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4 Committee for medicinal products for human use (CHMP)
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6 Guideline on declaration of herbal substances and herbal 7 preparations [1] in herbal medicinal products [2] /traditional 8 herbal medicinal products

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[1] The term "herbal substance" should be considered as equivalent to the term "herbal drug" as defined in the European Pharmacopoeia and the term "herbal preparation" should be considered as equivalent to the term "herbal drug preparation" as defined in the European Pharmacopoeia

[2] Throughout the guideline and unless otherwise specified, the term "herbal medicinal product" includes "traditional herbal medicinal product"

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INTRODUCTORY NOTE TO REVISION 1 (2008)

The guideline EMEA/HMPC/CHMP/CVMP/287539/2005 was limited to guidance on the declaration in the SmPC. It was revised to integrate the declaration in package leaflet and labelling. The revision is in line with the "Concept paper on the declaration of herbal substances/herbal preparations in finished herbal medicinal products" (EMEA/HMPC/241953/2005).

The main chapters that have been revised are the following:

- Executive summary: Declaration in the package leaflet and labelling has been introduced, besides declaration in the SmPC.
- Definitions: Definitions for the terms "declaration" and "strength" have been added.
- Annex 1: This new annex has been added to the guideline, providing guidance specifically on declaration in the package leaflet and labelling.

There are only editorial changes in the guidance on declaration in the SmPC (chapter 5 and 6).

INTRODUCTORY NOTE TO REVISION 2 (2026)

The guideline EMA/HMPC/CHMP/CVMP/287539/2005 Rev.1 was updated in line with the "Concept paper on revision of the 'Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products / traditional herbal medicinal products'" (EMA/HMPC/888811/2022).

The main changes in Revision 2 cover the following:

- General guidance and examples for declaration of extracts and other herbal drug preparations have been updated, to specify that in European procedures, declarations with both of two options (the genuine drug extract ratio; DERgenuine and the corresponding mass of herbal substance) should now be stated in the common SmPC. It is noted that application of the preferred one of the two options for the national SmPC is considered a national issue to be solved after the end of the procedure.
- Chapters 5 and 6 have been updated to elaborate the guidance on declaration of herbal substances and herbal preparations, most notably regarding naming of herbal substances, and declaration of fresh and frozen herbal substances, extraction solvents, excipients, and combination products.
- Editorial changes have been made throughout the guideline, primarily to take account of updated legislation, revisions of relevant Ph. Eur. provisions, and EU guidelines.

Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products

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Executive summary

The guideline EMEA/HMPC/CHMP/CVMP/287539/2005 was limited to guidance on the declaration in the Summary of Product Characteristics (SmPC). It was first revised to integrate the declaration in package leaflet and labelling.
This guideline outlines the principles for the uniform declaration of herbal substances/preparations in herbal medicinal products as well as in traditional herbal medicinal products. It focuses on the different types of herbal substances/preparations in relation to the quality documentation given. Examples of declaration of such active substances are provided. The main guideline describes declaration in the SmPC. Guidance on package leaflets, labelling and other herbal specific provisions, for SmPC, package leaflets and labelling, is described in Annex 1.
The guideline should be read in conjunction with current EU/(V)ICH guidelines and the relevant QRD templates.

1. Introduction

Common criteria for the declaration shall ensure clear differentiation between different types of herbal substances/preparations and proper description of their qualitative and quantitative particulars. As a result, a precise and consistent description of active substances of herbal medicinal products will be guaranteed within the Community.
The complex composition of herbal substances/preparations, which is essentially determined by various factors like the production process, the extraction solvent, the genuine drug extract ratio (DER genuine), and the type/physical state of the herbal substances/preparations, needs to be stated to guarantee identification and facilitate comparison of herbal substances/preparations. However, it is not feasible to provide full characterisation in the declaration, as the declaration should be kept as short and precise as possible.
The declaration is primarily intended to describe the identity and quantity of the herbal substance/preparation, being the active substance of the herbal medicinal product.
Therefore, a declaration system has been established which reflects the main characteristics of herbal substances/preparations. For this purpose, general guidance as given in the European Pharmacopoeia (particularly the monographs "Herbal Drugs", "Herbal Drug Extracts", "Herbal Drug Preparations", and "Herbal Teas") as well as in the guidelines listed under *References*, should be followed.

2. Scope

This guideline addresses the declaration of herbal substances/preparations when being the active substance of a herbal medicinal product. Examples of standardised, quantified, and other herbal substances/preparations are given.
The main guideline addresses only the declaration of herbal substances/preparations in herbal medicinal products (including fixed combinations) in the SmPC, whereas declaration in package leaflet and labelling is addressed in *Annex 1*. It shall apply to herbal medicinal products both for human and veterinary use and to traditional herbal medicinal products for human use. Traditional herbal medicinal products may additionally contain vitamins and/or minerals. Declaration of these chemically defined substances is not covered by this guideline. Reference is given to the INN-system and to "A Guideline on Summary of Product Characteristics (SmPC)".
This guideline reflects the current state of the art at the time it has been written. If necessary, the national regulatory authority/HMPC should be asked for additional guidance, especially in those cases not covered by examples in the guideline. Any translation exemption or the use of bi- or multilingual labelling is considered a national issue.

