

Biosimilar SmPC Recommendations

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Introduction

This document outlines the proposals put forth by EuropaBio members with regard to small yet meaningful changes to the Summary of Product Characteristics (SmPC) of biosimilars, which we consider would result in an enhanced level of transparency in the label.

EuropaBio advocates that the SmPC of a biosimilar product should contain information and data to facilitate greater transparency to physicians and patients; our position has been recognised in various publications and published on our websiteⁱ. Over the last few years, EuropaBio and its members have taken the opportunity to engage with stakeholders in various forums such as conferencesⁱⁱ, biosimilar labelling workshopsⁱⁱⁱ and publications of surveys^{iv,v}. EuropaBio recognises that stakeholders would like to understand the nature of the entire data package that has been generated as a basis for approval of Biosimilars. These constructive discussions have allowed EuropaBio to reflect on the changes most pertinent to biosimilar labels and to review the 2012 QRD General Principles^{vi} regarding the SmPC information for a generic/hybrid/biosimilar product.

In line with this background, we believe that the minor changes to the SmPC proposed in this document will help improve transparency for physicians and patients whilst remaining true to the QRD principles, i.e.:

"[...] 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."^{vii}

A review of biosimilar SmPCs, since the first approval in 2006, highlights how they have evolved to become closer to SmPCs used for chemical, small molecule generic drugs^{viii}. However, it is unclear why this evolution occurred, and it remains to be seen that such an outcome was not the result of inclusive stakeholder discussions.

With this in mind, EuropaBio urges that European and National Competent Authorities continue to engage with all stakeholders to ensure the information and data included in a biosimilar SmPC is appropriate to provide clarity for physicians when prescribing and utilising biosimilar products. Additionally, it remains important that any additional information or data included in the SmPC is still aligned with the principles of QRD template. The minor changes to the SmPC, recommended by EuropaBio in this document, are based on outcomes of stakeholder discussions and various

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physician, patient and pharmacist surveys, and seek to articulate the issues raised by all these stakeholders.

Recommendation 1 – add statement with definition of biosimilarity

Similar to the statement around the black triangle^{ix}, we recommend that there should be a short statement about the biosimilar paradigm, i.e. that the product is approved based on comparative quality, non-clinical and clinical data and shown to be highly similar to its reference.

Justification: The biosimilar paradigm has posed challenges for many physicians and patients, particularly with respect to the data needed for approval. This statement would help foster greater understanding with physicians and patients as well as providing transparency. The inclusion of a biosimilar statement was also a key outcome from the joint EuropaBio – EBE biosimilar labelling workshop held on 02 February 2016, which the EMA attended as observers^x.

Recommendation 2 – add direct link to EPAR next to the biosimilarity statement

Within the statement of biosimilarity (currently found in section 5.1 of the SmPC) we recommend that there is a link to the product EPAR/specific EPAR section (i.e. Assessment history) rather than the existing reference to the general EMA website. Additionally, it is important that it is made clear that information on the development of the specific biosimilar can be found in the EPAR.

Justification: The current link to the EMA website is non-specific. Prescribers and pharmacists require direct access to specific product data for decision making purposes. A direct link to the biosimilar EPAR/specific EPAR section would also allow healthcare professionals to easily compare the data generated during the biosimilarity exercise with the information in the SmPC, which may be reflective of data generated with the reference product.

Recommendation 3 – move biosimilarity statement to the top of the SmPC

The current statement '*[Product name]* is a biosimilar medicinal product' is found in section 5.1 of the SmPC. We recommend to move this expanded statement (see Recommendation 1) to the very beginning of the biosimilar SmPC to foster greater understanding with physicians and patients and improve transparency.

Justification: The EU physician survey demonstrated that SmPC section 5.1 is not routinely reviewed by prescribers, compared to other sections (section 4 "Clinical particulars"^{xi}) which are more commonly consulted when making prescribing decisions. It would therefore be prudent to include this statement at the beginning of the SmPC.

References

- ⁱ EuropaBio, "EuropaBio Position Paper on Biosimilars in Europe" (2014). Source: http://www.europabio.org/sites/default/files/europabio_biosimilars_position_paper_final.pdf
- ⁱⁱ European Commission – DG GROW, "Second multi-stakeholder event on biosimilar medicinal products, Brussels" (2016). Source: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8968
- ⁱⁱⁱ EBE, "EuropaBio and EBE host a multi-stakeholder debate on the labelling of biosimilar medicines" (2016). Source: <http://www.ebe-biopharma.eu/newsroom/86/56/EuropaBio-and-EBE-host-a-multi-stakeholder-debate-on-the-labelling-of-biosimilar-medicines>
- ^{iv} Hallersten, A., Furst, W., & Mezzasalma, R., "Physicians prefer greater detail in the biosimilar label (SmPC) – Results of a survey across seven European countries" (2016). Doi: <http://dx.doi.org/10.1016/j.yrtph.2016.03.021>
- ^v Watson, K., Akers, C., Hume, E., Torqui, A., Numan, S., Gargesi, M., & Mezzasalma, R. "A visible difference: clinical packaging" (2015). Source: <http://www.worldpharmaceuticals.net/features/featurea-visible-difference-clinical-packaging-4627678/>
- ^{vi} European Medicines Agency, "QRD general principles regarding the SmPC information for a generic/hybrid/biosimilar product" (2012). Source: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/05/WC500127589.pdf
- ^{vii} *Ibid.*
- ^{viii} Hallersten, A., Furst, W., & Mezzasalma, R., "Physicians prefer greater detail in the biosimilar label (SmPC) – Results of a survey across seven European countries" (2016)
- ^{ix} European Medicines Agency, "What does the black triangle mean?" (2013). Source: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/09/WC500150608.pdf
- ^x GaBI Journal Editor, "Biosimilar product labels in Europe: what information should they contain?" (2017). Source: <http://gabi-journal.net/biosimilar-product-labels-in-europe-what-information-should-they-contain.html>
- ^{xi} Based on the findings of the EuropaBio survey (see Reference IV), the biosimilarity statement could also be copied-pasted into more frequently consulted sections of the SmPC, i.e. Section 4, "Clinical particulars":
- When asked about the importance of the mandatory sections of the SmPC based on section numbers and headings according to the EU SmPC template (EU Commission, 2009) almost all surveyed physicians (91.9%) considered Section 4, "Clinical particulars" as the most important, followed by Section 5 "Pharmacological properties" (73.8%) (see Table S1 for structure of the EU SmPC with section numbers and titles). When asked about the most relevant sub-sections, these physicians selected "Contraindications", "Therapeutic indications" and "Posology and method of administration" within Section 4 and "Preclinical safety data", "Pharmacokinetic properties" and "Pharmacodynamic properties" within Section 5 (Fig. 2). Notably, of the three subsections of Section 5, "Pharmacodynamic Properties", where clinical data and the biosimilar statement are found in the SmPC, received the lowest importance rating.*