Update of questions and answers on biosimilar medicines

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Medical information
Q&A on biosimilar medicines

- Published in 2008
- In consultation with patient and consumer representatives
- Lay language for general public
- Linked to the EPAR pages of biosimilar medicines

Questions and Answers on biosimilar medicines (similar biological medicinal products)

What is a biological medicine?
A biological medicine is a medicine whose active substance is made by or derived from a living organism. For example, insulin can be produced by a living organism (such as a bacterium or yeast), which has been given the gene that enables it to produce insulin.

What is a biosimilar medicine?
A biosimilar medicine is a medicine which is similar to a biological medicine that has already been authorised (the “biological reference medicine”). The active substance of a biosimilar medicine is similar to the one of the biological reference medicine. Biosimilar and biological reference medicines are used in general at the same dose to treat the same disease. Since biosimilar and biological reference medicines are similar but not identical, the decision to treat a patient with a reference or a biosimilar medicine should be taken following the opinion of a qualified healthcare professional.

The name, appearance and packaging of a biosimilar medicine differ to those of the biological reference medicine. It may also contain different inactive ingredients. Like for all medicines, where precautions are necessary because of any inactive ingredient, these will be described both on the label and in the package leaflet of the medicine.

How is a biosimilar medicine authorised?
Like all medicines, a biosimilar medicine needs to receive a marketing authorisation before it can be marketed. The marketing authorisation is granted after a regulatory authority, such as the EMEA, has conducted a scientific evaluation of the efficacy, safety and quality of the medicine.

Innovative medicines benefit from a period of data protection following the pharmaceutical legislation. After expiry of this period, companies can apply for a marketing authorisation for a biosimilar medicine.

How is a biosimilar medicine evaluated?
As the biological reference medicine has been authorised for several years, there is available information, which does not need to be reproduced. The legislation defines the studies that need to be carried out to show that the biosimilar medicine is similar and as safe and effective as the biological reference medicine.

Due to the complex method of production of biological medicines, the active substance may differ slightly between the biological reference and the biosimilar medicine. Therefore, studies comparing...
Since then...

- Higher profile of biosimilars
- Increased number of approved biosimilars
- External enquiries
- Feedback on Q&A
Feedback on Q&A – How similar to reference medicine?

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Explaining similarity

“...is highly similar to a U.S.-licensed reference biological product notwithstanding minor differences in clinically inactive components,...

...and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.”

US FDA, information for consumers
Explaining similarity

“... that has been developed to be similar to an existing biological product ("reference" product).

...it is unlikely that the biosimilar product will have an identical structure to that of the “reference” product, thereby requiring evidence of safety and efficacy before approval.”

UK’s MHRA
Explaining similarity

“...must have the similar physico-chemical and biological properties, the same pharmaceutical substance, and the same pharmaceutical form as the reference medicines...

...Finally the efficacy and safety must be equivalent to the reference medicine’s.”

France’s Afssaps
Consideration given to...

...the need to explain the possibility of differences in the context of the complexity of biological products and the evaluations to show that differences are not clinically relevant.
Feedback on Q&A - Interchangeability

- The Q&A did not address:
  - Interchangeable use
  - Switching
  - Substitution
  - Shortages
Consideration given to...

...the fact that national authorities (not the EMA) are responsible for providing guidance on the interchangeability of biological medicines.
New wording in draft updated Q&A

• Comparability and differences
• National guidance on interchangeability
• Other minor updates
Next steps - PCWP and HCP WG feedback

The new wording and other text
Comments within 7 days please
Q&A to be finalised with the Agency’s Biosimilar Working Party
Published soon after