3. Legal basis

This guideline supports applications for marketing authorisations or registrations according to Directive 2001/83/EC and Regulation (EU) 2019/6 as amended.
A simplified registration procedure was established for traditional herbal medicinal products for human use under Directive 2001/83/EC as amended by Directive 2004/24/EC. The principles for declaration of

herbal substances/preparations in herbal medicinal products apply equally to such traditional herbal medicinal products for human use.

4. Main guideline text

This guideline presents a brief definition of each concept and gives examples of the declaration in the SmPC. Generally, if the classification of a herbal preparation is not unambiguous, alternative proposals should be justified by the applicant and approved by the regulatory authority before being put into effect.
In the different chapters the characteristics, which are generally needed for the declaration of the different kinds of herbal substances/preparations, are given, followed by examples. The examples in the guideline are for illustration purposes only and not intended to reflect binding specifications. Within each example, it is shown what information is needed to form the specific declaration of the active substance of the herbal medicinal product in section 2 of the SmPC. In this context it is pointed out that both excipients for adjustment (valid for standardised herbal preparations only) and/or other excipients (e.g. carrier substances) must be declared in section 6.1 of the SmPC, preferably listed with a subtitle "Excipients of the herbal substance/preparation". Extraction solvents are to be declared in section 2 of the SmPC only. Warning or information statements required according to the guideline "Excipients in the labelling and package leaflet of medicinal products for human use" and its annex have to be included in relevant sections of the SmPC (incl. section 2), as described in that guideline. Furthermore, section 5.3 of the (human) SmPC provides for the possibility to inform on limits of unwanted (i. e. toxicologically relevant) constituents of herbal substances/preparations for safety reasons, provided that these limits are laid down in the specification as part of the quality documentation.

5. Declaration of herbal substances in the SmPC

This section applies to the naming of a herbal substance being the active substance of a (traditional) herbal medicinal product, but not to a herbal substance being the starting material of a herbal preparation.

The declaration of a herbal substance should cover the name and the quantity of the herbal substance.

The name of the herbal substance is the [translated] common name of the monograph of the European Pharmacopoeia if available, or else of the Pharmacopoeia of a Member State, if available, or else the common name of the herbal substance including the plant part. The common name should be followed by the botanical scientific (Latin) name of the plant species according to the binomial system (genus and species in Italic font, variety if relevant, and author) with the Latin term of the plant part. In case a Pharmacopoeial monograph exists, the scientific name stated in the definition section of the monograph for the herbal substance should be used; and not the synonym name(s).
In those special cases, where many different plant species apply to the same herbal substance, the list of Latin names could be shortened to the genus name followed by the word "species", e.g. "*Crataegus* species". This option is only applicable in cases where no restrictions concerning the species used are known from the quality documentation. In special cases, e.g. where the scientific name exists but no common name for the species has been established, only the scientific name of the plant species may be used together with the [translated] common term for the plant part.

Additional information may be necessary for specific types of herbal substances (e.g. standardised, quantified) cf. below.

The following characteristics have to be stated in the declaration:
1. Name of the herbal substance.
2. Quantity of the genuine herbal substance (given as a range in case of standardised herbal substances).
3. Name and quantity of the constituent(s) with known therapeutic activity (in case of standardised herbal substances only).
4. Name and quantity (given as a range) of the active markers (in case of quantified herbal substances only).

For combination products, i.e. products containing more than one herbal substance as active substance, each individual herbal substance should be declared separately in section 2 of the SmPC. However, in case of a combination product containing two (or more) standardised herbal substances with the same constituent(s) with known therapeutic activity to be declared, it may be feasible to declare the total amount of the constituent(s) with known therapeutic activity, covering the contribution from both (all) of the herbal substances, instead.

5.1. Standardised herbal substances

Standardised herbal substances are adjusted within an acceptable tolerance to a given content of constituents with known therapeutic activity; standardisation is achieved by adding excipients for adjustment to the herbal substance or by blending batches of the herbal substance.
For such herbal substances, the name and defined content of the constituent(s) with known therapeutic activity should be stated. The corresponding quantity of the genuine herbal substance should be given as a range.

Example:

Pharmaceutical form: Herbal tea in bag

Senna leaflet, cut.
Constituents with known therapeutic activity in the herbal medicinal product: 2.54 % hydroxyanthracene glycosides, expressed as sennoside B.
Quantity of the genuine herbal substance as a range: 85 - 96 %.
Excipients for adjustment: 4 - 15 %.
Quantity of standardised herbal substance (herbal substance and excipients for adjustment) in the herbal medicinal product: 1.3 g/tea bag.

The declaration in section 2 of the SmPC of the herbal medicinal product is:

Each tea bag contains:
1.11-1.25 g senna leaflet (*Senna alexandrina* Mill., foliolum), corresponding to 33 mg hydroxyanthracene glycosides, expressed as sennoside B.

