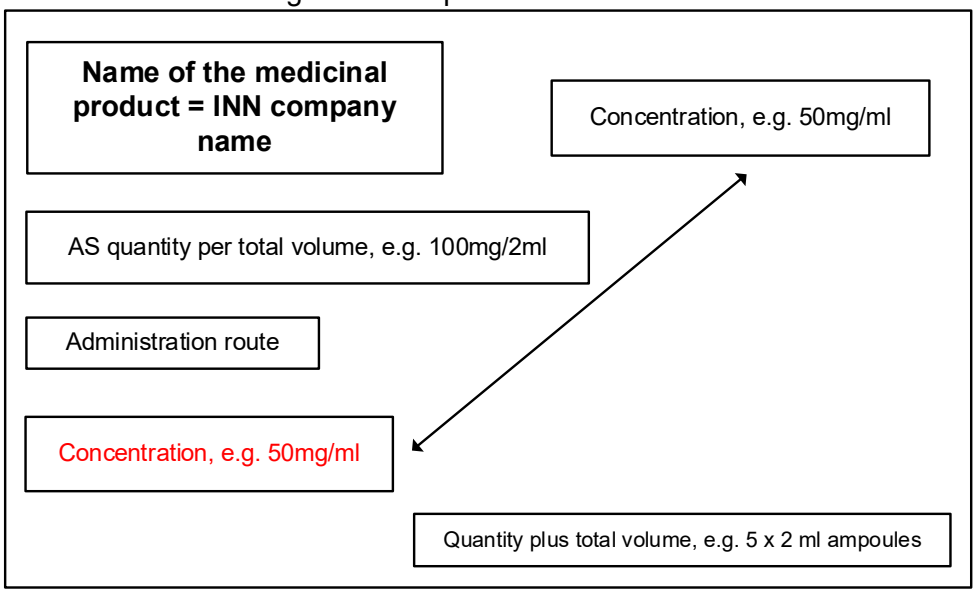


***Figure 4:*** *Example for parenterals, KAS without innovation, intended for LS/FOPH with up to three active substances, name of the medicinal product = INN and company name*

If it can be demonstrated that the legibility of the mandatory information is inadequate due to shortage of space, an exemption (e.g. to reduce the font size) may be requested provided an acceptable reason is given. If the lack of space is caused by the inclusion of non-mandatory information, e.g. logo or similar, this does not count as an acceptable reason.

## 6.7 Quantitative content

Quantitative content and the dosage form (number of tablets, ampoules, etc.) are mandatory. It is not acceptable to state, for example, "20 x" instead of "20 tablets" or "1 x" instead of "1 x 100 ml bottle".
The additional mention of "divisible", e.g. "X divisible tablets" is acceptable, provided the divisibility of the tablets is demonstrated in the documentation on quality.
Any medical devices included in the pack (applicators, alcohol wipes, etc.) must also be listed.


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## 6.8 Composition

### 6.8.1 Declaration of active substances and excipients

In the composition, the active substances must be stated quantitatively and the pharmaceutical excipients of particular interest must be stated qualitatively in accordance with Ann. 3a TPLRO. All excipients can also be stated qualitatively (this is required for parenteral products).

When stating the active substances and excipients, the specific requirements for the heading “Composition” in the Information for healthcare professionals must also be observed (in accordance with the guidance document *Product information for human medicinal products HMV4*).

For the excipients of particular interest listed in Ann. 3a of the TLPRO, the E number (from the list of food additives authorised in the European Union and Switzerland) should also be stated where one exists. Alternatively, only the E number can be stated. If all the excipients contained in the medicinal product are listed in the composition, then it is sufficient to state solely the respective E number where one exists.

The concentration of the extracting agent used for herbal substances and herbal preparations can be omitted if space is short.

Examples:
- Valerianae radicis pulvis
- Valerianae extractum hydroalcoholicum siccum (3 - 6 : 1)
- Valerianae tinctura (1 : 4.0 - 4.5)

Asian active substances should be stated with the pharmaceutical name and the name commonly used in the respective school of medicine (e.g. the Pinyin name for Chinese medicines).

For medicinal products with an alcohol content greater than 100 mg per single dose, the alcohol content should be given in % of volume.

If a medicinal product contains genetically modified organisms (GMO) as an active substance or excipient, the information “contains genetically engineered X”, “contains genetically modified X”, “consists of genetically engineered X” or “consists of genetically modified X” must be displayed on the container intended for dispensing and on the outer pack (Art. 27 para. 2 TPO).

