EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update of questions and answers on biosimilar medicines

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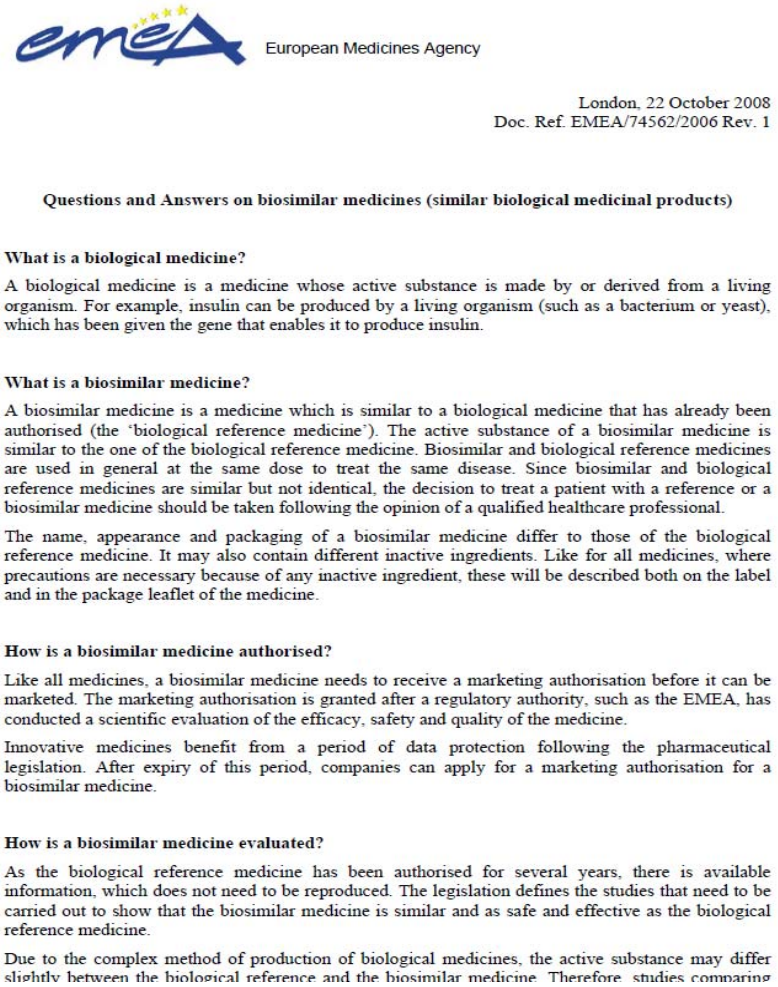
Medical information

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



European Medicines Agency

London, 22 October 2008
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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.