5.2. Quantified herbal substances

Quantified herbal substances are adjusted to a defined range of active markers; adjustments may be made by blending batches of herbal substances.
For quantified herbal substances, the name of the active markers should be stated and their content should be given in a range. The corresponding quantity of the genuine herbal substance should be given as a distinct content.

Example:

Pharmaceutical form: Herbal tea in bag

Willow bark, cut.

Quantification: 1.5 - 1.7 % of total salicylic derivatives expressed as salicin.
Quantity of the herbal substance in the herbal medicinal product: 3.0 g/tea bag.

The declaration in section 2 of the SmPC of the herbal medicinal product is:

Each tea bag contains:
3 g willow bark (*Salix* species including *S. purpurea* L., *S. daphnoides* Vill. and *S. fragilis* L., cortex), corresponding to 45-51 mg of total salicylic derivatives, expressed as salicin.

5.3. Other herbal substances

For other herbal substances, neither constituents with known therapeutic activity nor active markers are generally known.
For other herbal substances, the name and content of the analytical marker(s) should not be stated.
The quantity of the genuine herbal substance should be stated as a distinct content.

Example:

Pharmaceutical form: Oral herbal material
100 g linseed.
Quantity of herbal substance in the herbal medicinal product: 1 g/g.

The declaration in section 2 of the SmPC of the herbal medicinal product is:

1 g contains:
1 g linseed (*Linum usitatissimum* L., semen).

6. Declaration of herbal preparations in the SmPC

Herbal preparations are diverse in character ranging from simply processed, comminuted plant material to complex processed preparations such as refined extracts.

The declaration of a herbal preparation should cover the name of the herbal substance and characterisation of the herbal preparation including the physical state, ratio of herbal substance to genuine herbal preparation (genuine DER, also named native DER) or the corresponding quantity (mass) of the herbal substance, and extraction solvent(s) if appropriate.
Besides, various manufacturing parameters for the herbal preparation are crucial for the obtained composition of the final preparation, e.g. extraction temperature, extraction time, filtration and drying processes. Although these parameters should be defined in the dossier, they are not to be specified in the declaration of the related finished product. The aim is to include the most essential information in the declaration, but to keep it as simple as possible.

The name of the herbal substance used for manufacture of the herbal preparation should be stated as described in chapter 5.

If a fresh herbal substance is used as a starting material for manufacture of the herbal preparation, the word "fresh" should be added to the name of the herbal substance used for the production of the herbal preparation. This also applies in cases where a fresh herbal substance is frozen prior to herbal preparation manufacture.

For the declaration of the amount of a herbal preparation, the amount of the genuine herbal preparation must be stated, i.e. without the quantity of any excipient added after the extraction process (excipients used for standardisation or technological reasons). This also applies in cases where the herbal preparation includes excipients, even if, for technological reasons, the genuine herbal preparation is not present.

In case of dry extracts and oleoresins, the amount of genuine extract refers to the extract without excipients. For soft and liquid extracts, the genuine extract contains (extraction) solvent, which is included in the declared quantity of extract.

The genuine drug extract ratio (DERgenuine) or the corresponding mass of herbal substance should be declared for extracts. In European procedures, both two options (DER and corresponding quantity in mg) should be stated in the common SmPC (and PL and labelling). Application of the preferred one of the options in the national product information (SmPC, PL and labelling) is a national issue to be solved after the end of the procedure.

No matter whether the extract is prepared from a dry or a fresh or frozen herbal substance, the corresponding quantity of the herbal substance should simply be the quantity used, i.e., including any water naturally contained in the herbal substance. Due to the natural variability of the herbal substance, the DERgenuine will normally be a range, e.g., 3.0-5.5:1. In the case of soft and liquid extracts, where part of or all the extraction solvent is maintained in the final extract, the DERgenuine will equal the drug extract ratio (DER).

The name and strength of the extraction solvent used in the first extraction step should be included in the declaration. The declaration of the extraction solvent should be based on the concentration of the solvent used, without taking any water naturally contained in the herbal substance into account.

Example: An extraction solvent prepared as a mixture of 5,000 kg ethanol 96% (V/V) plus 1,000 kg purified water means that the declared solvent should be ethanol 84% (V/V), irrespective of the water contained in the herbal substance being extracted (regardless of whether the herbal substance is dried or fresh).

The following wording should be used, as appropriate:
"Extraction solvent: <name> <strength % V/V" (or % m/m, as applicable)>.

In case of a liquified gas used as extraction solvent, it should be declared as:
"Extraction solvent: Liquid <name>".

If an extraction solvent is used in a pressurized state, the state is not indicated in the declaration.

In case the extraction solvent is composed of different solvents, the name and strength of each have to be given together with the ratio of the composition.

If purification procedures are used in the manufacture of a herbal preparation, the word "refined" should be added to the name of the herbal preparation. However, solvent(s) used solely for the refining process should not be added to the declaration. In special cases, where the same herbal starting material undergoes two consecutive extractions by different solvents, and then fractions are combined, both extraction solvents should be considered for the declaration. In other special cases, other approaches for the declaration can be applied, if justified.