For medicinal products that contain active substances or excipients obtained from GMO that are subject to labelling requirements, the information “manufactured from genetically engineered X” or “manufactured from genetically modified X” (X = name of the GMO) must be placed directly after the substance concerned or marked with (*) as a footnote written in the same font size inserted at the end of the declaration of constituents (Art. 27 para. 3 TPO in conjunction with Art. 7 GMFO).

A title for the composition details is recommended, but not absolutely essential.

| German: | French: | Italian: |
|---|---|---|
| Zusammensetzung: ... | *Composition: ...* | *Composizione: ...* |
| *Zus.: ...* | *Comp. ...* | *Comp. ...* |

If the title is omitted, then "1 Tablette enthält / 1 comprimé contient / 1 compressa contiene" ["1 tablet contains"] can alternatively be stated either at the start of the declaration or following the constituents as "pro Tablette / par comprimé / pro compressa" ["per tablet"].

If not all excipients are listed (full declaration), an indication of the other excipients must be included following the list of declared excipients, e.g. “excipiens pro” / "and other excipients".

### 6.8.2 Negative declaration for the composition

Constituents that are not contained in the medicinal product may not be stated (negative declaration), e.g. "lactose-free", "gluten-free" or "without antibiotics".

## 6.9 Marketing authorisation holder

The marketing authorisation holder must be stated on the secondary packaging with the following title:



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| | | |
|---|---|---|
| German:<br>Marketing authorization holder: ...<br>Zul-Inh.: | French:<br>Titulaire de l'autorisation: ...<br>Tit.de l'AMM | Italian:<br>Titolare dell'omologazione: ...<br>Tit. omol. |

This title may only be omitted if the marketing authorisation holder and the manufacturer are identical. The term "Vertriebsfirma" (Distributeur, Distributore), "Vertrieb" [distributor] is not permitted.

If the legal **registered address and the company domicile (postal address)** are **identical**, the following applies:

| Title | Requirement |
|---|---|
| "Marketing authorisation holder:" | "Marketing authorisation holder" must be used Stated in two official languages in accordance with Art. 26 para. 1 TPO. |
| **Company name**<br>*Division, street, P.O. box, CH-postcode*<br>***locality**, Switzerland* | **bold:** mandatory name of company and registered address as per the commercial register;<br>*italics: optional* (Division, street, P.O. box, postcode, Switzerland), may be selected individually or in combination. If required for identification purposes, the locality of the registered office may, in exceptional cases, be combined with the nearest large town (e.g. Meyrin-Geneva). |

If the legal **registered address and the company domicile (postal address)** are **not identical**, the following applies:

| Title | Requirement |
|---|---|
| "Marketing authorisation holder:" | "Marketing authorisation holder" must be used. Stated in two official languages in accordance with Art. 26 para. 1 TPO |
| **Company name**, *postcode* **locality** | **bold:** mandatory (name of company and registered address as per the commercial register);<br>*italics: optional* (the postcode is permitted but should be omitted since it can be confused with the domicile address). |
| "Domicile:" or "Postal address:" or "Address:" | One of the elements "Domicile:" or "Postal address:" or "Address:" must be used. Stated in two official languages in accordance with Art. 26 para. 1 TPO |
| **Company name,**<br>*Division, street, P.O. box, CH-postcode*<br>**locality**, Switzerland | **bold:** mandatory (name of company and registered address as per the commercial register);<br>*italics*: optional |

**Division**
Stating a "Division" is acceptable if the company can be shown to constitute a subgroup of the marketing authorisation holder (extract from the commercial register).
Stating a "Division" is unacceptable if the company is at the same level as, or a higher level than, the marketing authorisation holder.

**Tel. no., e-mail address of the marketing authorisation holder on the packaging**
Telephone numbers and website or e-mail addresses are not permitted on packaging.

## 6.10 Manufacturer

Stating the manufacturer is optional. If the marketing authorisation holder wants the manufacturer to be stated, then the manufacturer should be clearly identified as such:

| | | |
|---|---|---|
| German:<br>Herstellerin: ...<br><br>Herstellung: ....<br>Herstellung durch: ... | French:<br>Fabricant: ...<br>Titulaire de l'AMM<br>Fabrication: ...<br>fabriqué par: ... | Italian:<br>Fabbricante: ...<br><br>Fabbricazione: ...<br>fabbricato da*: ... |

* Translation into Italian not correct, although this appears in the TPLRO; correct translation would be "prodotto da".



