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Human Medicines Evaluation Division

Policy on combined Summaries of Product Characteristics (SmPCs)

1. Criteria for combined SmPCs

In order to simplify the handling and review of product information annexes, it is recommended to use combined SmPCs throughout the evaluation and after the adoption of the opinion for different strengths of the same pharmaceutical form for all languages. The SmPCs must be fully identical to the exclusion of minor strength-specific details, e.g. if the indications are different for the different strengths, the SmPCs cannot be combined.

In case of combined terms, only the primary pharmaceutical form should be considered, e.g. *solution for injection in vial* and *solution for injection in pre-filled syringe* can be combined.

Different pharmaceutical forms will always be presented in separate SmPCs.

As a general rule, combined SmPCs should be used for initial Marketing Authorisation Applications (MAAs).

2. Implementation

This policy is reflected in the guidance of the annotated QRD template.

For initial MAAs: applicants are encouraged to use combined SmPCs.

For existing Marketing Authorisations: Marketing Authorisation Holders are encouraged to take the opportunity of the following procedures to combine the SmPC:

Renewal

Line Extension

Type IB and II variations affecting the Annexes

3. Presentation of combined SmPCs (see example below)

- Subheadings have to be included under each of the sections where information specific to the different strengths can be provided.

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- The subheading should be underlined and should specify the name of the product, the strength(s) it applies to and the pharmaceutical form (e.g. X 5 mg tablet, X 10 mg tablet, etc.). Some line spacing should be inserted after the strength specific information to clearly indicate where the latter stops and where the common information starts again.
- No subheading is required in Section 1 'NAME OF THE MEDICINAL PRODUCT'.

Example

1. NAME OF THE MEDICINAL PRODUCT

X 5 mg tablets
X 10 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

X 5 mg tablets
Each tablet contains 5 mg of Z.

X 10 mg tablets
Each tablet contains 10 mg of Z.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

X 5 mg tablets
White to slightly yellow tablets engraved with "5" on one side and "Y" on the other.

X 10 mg tablets
White to slightly yellow tablets engraved with "10"on one side and "Y" on the other.

The following sections can include different information for the purpose of combined SmPCs:

1. NAME OF THE MEDICINAL PRODUCT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

3. PHARMACEUTICAL FORM
The description of the pharmaceutical form (shape, colour, dimension).

4. CLINICAL PARTICULARS
(4.2 Posology and method of administration)

6. PHARMACEUTICAL PARTICULARS
(6.1 List of excipients)
(6.3 Shelf life)
(6.5 Nature and contents of container <and special equipment for use, administration or implantation
(6.6 Special precautions for disposal and other handling)

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4. Combined package leaflet (PL)

The process to request a combined PL is a separate one, independent from the use of a combined SmPC. Therefore, combined SmPCs can be used if the relevant criteria are met even if a combined PL has not been accepted.

Under the current practice for centralised medicinal products, an applicant can apply for a combined printed PL for more than one strength of the same pharmaceutical form. A combined PL can be acceptable if the following three conditions are met:

- The posology in the SmPC/PL foresees at least two dosages (e.g. titration phase, dose adjustment based on clinical response or for special populations);
- The PLs are fully identical to the exclusion of minor strength-specific details, and
- The proposed combined PL does not cause any confusion or risk of misuse for the patient or user.

In order to request a combined PL, the applicant has to include a justification/rationale as part of the application for a Marketing Authorisation, a Line Extension, a Renewal, a Variation or an Article 61.3 Notification. The request will be discussed at one of the QRD Plenary meetings (or via written procedure in case of urgency) and a decision will be made on a case-by-case basis.