In addition, the declaration of herbal preparations needs to reflect the different types of herbal preparations (taking into account the definitions for the extract types as described in the European Pharmacopoeia).

(i) '**Standardised herbal preparations'**: are adjusted to a defined content of one or more constituents with known therapeutic activity. This is achieved by adjustment of the herbal preparation with inert excipients or by blending batches of the preparation.

For such preparations the name and defined content of the constituent(s) with known therapeutic activity should be stated. The corresponding quantity of the genuine herbal preparation should be given as a range .

(ii) **'Quantified herbal preparations'**: are adjusted to one or more active markers, the content of which is controlled within a limited, specified range. Adjustments are made by blending batches of the herbal preparation.

For such preparations the name of the active markers should be stated and their content should be given in a range. The corresponding quantity of the genuine herbal preparation should be given as a distinct content, quoting either the corresponding amount of herbal substance (given as a range) or the DER genuine.

(iii) **'Other herbal preparations'**: are not adjusted to a particular content of constituents. For control purposes, one or more constituents are used as analytical markers. The content for these analytical markers is given in the specification.

For such preparations the name and content of the analytical marker(s) should not be stated. The quantity of the genuine herbal preparation should be stated as a distinct content, quoting either the corresponding amount of herbal substance (given as a range) or the DER genuine.

For combination products, i.e. products containing more than one herbal preparation as active substance, each individual herbal preparation should be declared separately in section 2 of the SmPC. However, in case of a combination product containing two (or more) standardised herbal preparations with the same constituent(s) with known therapeutic activity to be declared, it may be feasible to declare the total amount of the constituent(s) with known therapeutic activity, covering the contribution from both (all) of the herbal preparations.

6.1. Herbal preparations consisting of comminuted or powdered herbal substances

The following characteristics have to be stated in the declaration:

1. Name of the herbal substance used.
2. Herbal preparation type.
3. Quantity of the genuine herbal preparation (given as a range in case of standardised herbal preparations).
4. Name and quantity of the constituent(s) with known therapeutic activity (in case of standardised herbal preparations only).
5. Name and quantity (given as a range) of the active markers (in case of quantified herbal preparations only).

6.1.1. Standardised herbal preparations

Example a): Standardisation by adding excipients for adjustment

Pharmaceutical form: Oral powder

Senna leaflet, powdered.
Senna pods, powdered.
Constituents with known therapeutic activity in the herbal medicinal product: 2.0 % hydroxyanthracene glycosides, expressed as sennoside B.
Quantity of the sum of genuine herbal preparations as a range: 70 - 95 % (mixture of both senna preparations).
Excipients for adjustment: 5 - 30 %.
Other excipients: 0 %.
Quantity of the sum of standardised herbal preparations (genuine herbal preparations + excipients for adjustment) in the herbal medicinal product: 1 g/g (200 mg senna leaflet, powdered, + 500 mg - 750 mg senna pods, powdered and 50 mg - 300 mg excipients for adjustment).

The declaration in section 2 of the SmPC of the herbal medicinal product is:

1 g oral powder contains:
200 mg senna leaflet (*Senna alexandrina* Mill., foliolum), powdered and 500-750 mg senna pods (*Senna alexandrina* Mill., fructus), powdered, corresponding to 20 mg hydroxyanthracene glycosides, expressed as sennoside B.

Example b): Standardisation by mixing herbal preparations

Pharmaceutical form: Oral powder

Senna leaflet, powdered.
Senna pods, powdered.

Constituent(s) with known therapeutic activity: 2.7 % hydroxyanthracene glycosides, expressed as sennoside B.
Quantity of the sum of genuine herbal preparations (as a range): 100 % genuine herbal preparations (mixture of both senna preparations).
Other excipients: 0 %.
Quantity of the sum of genuine standardised herbal preparations in the herbal medicinal product: 1 g/g (200-350 mg senna leaflet, powdered, and 650-800 mg senna pods, powdered).

The declaration in section 2 of the SmPC of the herbal medicinal product is:

1 g oral powder contains:
200-350 mg senna leaflet (*Senna alexandrina* Mill., foliolum), powdered and 650-800 mg senna pods (*Senna alexandrina* Mill., fructus), powdered, corresponding to 27 mg hydroxyanthracene glycosides, expressed as sennoside B.

6.1.2. Quantified herbal preparations

Example:

Pharmaceutical form: Herbal tea in bag

Willow bark, powdered.
Quantification: 1.5 - 1.7 % of total salicylic derivatives, expressed as salicin.
Excipients in the herbal preparation: 0 %.
Quantity of the genuine herbal preparation in the herbal medicinal product: 2.5 g/tea bag.

The declaration in section 2 of the SmPC of the herbal medicinal product is:

1 tea bag contains:
2.5 g willow bark (*Salix* species including *S. purpurea* L., *S. daphnoides* Vill. and *S. fragilis* L, cortex), powdered, corresponding to 37.5-42.5 mg total salicylic derivatives, expressed as salicin.

