EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Section 1: Name of medicinal product

SmPC training presentation

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

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I. General objective of section 1

This section should provide the (invented) name of the product followed by strength and pharmaceutical form

When referring to properties of the active substance (rather than those of the product) throughout the SmPC text, the international non-proprietary name (INN) or usual common name of the active substance should be used

Throughout the SmPC text, the strength and the pharmaceutical form **do not have** to be mentioned in the name

II.1 Strength

Relevant quantity for identification and use of the product

Strength should be consistent with quantity stated in quantitative composition (section 2) and posology (section 4.2)

Please refer to

'QRD recommendations on the expression of strength in the name of centrally authorised human medicinal products'

Different strengths of the same medicinal product should be stated in same way

e.g. 250mg, 500mg, 750mg

Use of **decimal points should be avoided** where they can be easily removed

e.g. 250microgram, not 0.25mg

However when a range of medicinal products of the same pharmaceutical form includes strengths of more than one unit, it may be more appropriate in certain cases to state strengths in the same unit for the purpose of comparability

e.g. 0.25mg, 1mg and 6mg

Strength of **biological products** should be expressed in terms of mass units, units of biological activity or international units as appropriate, reflecting European Pharmacopoeia usage where relevant. Refer to CHMP Guidelines such as the *CHMP Guideline on potency labelling for insulin analogue containing products with particular reference to the use of "international units" or "units"*

For safety reasons, **micrograms and millions** (e.g. for units) should always be **spelled out in full rather than be abbreviated**

II.2 Pharmaceutical form

Should be described by **a single full Standard Term of the European Pharmacopoeia using the plural form if appropriate** (e.g. tablets) (should be the same as in Section 3)

A new term may be constructed from a combination of standard terms in accordance with the EDQM document “Standard terms, introduction and guidance to use”

A new Standard Term from the European Directorate For Quality of Medicines and Healthcare (EDQM) of the Council of Europe should be requested

No reference should be made to the route of administration or container unless:
- These elements are part of the standard term
- There is a particular safety reason for their inclusion
- Identical products can only be distinguished by reference to route of administration or container

III.1 Name of vaccine

The name of a vaccine should appear as (invented) name followed by (strength), pharmaceutical form and common name of the product

For complete guidance, please refer to:

CHMP guideline on pharmaceutical aspects of the product information for human vaccines

Thank you for consulting this training presentation

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