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If all manufacturing steps (incl. quality controls) are carried out by the same company, this company can be listed as the manufacturer. If the manufacturing steps are carried out by various companies, only the company stated as the manufacturer is allowed to issue the batch certificate. If several companies are registered as being responsible for batch release, either no company or all companies must be stated.

## 6.11 Supplier company

Stating the supplier company (Auslieferfirma, Répartiteur, Fornitore) is optional. It may be stated on application. The marketing authorisation holder must confirm that the supplier company possesses a corresponding wholesale trading licence. It must be stated as follows:
*Supplier: Name of company, place*
Stating *"under license of"* on the packaging is not permitted.

## 6.12 Batch number

The batch number may not be stated as a number on its own (risk of confusion with expiry/manufacturing date), but must be accompanied by prefixes such as *"Batch no.:...", "Bat.no..:...", "Bat. ref.:...", "B:...", "BN:…" "Lot:...", "Lot no.:...", "Lot:...",* etc.
Company-specific labelling of the batch is not accepted.

## 6.13 Manufacturing date

The manufacturing date may be stated on application. In order to ensure that this information is correctly identified, and to differentiate it from other numbers appearing on the packaging (expiry, batch number), a prefix such as "Manufacturing date": ..." / "MFD: …" must be added.

## 6.14 Expiry date

The expiry date may not be stated as a number on its own (risk of confusion with batch number / manufacturing date), but must be preceded by e.g. "EXP:...", "Expiry:", "Use by:" etc.
The expiry date must be stated as a month and year: e.g. 10.2001 or OCT 2001
If space is limited OCT 01, for example, is also permitted.
Ambiguous figures such as 10.01 are not permitted.
The day does not need to be stated.
Stating the month in just one language or any official Swiss language is acceptable.

If figures are used on their own, a dot, dash or a clear gap must be placed between the two groups of figures. The Exp/Lot notice must appear on the same side of the folding carton as the corresponding information. An arrow pointing to the other side of the carton is not permitted. The dates / figures must be printed on the same level (line) as the Exp / Lot statements.

The following presentation on one or two lines is preferred:
EXP: (Date) …….. / LOT: (Number)……..

EXP: (Date)
LOT: (Number)
The presentation *EXP/Lot: (date)/(number)* is permitted, provided the authorisation holder ensures that the information is clearly identifiable for the users.
The indications EXP and LOT and the corresponding information (date)/(number) on two different sides of the folding carton are permitted provided that an arrow links EXP and LOT with the corresponding information (date)/(number) on the other side of the folding carton.

## 6.15 Additional code on the folding carton

An additional company-specific code is accepted, provided Lot. / Exp. cannot be confused with this code and the identifiability of the information required by Annex 1 TPLRO is not adversely affected.

A company-specific barcode to identify the packaging and rule out mix-ups during manufacture is accepted, provided this cannot be confused with the EAN code and the identifiability of the


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information required by Annex 1 AMZV is not adversely affected. The information incorporated in the barcode should be stated by the applicant in the accompanying letter.

Affixing a data matrix (see also Chapter “Distinguishing features and safety precautions”) or a Radio Frequency Identification (RFID tag) to the packaging is permitted. The authorisation holder is responsible for the content of the data matrix or RFID tag. No promotional claims, references to a website or telephone numbers may be included, and this must be confirmed and ensured by the authorisation holder. It is therefore not permitted to use quick-response (QR) codes.

The producers and operators of RFID systems are responsible for taking the precautions required for ensuring that these are used in compliance with data protection requirements.

## 6.16 Use-by period after opening

A use-by period after opening should be stated where necessary (particularly for liquid dosage forms such as eye drops, cough syrups, etc.). The use-by period after opening must be demonstrated in Module 3.

## 6.17 Storage instruction

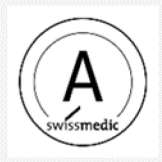
The storage instruction must be stated in accordance with the guidance document *Product information for human medicinal products HMV4*. The storage instruction must be the same in the Information for healthcare professionals, in the Patient information and on the packaging.

## 6.18 Warning regarding children

The statement "*Store (or keep) out of the reach of children" or "Keep medicines out of the reach and sight of children"* must be stated on the secondary packaging. Using the German word "soll", as in "Arzneimittel sollen für Kinder unerreichbar aufbewahrt werden" [Medicines are to be kept out of the reach of children] is not permitted.