6.1.3. Other herbal preparations

Example a):

Pharmaceutical form: Herbal tea in bag

Valerian root, cut.
Excipients in the herbal preparation: 0 %.
Quantity of the genuine herbal preparation in the herbal medicinal product: 2 g/tea bag.

The declaration in section 2 of the SmPC of the herbal medicinal product is:

Each tea bag contains:
2 g valerian root (*Valeriana officinalis* L. s.l., radix), cut.

Example b):

Pharmaceutical form: Capsule, hard

Valerian root, powdered.
Excipients in the herbal preparation: 0 %.
Quantity of the genuine herbal preparation in the herbal medicinal product: 300 mg/capsule.

The declaration in section 2 of the SmPC of the herbal medicinal product is:

Each capsule contains:
300 mg valerian root (*Valeriana officinalis* L. s.l., radix), powdered.

6.2. Herbal preparations produced by steps which exceed comminution/ powdering (e.g. extracts)

The following characteristics have to be stated in the declaration:
1. Name of the herbal substance used.
2. Type/physical state of the herbal preparation.
3. Quantity of the genuine herbal preparation.
4. Name and quantity of the constituent(s) with known therapeutic activity (in case of standardised herbal preparations only).
5. Name and quantity (given as a range) of the active markers (in case of quantified herbal preparations only).
6. Drug extract ratio (DER genuine) or equivalence in the quantity of the herbal substance (as a range) (in case of quantified and other herbal preparations).
7. Name and composition of extraction solvent(s).

6.2.1. Standardised extracts

Example:

Pharmaceutical form: Capsule, hard

Dry extract from horse chestnut seed
Constituent(s) with known therapeutic activity: 8 % triterpene glycosides, expressed as protoaescigenin.
Quantity of the genuine extract (as a range): 70 - 95 % genuine extract.
DER genuine: 5 – 8 : 1.

Excipients for adjustment: 30 - 5 %.
Other excipients: 0 %.
Extraction solvent: Ethanol 80 % V/V.
Quantity of the standardised extract (genuine herbal preparation and excipients for adjustment) in the herbal medicinal product: 200 mg/capsule.

The declaration in section 2 of the SmPC of the herbal medicinal product is:

Each capsule contains:
140-190 mg dry extract from horse chestnut seed (*Aesculus hippocastanum* L., semen), corresponding to 16 mg triterpene glycosides, expressed as protoaescigenin.
Extraction solvent: Ethanol 80 % V/V.

6.2.2. Quantified extracts

Example:

Pharmaceutical form: Capsule, hard

Dry extract from ginkgo leaf, refined and quantified.
Quantity of genuine extract in the herbal preparation: 100 % genuine extract.
DER genuine: 35 – 67 : 1.
Quantification (concentration in the genuine extract):
22.0-27.0 % of flavonoids expressed as flavone glycosides.
2.8-3.4 % of ginkgolides A, B and C.
2.6-3.2 % of bilobalide.
Excipients in the herbal preparation: 0 %.
First extraction solvent: Acetone 60 % m/m.
Quantity of the genuine quantified extract in the herbal medicinal product: 60 mg/capsule.

The declaration in section 2 of the SmPC of the herbal medicinal product is:

Each capsule contains:
60 mg ginkgo leaf (*Ginkgo biloba* L., folium) dry extract, refined (35 – 67 : 1), corresponding to:
13.2-16.2 mg flavonoids expressed as flavone glycosides
1.68-2.04 mg ginkgolides A, B and C
1.56-1.92 mg bilobalide.
Extraction solvent: Acetone 60 % m/m.

*or**

Each capsule contains:
60 mg ginkgo leaf (*Ginkgo biloba* L., folium) dry extract, refined, corresponding to 2.1–4.0 g ginkgo leaf, corresponding to:
13.2-16.2 mg flavonoids expressed as flavone glycosides
1.68-2.04 mg ginkgolides A, B and C
1.56-1.92 mg bilobalide.
Extraction solvent: Acetone 60 % m/m.

[one of the above options to be selected nationally]*

6.2.3. Other extracts

Example a: Other extracts such as dry extracts

Pharmaceutical form: Capsule, hard

Dry hydroalcoholic extract from valerian root.
Quantity of genuine extract in the herbal preparation: 80 % genuine extract.
DER genuine: 3 – 6 : 1.
Excipients in the herbal preparation: 20 %.
Extraction solvent: Ethanol 70 % V/V.
Quantity of the dry extract (genuine herbal preparation and other excipients) in the herbal medicinal product: 200 mg/capsule.

The declaration in section 2 of the SmPC of the herbal medicinal product is:

Each capsule contains:
160 mg dry extract from valerian root (*Valeriana officinalis* L. s.l., radix) (3 – 6 : 1).
Extraction solvent: Ethanol 70 % V/V.

*or**

Each capsule contains:
160 mg dry extract from valerian root (*Valeriana officinalis* L. s.l., radix), corresponding to 480–960 mg valerian root.
Extraction solvent: Ethanol 70 % V/V.

