

STANDARD TERMS

Introduction

and

Guidance for use

GENERAL PRINCIPLES AND INSTRUCTIONS FOR THE USE OF THE LISTS

The lists of Standard Terms were drawn up by the European Pharmacopoeia Commission further to the request of the EU Commission for the use in the marketing authorisation application, Summary of Product Characteristics (SmPC), labelling and electronic communications. It has the double purpose of bringing information to the patient/user/prescriber and distinguishing medicinal products having the same trade-name. Because of the SmPC and labelling purposes it is imperative that any Standard Term and combination of Standard Terms is constructed with a view to the patient. It should convey essential information on the properties and uses of the particular medicinal products. However, information on the container and the route of administration need not always be included in the Standard Term but may appear elsewhere in the labelling, package leaflet and SmPC.

The list of Standard Terms is only available electronically by subscription on the EDQM website (www.edqm.eu).

1. Definitions

For the purposes of the Standard Terms, the following definitions apply.

1.1. Pharmaceutical form

The pharmaceutical form may be:

- i. a dosage form;
- ii. a combination of dosage forms; or
- iii. a combination of dosage form(s) and route(s)/method(s) of administration and/or container/administration device.

In the assessment of marketing authorisation applications, pharmaceutical forms that differ only with respect to the containers/administration devices may not always be considered as different pharmaceutical forms.

1.2. Dosage form

The dosage form is the physical manifestation of a product that contains the active ingredient(s) and/or excipient(s) that are intended to be delivered to the patient; it may refer to the *form of presentation* or the *form of administration*, **which in some cases are identical**.

1.2.1. Form of presentation

The form of presentation is the dosage form of a medicinal product as manufactured and, where applicable, before reconstitution; where reconstitution is required before administration to the patient, the term includes the eventual form of administration.

Examples: Powder for solution for injection;
Tablet.

1.2.2. Form of administration

The form of administration is the dosage form of a medicinal product as administered to the patient, after any necessary reconstitution has been carried out.

Examples: Solution for injection;
Tablet.

1.3. Combined term

A combined term is a combination of existing Standard Terms or elements thereof that is constructed in order to properly characterise a medicinal product; a combined term may be a combination of dosage forms, or a combination of dosage form(s) and route(s)/method(s) of administration and/or container/administration device.

Examples: Powder and solution for solution for injection;
Eye drops, solution in single-dose container.

2. Pharmaceutical Forms

2.1. The Standard Terms database does not distinguish between medicinal products as presented by the manufacturer (form of presentation) and medicinal products as administered to the patient (form of administration). However, for a term representing a form of presentation such as ‘Powder for solution for injection’, the words ‘for solution for injection’ indicate that a reconstitution is required, and that the resulting form of administration is ‘solution for injection’.

The lists of Standard Terms may be used to characterise pharmaceutical forms intended for human and veterinary use or for veterinary use only, as indicated by the domain entries ‘H+V’ or ‘V’ respectively.

2.2. The list of Standard Terms for pharmaceutical forms is based on the following guiding principles and assumptions.

- Terminology is to be used consistently throughout the list.
- Each term should be as short as possible, commensurate with providing the necessary information to inform the patient or the user.
- Each term conveys at least two ‘elements’ of information, including the physical manifestation and the route/method of administration. The number of elements will vary from one product type to another. In some cases, established usage allows one word within a term to convey more than one element of information. For example, the term ‘Tablet’, unless otherwise qualified, denotes a product for oral use, i.e. to be swallowed.
- Where a term contains two or more dosage form elements, these elements are linked by ‘and’; e.g. ‘Powder and solvent for solution for injection’.
- If the same pharmaceutical form may be used in alternative ways, these ways are separated by ‘/’, e.g. ‘Gargle/mouthwash’, ‘Chewable/dispersible tablet’.

In both cases ('and', '/'), the terms are placed in alphabetical order (English language). For combinations created before June 2009, this rule may not have been followed. Future uses of the existing combinations will use the same order (e.g. 'Oromucosal/laryngopharyngeal suspension' or '... injection/infusion').

Where several routes of administration are intended for a medicinal product, the focus should be placed on the primary use for the creation of a standard term or a combination of standard terms, for example 'Oral solution' is sufficient as the primary use for a request of 'Oral/gastric/gastroenteral solution'.

- Terms in singular may also be used in plural when the same pharmaceutical form is presented in two or more containers prior to preparation of the medicinal product ready for use, e.g. 'Solutions for sealant', 'Powders for implantation suspension'.

The creation of unnecessary terms is discouraged.

- 2.3. In certain cases, further characterisation of the pharmaceutical form requires additional information about the immediate container/administration device. If the medicinal product has certain special characteristics that are relevant to its use, these need to be included in the term, e.g. 'Intravitreal implant in applicator'. This applies in any case to pre-filled syringes, pressurised preparations or single-dose **eye** preparations; it also applies in cases where the administration of the same physical form differs due to different design of the container/administration device. For example: 'Oral suspension' and 'Oral suspension in sachet'.
- 2.4. The same principle applies to the construction, when needed, of a product-specific term by combination of a Standard Term for the dosage form and a Standard Term for the route/method of administration, e.g. 'Powder for intravesical solution'.

The common parenteral routes (e.g. 'intravenous use' and 'intramuscular use') need not be included in a Standard Term unless they are needed to distinguish medicinal products having the same trade-name, in which case such elements may be necessary (e.g. 'Solution for intravenous injection' and 'Solution for intramuscular injection').

In particular, the construction of the term for a pharmaceutical form for veterinary use may require a combination of Standard Terms or elements thereof due to the specificity and multiplicity of veterinary routes of administration and associated administration devices.

