European Federation of Pharmaceutical Industries and Associations

Issued in May 2017

Statement on Biosimilars by EFPIA Japan (2017 version)

EFPIA Japan Biologics Committee

In recent years, remarkable progress has been made in the development of biologics, which continue to become increasingly more important in medical treatment. Meanwhile, with the coming loss of exclusivity for many original biological products, further active development of biosimilars is expected.

1. Characteristics of biosimilars

- Micro-heterogeneity is an inherent characteristic of biological medical products hence biosimilars are similar but not identical to their reference biologic product. Even so, all biologics, whether originators or biosimilars, approved by the Japanese regulatory authorities are safe, effective and of high quality.
- Biologic products require a specific approach in the development phase as they are not the same as chemically-synthesized small molecules, which have well-defined chemical structures and can usually be analyzed to determine all the various components.
- In principle, biosimilarity should be evaluated by comparative analytical, non-clinical and clinical pharmacokinetics/pharmacodynamics and/or clinical efficacy and safety study (ies), including the evaluation of immunogenicity.

2. Extrapolation of indications from the original bio-product

- It cannot be assumed that it is possible to extrapolate automatically and with ease all the indications granted to the original bio-product to the biosimilar. Before considering extrapolation, the mechanism of action or characteristics of the biosimilar as well as specificities of the target patient populations must be considered and evaluated. In line with Japanese guidelines and based on the totality of the evidence of all comparative data – including the assessment whether or not additional clinical trials are necessary – extrapolation of indications may be granted or not granted for the biosimilar product.

EFPIA Japan
Marunouchi Kitaguchi Building, 1-6-5 Marunouchi, Chiyoda-ku, Tokyo 100-8265
Tel: +81-3-6301-3066 Fax: +81-3-6301-3060

3. Post-marketing safety pharmacovigilance activities of biosimilars

- As with other biologic products, post-marketing safety pharmacovigilance activities must be performed for all biosimilars in order to support adverse event reporting and ensure safety and efficacy.
- The safety profile should be continuously investigated after launch because there are potentially some factors such as immunogenicity in the biosimilar that are different from the original bio-product.

4. Naming and Prescription of Biosimilars

- The decision to switch patients from one biological product to another should only be made by the treating physician, taking into account the product's characteristics, the patient's individual needs and current treatment status.
- When prescribing a biosimilar after switching from the original bio-product, the physician should provide a full explanation to the patient and obtain his or her understanding.
- Substitution of biological medicines at the pharmacy level is not acceptable.
- A non-proprietary name or trade name of a biosimilar should clearly specify that it is a biosimilar and its name should be easily distinguishable from the original bio-product and other biosimilars.

5. Pricing of biosimilars

- The pricing system for biosimilars should be kept separate from the pricing system for generics, and any changes to the current system would require careful discussion.

6. Industrial policy

- Japan is currently falling behind in the development of biologics compared to other developed countries, and efforts should be made to strengthen the sector as a whole. Instead of a focus in isolation on the promotion of the use of biosimilars, there should be a holistic approach that strengthens the ecosystem for all biological products.
- In policy by the government, promoting the use of biosimilars should not be about implementing a scheme to promote replacement simply in terms of cost, but should lead to fair and sustainable competition in the market.
- With respect to the value of biologics including biosimilars, it is important that health care professionals, payers, insurers and patients obtain a correct understanding and an increased awareness in order to ensure that drug choices are made by using accurate and transparent information.

END

Contact:
EFPIA Japan Secretariat Office: Naokazu Saito
EFPIA Japan Biological Products sub-committee: Satoru Hayata
TEL: 03-6301-3066, FAX: 03-6301-3060
Mail: info@efpia.jp
[Attachment]

Notices issued concerning biosimilars (As of 1 April 2017)

- “Application for approval of biosimilars”
  (Notice No.0304004 issued by PFSB. Dated 4 March, 2009)
- “Guidelines to ensure quality, safety and efficacy of biosimilars”
  (Notice No. 0304007 issued by PFSB/ELD. Dated 4 March, 2009)
- “Caution items when making application for approval of bio-products”
  (Notice No. 0304015 issued by PFSB/ELD. Dated 4 March, 2009)
- “Q&A related to guidelines to ensure the quality, safety and efficacy of biosimilars”
  (Office Memorandum: Dated 21 July, 2009)
- “Q&A related to guidelines to ensure quality, safety and efficacy of biosimilars”
  (Office Memorandum: Dated 31 March, 2010)
- “Handling of a non-proprietary name or trade name of a biosimilar”
  (Notice No. 0214-1 issued by PFSB/ELD. Dated 14 February, 2013)
- “Handling of a non-proprietary name or trade name of a biosimilar”
  (Office Memorandum: Dated 14 February, 2013)
- “Q&A related to guidelines to ensure quality, safety and efficacy of biosimilars”
  (Office Memorandum: Dated 15 December, 2015)

END