[one of the above options to be selected nationally]*

Example b): Other extracts such as liquid extracts

Pharmaceutical form: Oral liquid

Liquid extract from matricaria flower.
Quantity of genuine extract in the herbal preparation: 100 % genuine extract.
DER genuine: 1 : 1.
Excipients in the herbal preparation: 0 %.
Extraction solvent: 2.5 parts ammonia solution 10 % m/m.
50 parts of ethanol 96 % V/V.
47.5 parts of water.
Quantity of the genuine liquid extract in the herbal medicinal product: 1 ml/ml.

The declaration in section 2 of the SmPC of the herbal medicinal product is:

1 ml oral liquid contains:
1 ml liquid extract from matricaria flower (*Matricaria recutita* L., flos) (1 : 1).
Extraction solvent: Ammonia solution 10 % m/m : ethanol 96 % V/V : water (2.5 : 50 : 47.5).

*or**

1 ml oral liquid contains:
1 ml liquid extract from matricaria flower (*Matricaria recutita* L., flos), corresponding to 1 g matricaria flower.
Extraction solvent: Ammonia solution 10 % m/m : ethanol 96 % V/V : water (2.5 : 50 : 47.5).

[one of the above options to be selected nationally]*

Example c: Other extracts such as tinctures

Pharmaceutical form: Oral liquid

Tincture from valerian root.
Quantity of genuine extract in the herbal preparation: 100 % genuine extract.
DER genuine: 1 : 4.0 - 4.5.
Excipients in the herbal preparation: 0 %.
Extraction solvent: Ethanol 70 % V/V.
Quantity of the tincture in the herbal medicinal product: 1 ml/ml.

The declaration in section 2 of the SmPC of the herbal medicinal product is:

1 ml oral liquid contains:
1 ml tincture from valerian root (*Valeriana officinalis* L. s.l., radix) (1:4.0-4.5).
Extraction solvent: Ethanol 70 % V/V.

*or**

1 ml oral liquid contains:
1 ml tincture from valerian root (*Valeriana officinalis* L. s.l., radix) corresponding to 220-250 mg valerian root.
Extraction solvent: Ethanol 70 % V/V.

[one of the above options to be selected nationally]*

Example d: Other extracts such as dry extracts from a mixture

Pharmaceutical form: Capsule, hard
Dry extract from 3 parts valerian root
2 parts hop strobile
2 parts melissa leaf.
Quantity of genuine extract in the herbal preparation: 80 % genuine extract.
DER genuine: 4 – 7 : 1.
Excipients in the herbal preparation: 20 %.
Extraction solvent: Ethanol 70 % V/V.
Quantity of the dry extract (genuine herbal preparation and other excipients) in the herbal medicinal product: 200 mg/capsule.

The declaration in section 2 of the SmPC of the herbal medicinal product is:

Each capsule contains:
160 mg dry extract (4 – 7 : 1) from a mixture of valerian root (*Valeriana officinalis* L. s.l., radix), hop strobile (*Humulus lupulus* L., flos), and melissa leaf (*Melissa officinalis* L., folium) (3:2:2).
Extraction solvent: Ethanol 70 % V/V.

*or**

Each capsule contains:
160 mg dry extract corresponding to 0.64–1.1 g of a mixture of valerian root (*Valeriana officinalis* L. s.l., radix), hop strobile (*Humulus lupulus* L., flos), and melissa leaf (*Melissa officinalis* L, folium) (3:2:2).
Extraction solvent: Ethanol 70 % V/V.

[one of the above options to be selected nationally]*

6.3. Herbal preparations not covered by 6.1 or 6.2

The following characteristics have to be stated in the declaration:
1. Name of the herbal substance used.
2. Type of the herbal preparation.
3. Quantity of the genuine herbal preparation.
4. Drug extract ratio (DER genuine) or corresponding quantity of the herbal substance (as a range), if applicable.
5. Name and composition of extraction solvent(s), if applicable.

6.3.1. Other herbal preparations such as essential oils

Example:

Pharmaceutical form: Oral drops, liquid

Peppermint oil.
Quantity of essential oil in the herbal preparation: 100 % essential oil.
Excipients in the herbal preparation: 0 %.
Quantity of essential oil in the herbal medicinal product: 1 ml/ml oral drops, liquid.
1 ml = x drops (depending on the dropper used).

The declaration in section 2 of the SmPC of the herbal medicinal product is:

1 ml oral drops, liquid contains:
1 ml peppermint oil (*Mentha* × *piperita* L., aetheroleum).

1 ml corresponds to … drops.

6.3.2. Other herbal preparations such as expressed juices

Example:

Pharmaceutical form: Oral liquid

Expressed juice from fresh purple coneflower herb, stabilised without ethanol.
Quantity of genuine expressed juice in the herbal preparation: 100% genuine expressed juice.
DER genuine: 1.2 - 1.5 : 1.
Excipients in the herbal preparation: 0 %.
Quantity of the genuine expressed juice in the herbal medicinal product: 1 ml/ml oral liquid.

