EuropaBio Statement on Labelling of Biosimilars

September 2014

Transparent labelling is important to ensure that physicians and patients have readily available product-specific information about biosimilars, as is the case for originator products. Transparent labelling allows physicians to make informed decisions when selecting the most appropriate medicinal product for their patients.

We believe that both the Summary of Product Characteristics¹ (SmPC) and the Patient Information Leaflet² (PIL) should be the primary source of information for physicians and patients. A 2013 survey of the Alliance for Safe Biologic Medicines (ASBM) showed that 86% of EU physicians often use the SmPC to learn about the details of medicines they prescribe, whilst 81% rarely look at the European Public Assessment Report (EPAR).

Taking into account the importance of the SmPC for physicians’ information, we are concerned that the current labelling regime for biosimilars may be insufficient for these products, given their unique scientific and regulatory status. We therefore call for a specific guidance on the labelling of biosimilars.

The current EU approach to labelling does not distinguish between biosimilars and generics

Format and content of labelling is governed by the EMA’s QRD (Quality Review of Documents) guidance³ which does not distinguish between biosimilars, generics and hybrid products. In particular, the QRD guidance states that:

“*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*. However, “*the applicant should discuss and justify any differences of the proposed SmPC vis-à-vis the SmPC of the reference medicinal product*”.

We believe that this approach may be inconsistent with the nature of biosimilars and inappropriate for the following reasons.

Biosimilars’ labelling should reflect biosimilars’ specificities

From a legal standpoint, biosimilars are recognised as a distinct category of medicinal products and have a different regulatory approval pathway than both originator products and generics in the EU. The European biosimilar pathway recognises that, unlike generic products, a biosimilar product is similar (but not identical) to its reference product as it contains a version of the active substance of an

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¹ The SmPC is a legal document approved as part of the marketing authorisation of each medicine. It provides information for healthcare professionals on how to use the medicine. This information is updated throughout the life-cycle of the product as new data emerge.

² The PIL is a leaflet containing information for the user which accompanies the medicinal product.

³ EMA/627621/2011
already authorised biological product. Therefore, there can be minor differences between a reference product and its biosimilar(s) as well as among different biosimilars of the same reference product.

For this reason, the EMA’s biosimilar pathway uses a carefully designed, stepwise approach in which an extensive and thorough quality and in vitro comparison informs on the amount and type of (non-) clinical data needed to ensure that the previously proven safety and efficacy of the reference product is confirmed by the biosimilar. This same stepwise approach is used to decide whether and to what extent biosimilarity has to be demonstrated separately for each of the claimed indications. EuropaBio is of the opinion that a reference of these steps, and the data generated, in the SmPC and the PIL will contribute to facilitate physicians’ and patients’ understanding and acceptance of biosimilars. The wording in the SmPC should clearly identify by name each product the data were generated with (e.g., the reference product, the biosimilar, or a larger class of products, where there is a class issue). In addition to a brief discussion of the scientific justification for any extrapolation in the SmPC, an in-depth discussion should continue to be included in the European Public Assessment Record (EPAR).

It is of utmost importance that there should not be any disconnect between a biosimilar’s clinical and non-clinical data and the information included in the SmPC. In other words, the SmPC should not misleadingly imply that data generated from the reference product was generated from the biosimilar (or vice versa).

Biosimilars should be labelled in a consistent manner in order to help these products to be properly understood and accepted by physicians and patients.

The way forward: the label should combine information on both the reference product and its biosimilar(s)

In the publication “Setting the stage for biosimilar monoclonal antibodies”\(^4\), C.K. Schneider et al. consider three approaches for labelling of biosimilars:

- **Biosimilars’ label is an identical copy of the reference product’s label.**

- **Label only gives information on the biosimilar:** Users could have the misconception that the authorisation of biosimilars is based on a lower level of evidence as this labelling scheme does not take into account the proof of biosimilarity and the fact that the safety aspects of the reference product also apply to the biosimilar(s).

- **Label combines information on both the biosimilar and the reference product:** This approach would combine relevant information on the biosimilar and the reference product. It should be clarified whether the data was generated for the reference or the biosimilar product, and which indications were approved for each product.

EuropaBio supports a transparent label which combines information on both the biosimilar and the reference product. EuropaBio calls on European regulators to develop a specific guidance on the labelling of biosimilars and to no longer assign a generic label to biosimilars. We believe that a new and transparent labelling regime for biosimilars will contribute to facilitating physicians’ and patients’ understanding and acceptance of these products.

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