



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Section 2: Qualitative and quantitative composition

Rev. 1

SmPC training presentation

Note: for full information refer to the European Commission's [Guideline on summary of product characteristics \(SmPC\)](#)

SmPC Advisory Group

An agency of the European Union





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I. General objectives of section 2

This section should provide **full details of the qualitative and quantitative composition** in terms of the **active substance(s)** and **excipients**, knowledge of which are essential for proper administration of the medicinal product

Excipients listed in the Annex to the ["Guideline on the excipients in the label and package leaflet of medicinal product for human use"](#) should be stated here under a **separate subheading qualitatively, and, quantitatively**



II.1 Qualitative declaration

The active substance should be declared by its recommended INN
(accompanied by salt or hydrate if relevant)

or

European Pharmacopoeial name
(if it represents the established name in Europe or no INN exists)

In the absence of the above, the following should be used in order of preference:

- Usual common name
- Exact scientific designation
- Statement on how and from what the substances were prepared

References to the pharmacopoeial quality should not be included



II.2 Quantitative declaration

Quantity should be expressed per dosage unit, per unit volume or per unit of weight, using **internationally recognised standard term** (which could be complemented with another term more meaningful to healthcare professionals)

The quantity of the active substance should be related with the declaration of strength in section 1

SmPC examples
[1 Quantitative and qualitative declaration](#)
[2 Quantitative and qualitative declaration](#)

See SmPC Guideline for information on [specific presentations](#) described below:

Salts or Hydrates ————— e.g. 60mg toremifene (as citrate) or toremifene citrate equivalent to 60mg toremifene

Esters and Pro-drugs —————

Oral powder for solution or suspension

Parenterals excluding powders for reconstitution

Powders for reconstitution prior to parenteral administration

Concentrates

Transdermal patches —————

Multi-dose solid or semi-solid products

When active moiety is an active substance of an already approved medicinal product, the quantitative composition should also be stated in terms of quantity of active moiety (e.g. 75mg of fosphenytoin is equivalent to 50mg of phenytoin)

e.g. Each patch contains 750 micrograms of estradiol in a patch size of 10cm², releasing a nominal 25 micrograms of estradiol per 24 hours



Example 1-qualitative & quantitative declaration

Qualitative and quantitative composition in terms of the **active substance(s)** and **excipients (listed in excipient guideline under a separate subheading)**, *knowledge of which are essential for proper administration of the medicinal product*

Active substance XY 600 mg/300 mg film-coated tablets

Each film-coated tablet contains 600mg of X (as sulfate) and 300mg Y.

Excipient with known effect
Sunset yellow (E110) 1.7 mg per tablet

For a full list of excipients see section 6.1.



Example 2-qualitative & quantitative declaration

Qualitative and quantitative composition in terms of the **active substance(s)** and **excipients (listed in excipient guideline under a separate subheading)**, *knowledge of which are essential for proper administration of the medicinal product*

Active substance XYZ 600 mg/200 mg/245 mg film-coated tablets

Each film-coated tablet contains 600mg of X, 200mg of Y and 245 mg Z (as fumarate).

Excipient with known effect:

Each film-coated tablet contains 1 mmol (23mg) of sodium.

For a full list of excipients, see section 6.1.



III.1 Biological medicinal products

Expression of strength

In mass units, units of biological activity, or International Units as appropriate for the particular product, and reflecting *European Pharmacopoeia* usage where relevant

SmPC example
[3 biological product](#)

The **biological origin of active substance** should be defined briefly

[Example 4 wording from SmPC guideline](#)

Pegylated proteins: Refer to CHMP guideline on the description of composition of pegylated (conjugated) proteins in the SmPC

Immunoglobulins: In the case of normal immunoglobulins, the IgG subclass distribution should be stated in terms of percent of total IgG present. The upper limit of the IgA content should follow

Vaccines: In the case of vaccines, the content of active substance per dose unit (e.g. per 0.5 ml) should be stated. Adjuvants, if present, should be stated qualitatively and quantitatively. Additional specific guidance is available in CHMP guidelines on biotechnological medicinal products, e.g. the CHMP Guideline on the Pharmaceutical Aspects of the Product Information for Human Vaccines