- 2.5. In the case of a powder that is dissolved in a small amount of solvent before it is diluted in a larger volume to be infused and this dilution is mandatory for safety reasons, the term ‘concentrate’ should appear in the pharmaceutical form (e.g. ‘Powder for concentrate for solution for infusion’). If the powder that is dissolved in a small amount of solvent can either be administered as such or be further diluted before administration (i.e. no safety issue), there is no need to use the term ‘concentrate’ (e.g. ‘Powder for solution for infusion’).
- 2.6. The term ‘modified-release’ is not sufficiently precise for describing a particular product. A more specific term such as ‘prolonged-release’ or ‘gastro-resistant’ should be used, wherever applicable.
- 2.7. The label of the medicinal product may be too small to permit the inclusion of the Standard Term(s).

Therefore, in addition to the Standard Terms given in the Dosage forms section, a number of patient-friendly terms (generally shortened versions of existing terms), which may be used for labelling *only, in case of space limitation*, are given in the Patient-friendly (formely Short) terms section of the Standard Terms lists.

3. Routes and methods of administration

The route of administration indicates the part of the body on which, through which or into which the medicinal product is to be introduced. Mostly in the veterinary field, the method of administration indicates the way the medicinal product is to be administered to the animals.

Where several routes of administration are intended for a medicinal product, the focus should be placed on the primary use for the creation of a standard term or a combination of standard terms, for example ‘Oral use’ is sufficient as the primary use for a request of ‘Oral/gastric/gastroenteral use’.

The creation of unnecessary terms is discouraged.

4. Containers, closures and administration devices

The pharmaceutical form is supplied in an *immediate packaging* which is the *container* or other form of packaging immediately in contact with the medicinal product. A *closure* is a means to close an immediate container for the purpose of the correct storage

and use of the medicinal product. In some cases a special *administration device* is needed for the correct administration of the medicinal product. The administration device may be an integral part of the immediate container or closure.

5. New Standard Terms

A request for a new Standard Term will only be made to the European Directorate for the Quality of Medicines & HealthCare (EDQM) when the nature of the medicinal product is such that no existing Standard Term or combination of Standard Terms accurately describes it. Such requests will be made in accordance with the procedure described at the end of this document.

The creation of unnecessary Standard Terms is discouraged.

6. Combined Terms

- 6.1 In the case of a novel medicinal product, the member state or the European Medicines Agency (EMA) may consider that a suitable product-specific term should be constructed by combination of existing Standard Terms or elements thereof.

A request is made to the EDQM so that the suitability of the proposed combined term is assessed by the EDQM. Such requests will be made in accordance with the procedure described at the end of this document. Where appropriate, the term will be included in the list of Combined terms.

The creation of unnecessary terms is discouraged.

Where no existing Standard Term applies, characterisation of the pharmaceutical form may be obtained by combination of elements of Standard Terms, or combination of such elements with Standard Terms. For example, when the form of presentation (e.g. solution/suspension/emulsion or ointment/cream/gel) differs from that of the existing Standard Term, replace the form in the Standard Term. For example, the term ‘Powder for intravesical suspension’ exists, and can be used as the basis to create the term ‘Powder and solvent for intravesical suspension’.

- 6.2 Combination of existing Standard Terms, e.g. combination of the dosage form and the immediate container/administration device (c.f. item 2.3) and combination of the dosage form and the route/method of administration (c.f. item 2.4) may be necessary for safety reasons or to distinguish marketed products.
- 6.3 In some cases, a medicinal product may be intended for more than one route and/or method of administration. In these cases, the two (or more) terms may be included, for example ‘Chewable/dispersible tablet’.

PROCEDURE FOR THE ADDITION OR MODIFICATION OF TERMS IN THE LIST OF STANDARD TERMS

Before submitting any request for the addition or modification of a Standard Term, please read the Introduction to Standard Terms publication which provides information on the general principles on which Standard Terms are established. In particular, attention is drawn to the expectation that a request for a new Standard Term or a Combined Term will only be made when the nature of the medicinal product is such that no existing Standard Term or Combined Term accurately describes it.

1. The member state, the European Commission or the EMA send the completed request form to the EDQM.
2. The EDQM sends immediately (within one week) the proposal to the Standard Terms Working Party of the European Pharmacopoeia Commission.
3. The Working Party examines the proposal in a meeting, or by correspondence if required, and if necessary designates a rapporteur.
4. The Working Party gives an opinion together, if necessary for a new term, with a proposal for a provisional definition.

The European Commission, the member states' competent authorities and the EMA are informed about this opinion and are asked to comment within 1 month. Any disagreement should be justified.

The opinion may be submitted to Group of Experts No. 12 of the European Pharmacopoeia Commission so that, where necessary, it can make a proposal on the revision of the corresponding monograph or on the elaboration of a new monograph.

5. Taking into account any comments received and the advice of the Working Party, the European Pharmacopoeia Commission adopts (by correspondence) the new Standard Term(s) or the modification of a Standard Term so that the change can be introduced into the list of Standard Terms. It authorises, if necessary, the revision of the corresponding monograph or elaboration of a new monograph.

A new or modified Standard Term is introduced into the list of Standard Terms and is then translated into the various languages by the national authorities, each authority translating it into its own language.

6. In case the request for a new Standard Term is made for a licence application, the request mentions the date of the receipt of the valid application so that an approved Standard Term is provided within 120 days.

The EDQM is duly informed of the result of the assessment of the licence application before publishing the new Standard Term.

7. The requests for new combined terms are examined by the Standard Terms Working Party during its meetings. The European Commission, the member states' competent authorities and the EMA are informed about its opinion. The new combined terms are then introduced into the list of Standard Terms.