## 6.19 Dispensing category and the Swissmedic licence symbol

The dispensing category must be stated **on the folding carton** using the Swissmedic pictogram (licence symbol). Although the font size is not specified, the dispensing category must be clearly legible.




The "CE" mark for medical devices may not appear on medicinal product packages.

## 6.20 Labelling of narcotics

According to the Narcotics Control Ordinance (Art. 55 para. 4 NarcCO), for medicinal products containing narcotics in Lists a or d (see Narcotics Lists Ordinance) a vignette provided by Swissmedic ("narcotics vignette) must be affixed to the outer packaging. Alternatively, an overprint that corresponds in all parts to the vignette can be affixed to the packaging. There is no standard specification of size and shape, but the writing must be clearly legible.


Furthermore, according to Art. 55 para. 3 NarcCO, the labelling of medicinal products with controlled substances must satisfy the legal provisions applicable to therapeutic products.



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## 6.21 Authorisation number and the packaging code

The authorisation number, incl. the packaging code, must be stated on the secondary packaging. The authorisation number, incl. the packaging code, is usually integrated in the EAN code, in which case the authorisation number should be bracketed off with the lettering "Swissmedic". The figures in the authorisation number, incl. the packaging code, must be highlighted by being printed in bold or larger than the rest of the EAN code.


If no EAN code exists, the authorisation number, incl. the packaging code, should be stated as follows:

| German: | French: | Italian: |
|---|---|---|
| Zulassungsnummer: *41557 001*<br>Zul-Nr.: *41557 001* | *Numéro d'autorisation: 41557 001*<br>*Numéro d'autorisation de mise sur le marché: 41557 001*<br>*No AMM: 41557 001* | *Numero di omologazione: 41557 001*<br>*No. di omol.: 41557 001* |

## 6.22 Medically essential information for use

This information should be kept to a minimum, and may not be of a promotional nature or interfere with the other essential information required on the packaging.
Examples of medically essential information for use:
e.g. warning: "*N.B.: Avoid pregnancy! Risk of malformation!*"

### 6.22.1 Brief description

A brief description may be stated. For complementary medicinal products, the brief description (brief claim) must relate exclusively to the approved indication and must fully reflect this area of application. For OTC medicinal products, the brief description should be understandable for laypersons, e.g. "loosens up tenacious mucus in coughs and colds" instead of mucolytic. The listing of active substance properties as a brief description is permitted for OTC medicinal products, provided the active substance properties are described and approved in the IHP, e.g. "Pain-relieving / Disinfecting / Antibacterial".
Stating the indications on the secondary packaging is optional. However, if the indications are listed, these should always be stated in full in accordance with the IHP (or the PI if no IHP is available). The selective stating of individual indications is not permitted. For List D medicinal products, only those indications for simplified self-medication (D indications) may be listed, not the B indications.

## 6.23 Reference to package leaflet

An instruction to refer to the package leaflet is mandatory, e.g. “(Please) read the package leaflet”.

## 6.24 Dosage and administration

Stating the title "Dosage / Administration: see package leaflet", "follow package leaflet before administration" or similar is not permitted.
If Dosage / Administration is stated, this should appear **in full** as shown in the medicinal product information. All age groups must be listed. For List D medicinal products, dosage / administration details that concern the B indications may not be listed on the secondary packaging.
For parenterals, the direction "Do not use without (prior) dilution" may be stated. It is important that the information is complete and corresponds with that in the medicinal product information texts. If two solvents are listed in the IHP, either both must be stated on the secondary packaging or else solvents must not be mentioned at all on the secondary packaging.



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# 7 Design and illustrations on folding cartons

## 7.1 General principles

From the standpoint of drug safety, the graphic design of the medicinal product packaging must be such that the information required by Art. 12 TPLRO in conjunction with Ann. 1, 1a, 1b TPLRO is easily identifiable and dominant. To prevent this information from being displaced by other statements, the information and texts (incl. illustrations) on the packaging material should be restricted to the information stated in Ann. 1, 1a, 1b TPLRO (especially section 1 para. 1 a–g). Other information, texts and illustrations are permitted only if they are directly connected with the use of the medicinal product (e.g. directly connected with the composition or name of the medicinal product, with its authorisation holder or the company logo), are important for providing health information, do not conflict with statements in Ann. 4, 5.1, 5.2, 5.3 and 6 TPLRO and are not misleading (Art. 1 para. 2 a TPA). Medicinal product advertising on containers or packaging materials is not permitted.

