First Latin American Educational Workshop on
Similar Biotherapeutic Products

20 January 2015, Sheraton Maria Isabel Hotel & Towers, Mexico City, Mexico

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GaBI Educational Workshops

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Introduction to a global view of biologicals, biosimilars and non-originator (non-comparable) biologicals

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GENERICS AND BIOSIMILARS INITIATIVE
Building trust in cost-effective treatments

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Biologicals – Definition

A biopharmaceutical, also known as a biological medical product or more simply as a biologic or biological, is any medicinal product manufactured in or extracted from biological sources. Biopharmaceuticals are distinct from chemically synthesized pharmaceutical products. Examples of biopharmaceuticals include vaccines, blood products or components, allergens, somatic cells, gene therapies, tissues, recombinant DNA products, and living cells.

Biosimilars – EMA Definition

A biosimilar is a biological medicinal product that contains a version of the active substance of an already authorised original biological medicinal product (reference medicinal product). A biosimilar demonstrates similarity to the reference medicinal product in terms of quality characteristics, biological activity, safety and efficacy based on a comprehensive comparability exercise.

Biosimilars: Comparability concept

Comparability studies are needed to generate evidence substantiating the similar nature, in terms of quality, safety and efficacy, of the new similar biological medicinal product and the authorized chosen reference medicinal product.

Biosimilars – Development

A stepwise approach is normally recommended throughout the development programme, starting with a comprehensive physicochemical and biological characterisation. The extent and nature of the non-clinical *in vivo* studies and clinical studies to be performed depend on the level of evidence obtained in the previous step(s) including the robustness of the physicochemical, biological and non-clinical *in vitro* data.

Biosimilars in the EU

Biosimilars are now firmly established in the EU as copy biologicals with a clear and effective regulatory route for approval, which allows marketing of safe and efficacious biosimilar products.

Biosimilars and WHO

WHO has produced a guideline for evaluation of 'similar biotherapeutic products' (effectively biosimilars) which proposes a very similar approach to that described in the EU guidelines.

Biosimilars outside the EU

Outside the EU, several countries have adopted an identical or similar regulatory approach to the EU for approval of biosimilars, e.g. Australia, Canada, Japan.

But, this is not the case for all countries. Several have different approaches, inconsistent approaches or no approach at all for biosimilars.

Are all Biosimilars really Biosimilars?

- Terms 'Biosimilars', 'Similar Biological Products' & 'Non-Innovator Products' etc often used interchangeably. Can be incorrect.
- Non-Innovator Products or 'Me-to' products usually have not been evaluated using comprehensive comparability studies as required by EU and WHO guidelines. They are not biosimilars and should not be called biosimilars.

Quality of Products

The quality of products varies worldwide.

Some are very good. Others are not.

Batch-to-batch consistency also can vary.

Some products called ‘biosimilars’ in some countries are of inferior quality. But are they ‘real’ biosimilars?

The quality of biosimilars approved in the EU is high – like innovator products.