Residues: Residues that are of special relevance (e.g. ovalbumin in egg derived vaccines) should be specified



Example 3-biological products

Expression of strength in mass units, units of biological activity, or International Units as appropriate for the particular product, and reflecting *European Pharmacopoeia* usage where relevant

The **biological origin of active substance** should be defined briefly

Active substance X suspension for injection

1 dose (0.5 ml) contains:

Hepatitis B surface antigen ^{1, 2, 3} 20 micrograms

¹adjuvanted by AS04C containing:

- 3-O-desacyl-4'- monophosphoryl lipid A (MPL) ² 50 micrograms

²adsorbed on aluminium phosphate (0.5 milligrams Al³⁺ in total)

³produced in yeast cells (*Saccharomyces cerevisiae*) by recombinant DNA technology.

For a full list of excipients, see section 6.1



Example 4-biological product

The **biological origin** of active substance should be **defined briefly**. Thus, the nature of any cellular system(s) used for production and, if relevant, the use of recombinant DNA technology should be specified

The entry should take the form:

"produced in XXX cells <by recombinant DNA technology>".

The following are examples of the application of this principle:

"produced in human diploid (MRC-5) cells",

"produced in Escherichia coli cells by recombinant DNA technology",

"produced in chick-embryo cells",

"produced from the plasma of human donors",

"produced from human urine",

"produced from <animal>blood",

"produced from porcine pancreatic tissue",

"produced from porcine intestinal mucosa".

SmPC guideline



III.2 Herbal medicinal products



The quantitative declaration should be in accordance with the existing quality guidelines on herbal medicinal products

[Click here for access to the **European Medicines Agency** webpage on herbal medicinal products](#) (which includes access to community monographs and guidance)



IV. FAQs

1. [How should the expression of strength be defined?](#)*
2. [Should an excipient not supplied with a medicinal product but necessary for dilution of the product be stated in section 2 with the respective warning in section 4?](#)
3. [Should overages or overfills be included in the SmPC?](#)*
4. [Should residues or impurities be listed in the SmPC?](#)*



1. How should the expression of strength be defined? *

- The strength of a medicinal product should be relevant for its identification and use and should be consistent with the quantity stated in the quantitative composition and in the posology. With this objective, the following should be considered when defining the strength:
 - The recommendations of the SmPC guideline, in particular that the quantitative composition should be expressed in terms of the mass of the active moiety;
 - See the guideline [‘QRD recommendations on the expression of the strength in the name of centrally authorised human medicinal products’](#)
 - It is important to express adequately the strength of the medicinal product as early as possible during development to avoid any confusion (e.g. because of publication with different expression of strength)



2. Should an excipient not supplied with a medicinal product but necessary for dilution of the product be stated in section 2 with the respective warning in section 4?

- Information in section 2 and 6.1 relates to the composition of the medicinal product. Information on diluent that is not supplied as part of the product is therefore not required. Precautions and other information for use of the diluent e.g. 0.9% sodium chloride solution, are described in the SmPC of these products and are not expected to be repeated in the SmPC of products which have to be diluted in the diluent solution provided separately



3. Should overages or overfills be included in the SmPC?*

- Overages or overfills should not be included when stating the quantity of the active substance, because they are not intended for administration. Presenting too many quantities may cause confusion regarding the final deliverable quantity of active substance which may lead to medical errors.
- However, in cases where the presence of overfill is obvious (e.g. when reconstituting or handling the product) and could create confusion, it may be mentioned qualitatively in the SmPC and package leaflet, on a case by case basis in the most appropriate section (e.g. as part of the instructions for use).



4. Should residues or impurities be listed in the SmPC?*

- No; residues of substances arising from manufacturing process, impurities, residual solvents and degradation products should not be listed in the SmPC given that their presence and limits are controlled through specific validation methods covered by the quality assessment.
- Only residues of special relevance (e.g. ovalbumin in egg derived vaccines, residues of antibiotic or other antimicrobial agents used in production that are known allergens) should be specified in section 2. In this case, the associated risk should be communicated in section 4.4 (or 4.3, if applicable).



Thank you for consulting this training presentation

SmPC Advisory Group

Please note the presentation includes examples that may have been modified to best illustrate the related principle