



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

QRD general principles regarding the SmPC information for a generic/hybrid/biosimilar product

Background information

- This document outlines the general principles to follow for the preparation of the summary of product characteristics (SmPC) for a generic, hybrid or biosimilar medicinal product to be authorised via the centralised procedure using a reference medicinal product authorised either at national level or centrally.
- The following types of applications are discussed in this document: generic applications (as per Art. 10(1) of Directive 2001/83/EC), hybrid applications (as per Art. 10(3) of Directive 2001/83/EC) and biosimilar applications (as per Art. 10(4) of Directive 2001/83/EC).

General principles

- The content of the generic's summary of product characteristics (SmPC) should be in all relevant aspects consistent with that of the reference medicinal product except for indications or dosage forms still covered by patent law.
- Following the same general principles, the SmPC content for a hybrid or biosimilar medicinal product has to be consistent with the reference medicinal product for the common information applicable to the hybrid or biosimilar product. In other words, the information from the reference medicinal product's SmPC that applies to the hybrid or biosimilar should be included in the SmPC of the hybrid or biosimilar.
- The applicant should discuss and justify any differences of the proposed SmPC vis-à-vis the SmPC of the reference medicinal product.

QRD template and SmPC guideline

- Format changes to the generic, hybrid or biosimilar's SmPC in comparison to the reference medicinal product's SmPC are acceptable as long as the content remains consistent. The current QRD template and the SmPC guideline should be applied to the generic, hybrid or biosimilar SmPC as far as possible, if the relevant information is available.
- If the relevant information from the reference medicinal product's SmPC is not available to allow the update of the SmPC to the current QRD template and/or SmPC guideline, the update should not be applied to the generic, hybrid or biosimilar's SmPC (as the content has to be consistent).



Cases where changes are needed compared to the reference medicinal product's SmPC.

- If the applicant believes additional information is required in the generic, hybrid or biosimilar's SmPC compared to the SmPC of the reference medicinal product, they should support and justify the additional information in their application.
- During assessment, the CHMP may consider that the information in the reference medicinal product's SmPC should be updated, especially for safety reasons. For centrally authorised products, the CHMP will discuss the requirement for the update of the relevant reference medicinal product(s). In case of nationally authorised reference medicinal products, the need for update of the reference medicinal product's SmPC should be brought to the attention of the relevant competent authority (e.g. the Reference Member State for a DCP/MRP or the competent authority(ies) where the product is authorised).

Translations

- For sections of the product information where the information for the generic, hybrid or biosimilar product is identical to the reference medicinal product's information, the corresponding translations from the reference medicinal product's product information must be used, if available, for the generic, hybrid or biosimilar product in order to avoid unnecessary linguistic review exercise. Obvious translation mistakes in the reference medicinal product's product information should be corrected.

Package Leaflet

- The package leaflet should reflect the scientific content of the SmPC of the generic, hybrid or biosimilar, for the relevant information for patients.
- With the exception of differences based on scientific grounds, deviations from the reference medicinal product's package leaflet are expected to be justified by results of user testing consultation with target patient groups.

References

Directive 2001/83/EC

Regulation (EC) No 726/2004

Guideline on summary of product characteristics, September 2009

QRD Template