The declaration in section 2 of the SmPC of the herbal medicinal product is:

1 ml oral liquid contains:
1 ml expressed juice from fresh purple coneflower herb (*Echinacea purpurea* (L.) Moench, herba) (1.2-1.5:1)

*or**

1 ml oral liquid contains:
1 ml expressed juice from fresh purple coneflower herb (*Echinacea purpurea* (L.) Moench, herba), corresponding to 1.2–1.5 g fresh purple coneflower herb.

[one of the above options to be selected nationally]*

6.3.3. Other herbal preparations such as processed exudates

Example:

Pharmaceutical form: Oral solution

Tincture from myrrh.
Quantity of processed exudate in the herbal preparation: 100 % processed exudate.
DER genuine: 1 : 4.0 - 4.5.
Excipients in the herbal preparation: 0 %.
Extraction solvent: Ethanol 90 % V/V.
Quantity of the tincture in the herbal medicinal product: 25 mg/ml oral solution.

The declaration in section 2 of the SmPC of the herbal medicinal product is:

1 ml oral solution contains:
25 mg tincture from myrrh (*Commiphora myrrha* (Nees) Engl. and/or other species of *Commiphora*) (1:4.0-4.5).
Extraction solvent: Ethanol 90 % V/V.

*or**

1 ml oral solution contains:
25 mg tincture from myrrh (*Commiphora myrrha* (Nees) Engl. and/or other species of *Commiphora*) corresponding to 5.6-6.3 mg myrrh.
Extraction solvent: Ethanol 90 % V/V.

[one of the above options to be selected nationally]*

Definitions

Constituents with known therapeutic activity: are chemically defined substances or groups of substances which are generally accepted to contribute substantially to the therapeutic activity of a herbal substance, a herbal preparation or a herbal medicinal product.

Declaration: A statement of the content of the active substance(s) expressed qualitatively and quantitatively per dosage unit, per unit of volume or weight according to the dosage form.

Drug extract ratio (DER): means the ratio between the quantity of herbal substance used in the manufacture of a herbal preparation and the quantity of herbal preparation obtained. The number (given as the actual range) written before the colon is the relative quantity of the herbal substance; the number written after the colon is the relative quantity of the herbal preparation obtained.

Excipients: In general, excipients may be defined as constituents of the medicinal product other than the active substance(s). However, in the context of this guideline only two categories of excipients are addressed:

Excipients for adjustment are used for standardisation of herbal substances/preparations.

Other excipients are technological excipients (e.g. carrier substances) which may be part of herbal preparations.

Extraction solvents: are solvents which are used for the extraction process.

Genuine (Native) herbal preparation: refers to the preparation without excipients, even if for technological reasons the genuine herbal preparation is not available. However, for soft and liquid herbal preparations the genuine herbal preparation may contain variable amounts of (extraction) solvent.

Ratio of herbal substance to genuine herbal preparation (DER genuine): is the ratio of the quantity of the herbal substance to the quantity of the resulting genuine herbal preparation. The number (given as the actual range) written before the colon is the relative quantity of the herbal substance; the number written after the colon is the relative quantity of the genuine herbal preparation obtained.

Herbal medicinal products: any medicinal product, exclusively containing as active substances one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.

Herbal preparations: are obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

Herbal substances: all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried form but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).

Herbal teas: consist exclusively of one or more herbal substance(s) intended for oral aqueous preparations by means of decoction, infusion or maceration. The preparation is prepared immediately before use. Herbal teas are usually supplied in bulk form or in bags.

Markers: are chemically defined constituents or groups of constituents of a herbal substance, a herbal preparation or a herbal medicinal product which are of interest for control purposes independent of whether they have any therapeutic activity. Markers serve to calculate the quantity of herbal substance(s) or herbal preparation(s) in the herbal medicinal product if the marker has been quantitatively determined in the herbal substance or herbal preparation.

There are two categories of markers:

Active markers are constituents or groups of constituents which are generally accepted to contribute to the therapeutic activity.

Analytical markers are constituents or groups of constituents that serve for analytical purposes.

Quantification: means adjusting the herbal substance or herbal preparation to a defined range of constituents (active markers) exclusively achieved by blending different batches of herbal substances and/or herbal preparations (e.g. quantified extract).

Specification: A list of tests, references to analytical procedures, and appropriate acceptance criteria which are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which a herbal substance/preparation or herbal medicinal product should conform to be considered acceptable for its intended use. "Conformance to specifications" means that the herbal substance/preparation and/or herbal medicinal product, when tested according to the listed analytical procedures, will meet the listed acceptance criteria. Specifications are binding quality standards that are agreed to between the appropriate governmental regulatory agency and the applicant.

Standardisation: means adjusting the herbal substance/preparation to a defined content of a constituent or a group of constituents with known therapeutic activity respectively either by adding excipients or by blending batches of the herbal substance and/or herbal preparation (e.g. standardised extracts).

Strength: The content of the active substance(s) expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form.

Traditional herbal medicinal products: are medicinal products for human use that fulfil the conditions laid down in article 16a (1) of Directive 2001/83/EC, as amended.