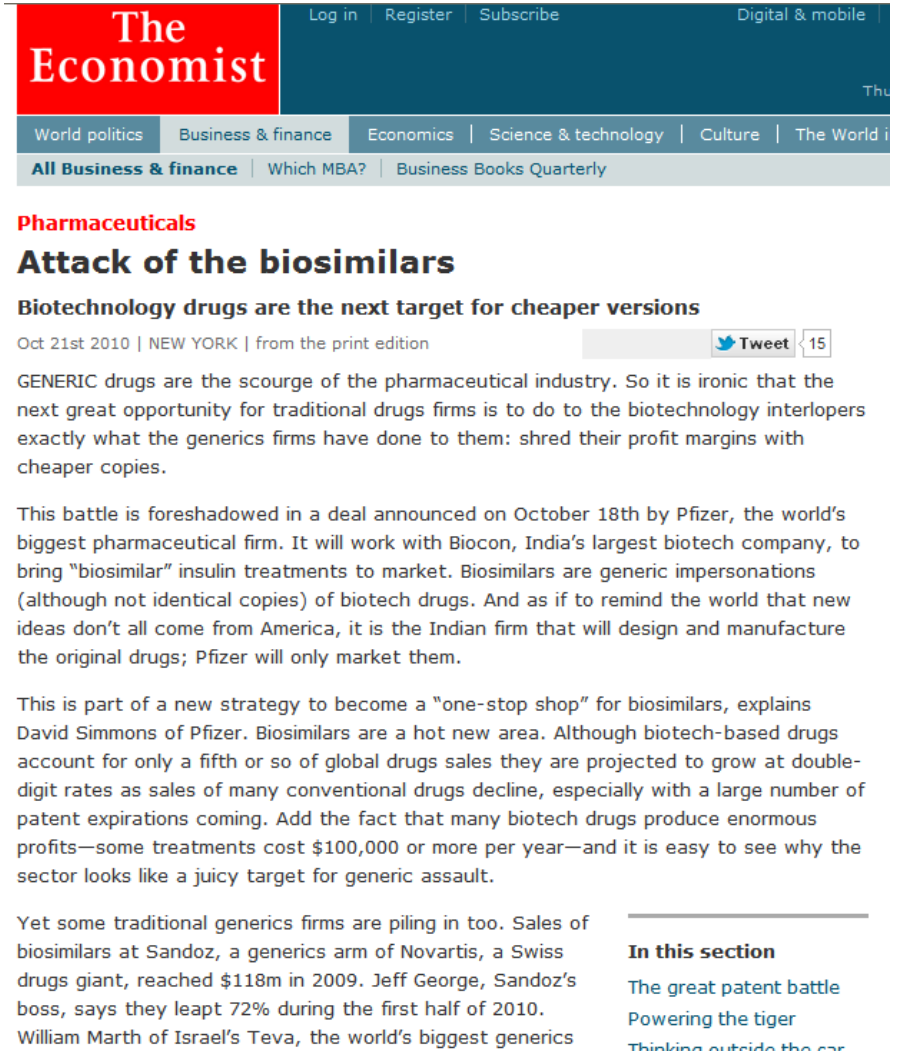
How is a biosimilar medicine evaluated?

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



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Pharmaceuticals

Attack of the biosimilars

Biotechnology drugs are the next target for cheaper versions

Oct 21st 2010 | NEW YORK | from the print edition

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GENERIC drugs are the scourge of the pharmaceutical industry. So it is ironic that the next great opportunity for traditional drugs firms is to do to the biotechnology interlopers exactly what the generics firms have done to them: shred their profit margins with cheaper copies.

This battle is foreshadowed in a deal announced on October 18th by Pfizer, the world's biggest pharmaceutical firm. It will work with Biocon, India's largest biotech company, to bring "biosimilar" insulin treatments to market. Biosimilars are generic impersonations (although not identical copies) of biotech drugs. And as if to remind the world that new ideas don't all come from America, it is the Indian firm that will design and manufacture the original drugs; Pfizer will only market them.

This is part of a new strategy to become a "one-stop shop" for biosimilars, explains David Simmons of Pfizer. Biosimilars are a hot new area. Although biotech-based drugs account for only a fifth or so of global drugs sales they are projected to grow at double-digit rates as sales of many conventional drugs decline, especially with a large number of patent expirations coming. Add the fact that many biotech drugs produce enormous profits—some treatments cost $100,000 or more per year—and it is easy to see why the sector looks like a juicy target for generic assault.

Yet some traditional generics firms are piling in too. Sales of biosimilars at Sandoz, a generics arm of Novartis, a Swiss drugs giant, reached $118m in 2009. Jeff George, Sandoz's boss, says they leapt 72% during the first half of 2010. William Marth of Israel's Teva, the world's biggest generics

In this section

The great patent battle

Powering the tiger

Thinking outside the car

Feedback on Q&A – How similar to reference medicine?