The appearance of a medicinal product should not lead to any trivialisation or confusion with a consumer product (food or tobacco product, drink or cosmetic) or to drug abuse.

In order to avoid confusion, secondary packages for differing dosage strengths must be clearly distinguishable from each other visually, for example by using different colours.

## 7.2 Illustration of plants or active substances

Illustrations of plants or active substances may appear on packages of **herbal** and **complementary medicinal products**, provided the plant or plant part can be considered as contributing to the efficacy of the medicinal product. The graphical highlighting of individual active constituents is not permitted. The principle of completeness applies, i.e. either all of the plants or active substances contained in the medicinal product or no plant or active substance should be illustrated. Otherwise plants may be illustrated as a graphical element in a form that is so highly stylised that the plant cannot be directly identified as such.
Illustrations of plants on **synthetic** medicinal products is not permitted, except as a graphical element in a form that is so highly stylised that the plant cannot be directly identified as such.

## 7.3 Logos

Logos are permitted as a rule provided, in particular, that

- the company name of the authorisation holder for the respective medicinal product is stated as it appears in the commercial register and
- the packaging is designed in such a way that the information required by Ann. 1, section 1, TPLRO remains easily identifiable and dominant.
- Logos of other companies may also appear, provided these can be connected with the medicinal product; e.g. logo of the manufacturer in combination with the manufacturer information.
- If an additional logo is shown, the logo of the MAH must also be presented in at least the same size.
- It is permissible, e.g. after a merger, to show the logos of the current marketing authorisation holder and the premerged company. The logo of the premerged company may not push the logo of the current authorisation holder into the background.
- An additional text reference "Developed in cooperation with xxx AG" is not permitted.
- The statement "Swiss made" or the Swiss cross on packaging is not permitted.
- The statement "human genome sciences" next to the logo on the folding carton is not permitted.



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### 7.4 Pictograms

The following pictograms relating to disinfectants are accepted.

Hand disinfection for washing (scrubbing)

Alcoholic hand disinfection for rubbing in

Skin disinfection

Mucous membrane disinfection

Pictograms relating to the dosage form (as an individual dose) and recycling pictograms recognised by the Swiss Association for Standardization are also accepted.
A thermometer pictogram is accepted as an addition to the storage instruction (e.g. "Store in the refrigerator (2-8°)").
Other pictograms are permitted only if their meanings are clearly defined and generally known.
Pictograms must be self-explanatory.

**"Happy tooth" symbol**

The description of a medicinal product as “tooth-friendly” or “kind to teeth” and the inclusion of the “happy tooth” symbol on the packaging is possible for dosage forms whose use entails prolonged contact with the teeth. Generally, this can be considered to be the case for lozenges, gargles, tooth gels and toothpaste, etc.

A medicinal product may be described as "tooth-friendly" or “kind to teeth” only if the sugar substitutes that it contains do not degrade *in vivo* with acid formation. This must be confirmed scientifically by pH telemetry and submitted in Module 1. Provided the acid content in plaque does not fall below the safety threshold of 5.7 for up to 30 minutes after sucking the medicinal product, the corresponding product is considered to be "tooth-friendly" and may be labelled with the "happy tooth with umbrella" emblem.


## 8 Information on blisters and labels

### 8.1 Information on and design of a blister

The name of the medicinal product, lot, EXP and – if several dosage strengths of the same medicinal product exist – the dosage strength must be shown on the blister as a minimum. Once the blisters are opened, the readability of the minimum information must also be ensured up to the last dose.



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The lot and EXP details must be placed at the edge of the blister and may not be printed transversely across the blister as this ensures readability even after the blisters are opened. Individual pocket lettering is excluded from this rule.

Stating the marketing authorisation holder on the blister is optional. It is acceptable to include the marketing authorisation holder without stating its registered office (postcode/place).

The presentation of a calendar pack on the blister is permitted (if this is compatible with the dosage recommendation). The days may not be shown as numbers, but must be stated on each tablet pocket with the abbreviation of the day, e.g. Mon, Tue, Wed, etc. (details in two or all official languages).

The perforation of blisters is permitted if all the particulars (incl. batch number and expiry date) are stated on each individual pocket.

## 8.2 Design of and information on a label for parenterals

A (non-transparent) label must usually be affixed to ampoules and prefilled syringes. If the readability of overprinting is just as good as that of a label (e.g. by using a white background or inverse printing), this is accepted.

