European Biosimilars Group
EGA sector group

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French Parliament Public Hearing on Biosimilar Medicines, Paris, 29 January 2015
Intervention from the European Medicines Agency (EMA) Spokesperson Camille Vleminckx

[Unofficial EGA translation – June 2015]

"I would like to remind everyone of the main principles applicable to the evaluation of biosimilar medicines and the requirements that they need to comply with before obtaining a marketing authorisation.

Within the EU we have benefited from a robust and well-established regulatory framework since 2004, as well as guidelines and recommendations which explain the detailed requirements applicable to biosimilar medicines thus facilitating the development of this kind of product. These requirements are regularly updated, thanks to experience acquired over time as well as the latest scientific and technological progress.

1.1. What are the underlying principles to demonstrate biosimilarity?

In reality the same principles are applied to any biological medicine when introducing a change to the manufacturing process. Biological substances have a certain intrinsic variability and are sensitive to the manufacturing process used. So before authorising such modifications, one needs to ensure that the active substance produced with the new method is comparable to the active substance produced with the former method and that there is no impact on the efficacy or safety of the medicines.

In this context, the active substance of a biosimilar medicine is in fact a version of the active substance of the reference product. In other words, it is the same active substance with small differences that comes from the complex nature of the product but also from the manufacturing process used. However, these differences do not have any impact on the safety and efficacy of the product. The objective of biosimilar medicines development is to demonstrate 3 levels of similarity: quality, efficacy and safety.

1.2. What is this development all about?

It is an in-depth step-by-step evaluation of the comparability between two products. Throughout the entire programme, it is important to use methods and put into place studies that are sufficiently sensitive to detect the differences linked to the product and therefore limit the variability that could be due to other factors. This programme always starts with an in-depth evaluation and a comparison of physico-chemical characteristics but also of the biological activity, as well as of the impurity profile of the candidate medicine compared to the reference medicine. This is actually the key step of the development.

It is also important to highlight that the quality data relating to the biosimilar product constitutes a complete dossier, as for any other biological product; it must comply with all applicable regulatory and scientific requirements in the field. In addition, the data mentioned previously are supplementary data provided in this quality file.

In terms of non-clinical and clinical data, it is necessary to provide comparative studies. The extent and number of these studies will depend not only on the results obtained during the previous steps of the development but also on the nature and complexity of the reference medicine.

It is therefore important to note that the clinical benefit of the medicine has already been established for the reference medicine, hence the objective of the biosimilar medicine development is to demonstrate the therapeutic equivalence

EGA | EUROPEAN GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION
Rue d'Arlon 50 B-1000 Brussels, Belgium
T: +32 (0) 2 736 84 11 | F: +32 (0) 2 736 74 38
www.egagenerics.com | info@egagenerics.com

between the two treatments. The medicine's efficacy does not need to be re-established but simply its therapeutic equivalence. The studies are carried out as needed and must be sufficiently sensitive to detect differences.

Regarding clinical data, one must also cover safety in the use of the medicine as well as the immunogenic potential of the molecule.

I would like to say a few words about extrapolation. Extrapolation is not systematic. It always needs a justification based on scientific data, considerations on the mechanism of action, patho-physiological mechanisms of the disease, but also the safety and immunogenicity profiles of the product in different pathologies. In certain cases, this requires additional clinical and non-clinical studies.

To conclude, the EU regulatory framework is robust, based on science and allows the possibility to grant marketing authorisation for biosimilar products of the same quality, efficacy and safety as the reference medicines".

Full debate in French can be viewed here:

http://videos.assemblee-nationale.fr/video.6348.opecst--les-medicaments-biosimilaires-29-janvier-2015

FOR MORE INFORMATION ON BIOSIMILAR MEDICINES:

EUROPEAN COMMISSION CONSENSUS INFORMATION DOCUMENT

A consensus information document was published by the European Commission in 2013. This multi-stakeholder consensus document has been developed to provide comprehensive information on the concept of biosimilar medicinal products, including science, regulatory and economic aspects.

All elements in this document are relevant to decision makers such as scientific societies, healthcare professionals and competent authorities, as well as to patients and their representative organisations. The document includes a Q&A for patients, physicians and payers.

The document is available in English, French, German Italian, Polish, Portuguese and Spanish here.