References

"Guideline on specifications: Test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products" (EMA/HMPC/CHMP/CVMP/162241/2005 Rev. 3)

"Guideline on quality of herbal medicinal products/traditional herbal medicinal products" (EMA/HMPC/CHMP/CVMP/201116/2005 Rev. 3)

"A Guideline on Summary of Product Characteristics (SmPC)" (Human Medicinal Products) Eudralex Vol. 2C, Rev. 2, September 2009

Guideline on "Summary of the Product Characteristics (SPC) – Pharmaceuticals" (Veterinary Medicinal Products) Eudralex Volume 6C, Rev. 2, July 2006

"Concept paper on revision of the Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products" (EMA/HMPC/888811/2022)

"Excipients in the labelling and package leaflet of medicinal products for human use" (Notice to Applicants Volume 2C, SANTE-2017-11668 Rev. 2)

"Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668)" (EMA/CHMP/302620/2017 Rev. 1)

"Information for the package leaflet regarding ethanol used as an excipient in medicinal products for human use" (EMA/CHMP/43486/2018)

Annex 1 Declaration in the package leaflet and labelling

1. Introduction

Suitable declaration of herbal substances and herbal preparations in herbal medicinal products should be included in the package leaflets and product labelling. The declaration should follow the regulations of Directive 2001/83/EC and Regulation (EU) 2019/6 as amended, and it should be consistent with the declaration given in the SmPC. Therefore, overall the declaration in the SmPC should form the basis of the declaration in the package leaflet and labelling.

The main guideline on declaration in the SmPC was developed to obtain an agreed view in the harmonisation process for herbal medicinal products. Likewise, harmonisation of the declaration in package leaflet and labelling is desirable. As the declaration should be as precise as possible, satisfactory declaration of a herbal medicinal product is most often extensive and requires much space in writing. Therefore, declaration in labelling could be abbreviated, although still in line with the principles of the main guideline for the SmPC.

This annex focuses on acceptable abbreviation in the declaration in the package leaflet and labelling compared to the declaration in the SmPC.

In general, due to different national traditions, the exact wording and the order of the elements of the declaration could be different from the SmPC. However, it should be ensured that the information and meaning is the same as in the SmPC. No new information is allowed to be added compared to the SmPC.

For requirements on Braille, see separate guidance documents ("Guideline on the readability of the labelling and package leaflet of medicinal products for human use").

2. Declaration of herbal medicinal products - in package leaflets

Because writing space is not a limiting factor for package leaflets, the declaration in the package leaflet should be the same as the one given in the SmPC section 2.

3. Declaration of herbal medicinal products - in labelling

As the size of the immediate and outer packaging is limited, the space on the label is likewise limited. Therefore, the declaration may be abbreviated, provided that this will not affect the safe use of the product.

Examples of abbreviated declaration in labelling:

Wherever possible the labelling should include the scientific plant name(s) stated in the SmPC unless otherwise authorised by the competent authority.

The extraction solvent may be omitted, if justified.

The physical state of a herbal preparation may be omitted, e.g. "dry extract" may be abbreviated to "extract".

If justified for a herbal preparation, the corresponding quantity of the herbal substance may be replaced by the ratio of the herbal substance to the genuine herbal preparation and vice versa, in this case the SmPC should include both versions.

4. Strength of herbal medicinal products – in the SmPC, package leaflets and labelling

In general, for a medicinal product, the (invented) product name should be followed by its strength, cf. Dir. 2001/83/EC; article 54, 55 and 59 and Regulation (EU) 2019/6 article 10, 11, 12, 13 and 14, as amended.

For herbal medicinal products this requirement is normally not appropriate: The declaration in the SmPC most often includes more than one quantity (mass). For e.g. a quantified extract the declaration includes both the quantity of active marker(s), the quantity of the genuine extract and the corresponding quantity of the herbal substance (or DERgenuine). So, if the name is to be followed by the strength expressed as a single unspecified mass (e.g. 40 mg), the meaning will not be clear and could be misleading. This could create confusion to the patients and other readers. In conclusion, the 'invented' product name should not be followed by a designation 'strength', but the quantitative composition would be fully detailed in the declaration of the product.

5. "Common names" of active substances – in the SmPC, package leaflets and labelling

In general, if the name of a medicinal product is an invented name, the product name should be followed by the international non-proprietary name (INN) for each active substance, cf. article 54, 55 and 59 of Directive 2001/83/EC and article 10, 11, 12, 13 and 14 of Regulation (EU) 2019/6, as amended.

As no INN's for herbal substances or herbal preparations exist, it is recommended to use a shortened form of the name for the active substance, based on the respective monograph in Ph. Eur., if available,

for example "valerian dry extract" or "valerian tincture". In absence of a Ph. Eur. monograph for the herbal substance/herbal preparation, the shortened form of the name should include the plant part, unless otherwise justified, e.g. "dandelion root with herb dry extract" or "dandelion root dry extract". This applies to the package leaflet and labelling, when the product contains up to 3 active substances.