Labels should be affixed in such a way that the information on each line can be read without having to rotate the ampoule or prefilled syringe.
The specified minimum size of the lettering is 1.4 mm, measured for an upper case letter without a descender (e.g. E, L, V). This requirement is fulfilled by the use of a 6-point font.

The following information is required for **solutions** for injection/infusion:
- the name of the medicinal product
- the INN of the active substances (for medicinal products containing no more than two active substances)
- the total quantity of active substances (for medicinal products containing no more than two active substances)
- the concentration (for medicinal products containing no more than two active substances)
- the administration route (as stated in the IHP, for solutions that are used both as carrier and flushing solutions, the administration routes can be omitted (e.g. NaCl 0.9%).
- the total volume (only state the total volume in ml)
- storage instruction where this deviates from room temperature (15 - 25° C)
- the expiry date
- the batch number

The statement "mg per ml" is not required for disposable syringes without graduations and whose full contents are to be administered according to the dosage recommendation.

The following information is required for medicinal products in **freeze-dried form** intended for injection/infusion:
- the name of the medicinal product
- the INN of the active substances (for medicinal products containing no more than two active substances)
- the administration route (as stated in the IHP)
- the total volume (only state the total quantity of active substance in mg)
- the expiry date
- the batch number

The total volume after reconstitution does not need to appear on the label since the information on reconstitution is included in the medicinal product information.

Labels for parenterals



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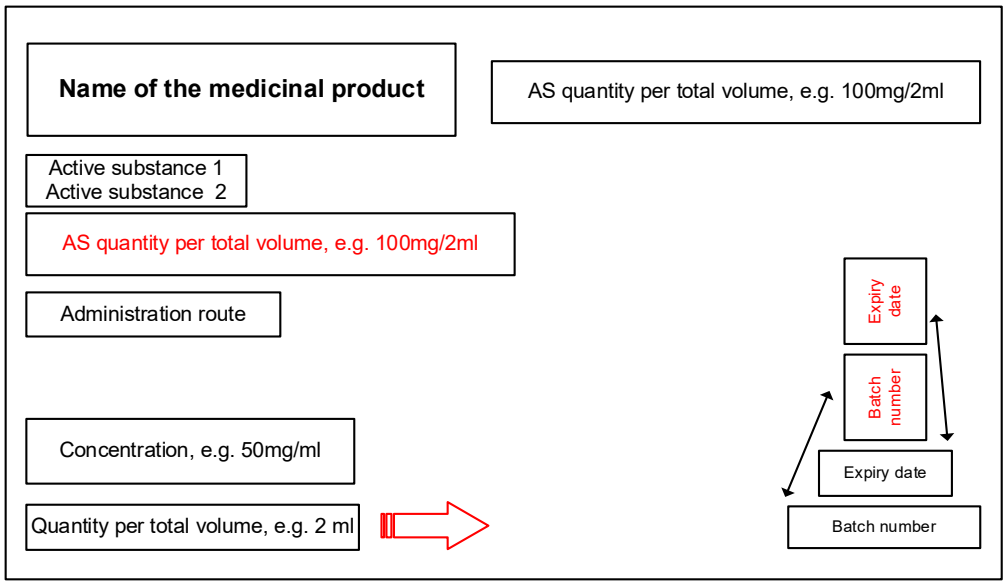


***Figure 5:*** *Example for parenterals with no more than two active substances (without KAS, intended for LS/FOPH)*
*The variants shown in red are alternative variants.*

The following exemption applies to the labelling of the **primary packaging for homeopathic and anthroposophic medicinal products**:
The information required by Ann. 1, section 2$^{bis}$ para. 2 TPLRO (i.e. the INN of the active substances, the total quantity of active substance or active substances and the concentration) does not need to be stated.

### 8.3 Traceability of medicinal products

Adhesive labels are permitted on the primary packaging for the purpose of tracing the medicinal product. The adhesive labels can be removed by the healthcare professional and affixed to the patient card. No information that is not already included on the label may be added to the adhesive label. The information on the adhesive label must be complete even after it is removed.

### 8.4 Distinguishing features and safety precautions

If a data matrix and/or safety precautions are affixed to packaging in accordance with Art. 17a TPA, the requirements stated in the “Ordinance on Individual Distinguishing Features and Safety Precautions on the Packaging of Medicinal Products” must be observed. It is the responsibility of the marketing authorisation holder to affix these features and this is not checked by Swissmedic.

## 9 Information on special packs

### 9.1 Information on multipacks

The following applies to multipacks:
Multipacks are subject to authorisation and are issued with a separate 8-character packaging code / EAN code.

