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Regional regulatory processes for the approval of biosimilars; differences and similarities

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The situation in many countries regarding the procedure used to evaluate 'biosimilars' is not always clear. In this issue of *GaBi Journal*, Azevedo et al. review the regulatory situation for biosimilars in Latin America. It is intended to publish reviews covering the regulatory situation with biosimilars in other countries/geographical areas in future issues of *GaBi Journal*.

Keywords: Biosimilars, follow-on products, Latin America, regulatory processes

The availability of biosimilars can clearly benefit patients, as access to optimal treatment can be provided at acceptable cost, which may not be possible, at least for some patients without them.

The lead taken by the European Medicines Agency (EMA) in providing a suitable regulatory process for the evaluation and approval of biosimilars has ensured that biosimilar approval is feasible and that approved biosimilars in the European Union (EU) are of appropriate quality. Biosimilars approved in the EU are evaluated according to criteria set out in a range of guidelines, which ensures the necessary safety and efficacy [1].

However, although some other countries have adopted a similar regulatory stance for biosimilars, some adopting the EU guidelines, others producing their own guidelines or following the World Health Organization (WHO) biosimilar guideline [2], the situation in many countries regarding the procedure used to evaluate 'biosimilars' is not always clear. At least in some countries, approved 'biosimilars' are not evaluated using the comparability approach formulated in the EMA and WHO guidelines and so would not be regarded as biosimilars in this sense, at least in the EU and by WHO. Although some appear to be appropriate for clinical

use, others are not. This issue has been described before [3] and received considerable attention in the literature and at conferences focused on biosimilars.

It has been proposed by some authors that the EMA/WHO approach for approval of biosimilars may be too arduous for adoption by poorer nations who urgently require cheaper biological products [4, 5] but this view has been questioned on grounds of required safety and efficacy [6].

It is therefore of considerable importance and interest to review the situation concerning biosimilar development and particularly the regulatory procedures available for biosimilars and other follow-on products on a country/geographical area basis.

In this issue of *GaBi Journal*, Azevedo et al. review the regulatory situation for biosimilars in Latin America in their paper 'Recommendations for the regulation of biosimilars and their implementation in Latin America' [7]. This review clearly shows that even in a specific geographical area the procedures required for approval of biosimilars varies considerably. Although there is general acceptance of the sentiments of the EMA/WHO guidelines these have often not been followed in the past and may not be fully applied at present. Some countries in the region have drafted their own guidelines, often taking considerable account of the

WHO guideline; and some follow more than one guidance. The quality of products also varies and there is sometimes a lack of knowledge of the quality of 'biosimilar' products and the implications of this for their clinical use. In some cases more than one procedure is available for approval of follow-on products, for example, in Brazil a 'comparability' pathway and an 'individual development' pathway co-exist. The comparative pathway is almost identical to that proposed in WHO guidelines on evaluation of similar biotherapeutic products. In the 'individual development' pathway, quality issues and clinical study requirements are reduced relative to the comparative pathway, but an extrapolation of indications is not permitted.

In other Latin American countries 'biosimilars' have been approved using the procedure used for chemical generics, with little information available for the basis of approval although this route is not currently favoured.

The review highlights various problems currently experienced in Latin America with the approval of follow-on biologicals. These include lack of clarity on details of procedures, use of different nomenclature for products, difficulties with assessing products, lack of consensus or knowledge of what the requirements for biosimilars should be and limitations relating to resources available. The review concludes with some final recommendations from the authors which they consider would 'significantly enhance the appropriate review, approval and safe use of biosimilars' in Latin America.

It is intended to publish reviews covering the regulatory situation with biosimilars in other countries/geographical areas in future issues of *GaBi Journal*.

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