The following minimum information is required on the label or folding carton of a multipack:
- Name of the medicinal product,
- quantitative content and dosage form (e.g. 90 (3 x 30) tablets)
- dosage form,
- EXP/LOT,
- name of the marketing authorisation holder,
- auth. no. supplemented by the packaging code / EAN code (must differ from the EAN for the individual packs)
- dispensing category


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The following applies to the individual packs in the multipack:

- The individual packs in a multipack are not authorised to be sold separately even if they are original packs. The statement *"Part of a multipack"* must appear on the individual pack, either as a direct overprint or by means of a non-removable label, otherwise it will not be possible to differentiate between an original pack as a separately authorised individual pack and an original pack that is not authorised as an individual pack. The addition of the overprint "Not to be sold separately" is permitted but not mandatory.
- The individual pack of a multipack can either show no packaging code (just the authorisation number) or the packaging code of the multipack or the original pack (if it is an authorised individual pack) in combination with the statement "Part of a multipack". The marketing authorisation holder is free to affix a separate identification code (e.g. barcode). This is not checked by Swissmedic and it should not simulate an authorisation number or packaging code approved by Swissmedic.
- The individual pack of a multipack is assigned to the same dispensing category as the multipack.
- The package leaflet may be, but does not have to be, included with each individual pack. It is sufficient to enclose a package leaflet in the large folding carton between the cellophane and the individual packs.

## 9.2 Information on combination packs

The following applies to combination packs:

- A combination pack is issued with an authorisation number and an IHP / PI.
- The dispensing category is the strictest one for the individual components
- LOT – has a separate LOT no.
- Exp. always the earliest expiry date for the individual components

Combination packs are subject to authorisation and are issued with a separate 8-character packaging code / EAN code.

## 9.3 Hospital packaging

On the authorisation document, hospital packaging will not be designated as such (any longer).
In the Information for healthcare professionals, the authorisation holder is free to specify packaging as “hospital packaging” (at its own responsibility); in the Patient information, no reference may be made to hospital packaging since it is not accessible for patients.

## 9.4 Folding carton with pull-out tab

Affixing a pull-out tab to the FC for the doctor to write on (dosage) is not permitted. A healthcare professional is responsible for adding a specific dosage recommendation, which should be affixed in the form of an adhesive label.

## 9.5 Packaging not placed on the market

The same requirements for packaging placed on the market also apply to packaging not placed on the market, i.e. the original prints (OP) for the folding carton must be submitted for first authorisation / new authorisation. Instead of the OP, a colour laser printout incl. confirmation of identity can also be submitted.
No packaging will be approved for medicinal products that are authorised exclusively for distribution abroad.



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# 10 Specific requirements for sample packs

## 10.1 Pack size

Sample packs may not be larger than the smallest original pack placed on the market.

**Sample pack < smallest authorised original pack**
Sample packs that are smaller than the smallest original pack placed on the market must be authorised as an additional pack size. This is not usually the case for sample packs of non-prescription medicinal products, because the samples dispensed directly to the public may contain a maximum of one daily dosage (Art. 19 para. 2 TPAO)). The recommended daily dose is based on the product information sections "Dosage/Administration" and "How should you use…".

**Sample pack = smallest authorised original pack**
Separate authorisation is not necessary if the smallest authorised pack is to be dispensed as a sample pack. This is usually the case for prescription-only medicinal products.
**Special case of psychotropic substances and narcotics**
Sample packs may not be dispensed for medicinal products containing controlled substances on Lists a, b or d (Art. 56 para. 3 NarcCO).

## 10.2 Labelling and package leaflet

Samples that are free of charge must be identifiable as such, i.e. in clearly visible terms. The "free sample" label in at least two official languages must be permanently affixed to the sample pack such that it cannot be removed (Art. 10 para. 2 letter a TPAO). Accordingly, a pack must be labelled with a non-detachable label or using some other non-removable technique.

The sample must be provided with the following up-to-date information:

*For advertising to professionals:*
The sample pack must contain the most recently approved package leaflet.
For medicinal products that may be marketed without a package leaflet, the sample pack must display the required information on the container and packaging materials.
The dispensed sample pack must also be accompanied by the latest Information for healthcare professionals approved by Swissmedic (Art. 10 para. 2 letter b TPAO). If the latter is already published according to Art. 67 para. 3 TPA, a reference to this publication is sufficient.

*For advertising to the public:*
A package leaflet is not absolutely essential according to TPAO, but may be included in the sample pack. If the sample pack does not contain a package leaflet, the information shown on the container and packaging materials must include all of the medically essential information for use (in at least two official languages). The following details at least are required in accordance with the product information:

- Indication details
- Dosage details (including a reference to the maximum treatment period and any age restriction, unless this is mentioned under "Contraindications");
- Contraindications;
- Precautions (including interactions and, for example, reference to alcohol consumption);
- Information on use during pregnancy;
- Undesirable effects (if these can affect use in any way – e.g. in terms of an absolute or relative contraindication - for example the effect on ability to drive)


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# 11 Annex: Changes to packaging

## 11.1 General

The following rules specify what changes can be made to packaging on one's own initiative (without an application) and what changes need to be notified.

## 11.2 Changes that can be made by marketing authorisation holders on their own initiative

The "editorial" changes to packaging listed below can be made by the marketing authorisation holders on their own initiative without having to submit an application to Swissmedic. This concerns the following changes:

a) Minor adaptations to the lettering (colour change, font, size within the range +/- 10%): It should be borne in mind that the marketing authorisation holder is responsible for the unambiguous identification of the medicinal product. For example, the MAH must ensure that the core brand and suffix form a single entity (the suffix should be printed at least half as large as the core brand).
b) Discreet changes to the packaging, e.g. changes in the size of the folding carton (without any changes to the packaging texts).
c) Inclusion/omission of Braille.
d) Updates to existing approved pictograms or photos of the pharmaceutical form (same size and placement). The marketing authorisation holder is responsible for the correct presentation of the pharmaceutical form.
e) Updates to existing approved illustrations of a plant (new photo of the same plant) for complementary and herbal medicines (roughly the same size and placement), provided the requirements concerning the illustration of plants are fulfilled.
f) Inclusion of a data matrix.
g) Deletion of redundant information (e.g. name of the medicinal product and dosage strength on one side of the folding carton).
h) Inclusion or deletion of the superscripted R (“Registered”) or TM (“Trademark”) in the brand name
i) Replacement of the superscripted R ("Registered") in the brand name with TM ("Trademark")
j) Modification of placement of EXP.:/Lot.:
k) Modification of placement of Swissmedic licence symbol and EAN code.
l) Switching around two sides of a folding carton with no other changes (i.e. no change to text, font size and colour, size of the folding carton or design).
m) Rotating the printing (landscape <-> portrait) with no other changes (i.e. no change to text, font size and colour, size of the folding carton or design).



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## 11.3 Minor variations to be notified in advance, type IB

Variations to the packaging which may not be implemented on one's own initiative must be submitted as a type IB variation, regulatory variation A 100 "Change in the product information and/or packaging texts without submission of scientific data" (see Annex 7 TPLRO).

Examples of this type of variation are:

a) Change to the fixed text for the expiry statement on the packaging elements ("EXP" instead of "use by", or "use by" instead of "EXP").
b) Deletion, inclusion or modification of the name of the supplier company.
c) Addition to the active substance name (without further changes)
d) Deletion of non-mandatory information (e.g. company logo, illustration, photo or pictogram of the pharmaceutical form, brief description).
e) Changes to the corporate identity (usually associated with a major change to the lettering in respect of size, shape, colour and / or a change to the background design).
f) Other major and conspicuous changes to the design (new visual appearance).
g) Inclusion of, or distinct change to, the company logo (not covered by 11.2.a).
h) First inclusion of a pictogram or photos of the pharmaceutical form or modification of a pictogram or photo of the pharmaceutical form that does not correspond to the requirements of 11.2.e.
i) First inclusion of an illustration (e.g. plant illustration for complementary and herbal medicines) or a modification of an illustration that does not correspond to the requirements of 11.2.f.
j) Inclusion or modification of the indications or brief description.
k) Inclusion or deletion of the manufacturer.
l) Deletion of redundant information and texts resulting from inclusion of a data matrix.

### 11.3.1 Implementation of the design change (corporate identity) as an A.100, type $IA_{IN}$ variation

Once the first pack has been submitted as a regulatory variation A.100, type IB and subsequently approved, the implementation of the design change (corporate identity) may be notified as an A.100, Typ $IA_{IN}$ variation as of the second pack, provided no further changes are made.

### 11.3.2 Changes to the packaging in connection with other applications

Changes to the information on packaging and the IHP/PI that are directly connected to the processing of another variation application – e.g. a change in storage conditions – do not need to be submitted as a separate application, nor are they billed separately.



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