What is a biosimilar 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

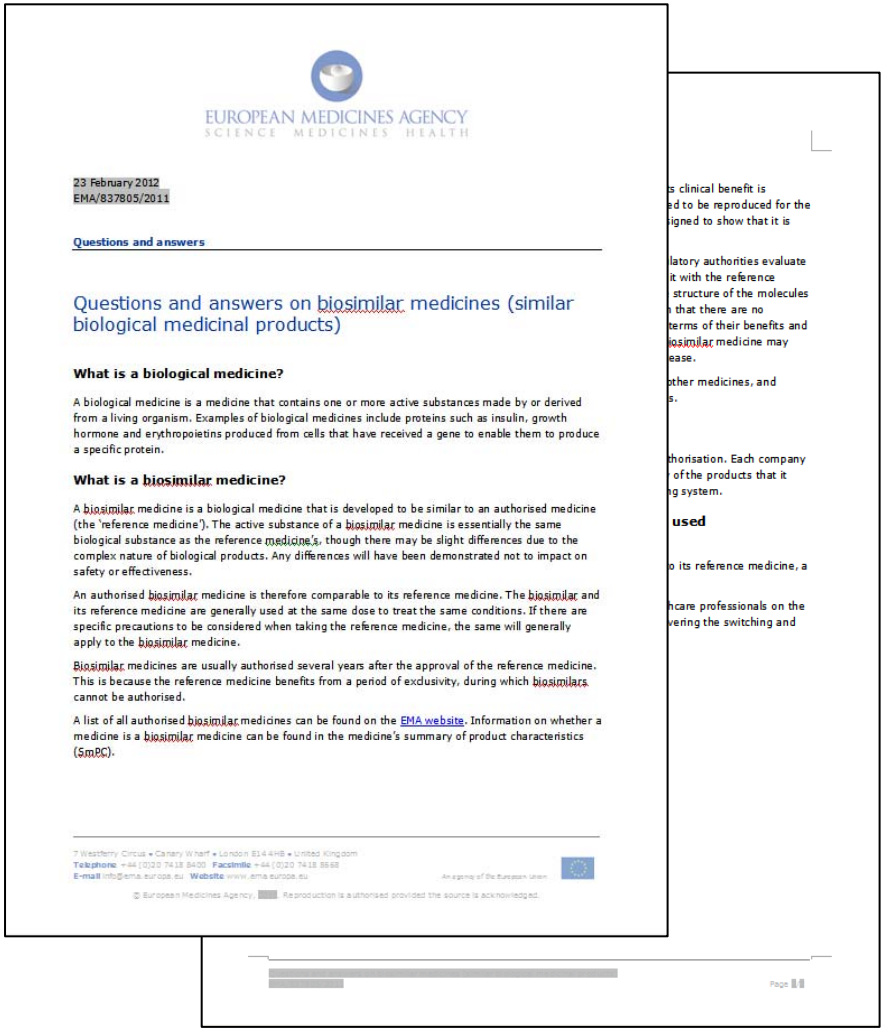
- The Q&A did not address:
  - Interchangeable use
  - Switching
  - Substitution
  - Shortages

Consideration given to…

…the fact that national authorities (not the EMA) are responsible for providing guidance on the interchangeabilty of biological medicines.

New wording in draft updated Q&A

- Comparability and differences
- National guidance on interchangeability
- Other minor updates



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23 February 2012
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Questions and answers

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

What is a biological medicine?

A biological medicine is a medicine that contains one or more active substances made by or derived from a living organism. Examples of biological medicines include proteins such as insulin, growth hormone and erythropoietins produced from cells that have received a gene to enable them to produce a specific protein.

What is a biosimilar medicine?

A biosimilar medicine is a biological medicine that is developed to be similar to an authorised medicine (the 'reference medicine'). The active substance of a biosimilar medicine is essentially the same biological substance as the reference medicine's, though there may be slight differences due to the complex nature of biological products. Any differences will have been demonstrated not to impact on safety or effectiveness.

An authorised biosimilar medicine is therefore comparable to its reference medicine. The biosimilar and its reference medicine are generally used at the same dose to treat the same conditions. If there are specific precautions to be considered when taking the reference medicine, the same will generally apply to the biosimilar medicine.

Biosimilar medicines are usually authorised several years after the approval of the reference medicine. This is because the reference medicine benefits from a period of exclusivity, during which biosimilars cannot be authorised.

A list of all authorised biosimilar medicines can be found on the EMA website. Information on whether a medicine is a biosimilar medicine can be found in the medicine's summary of product characteristics (SmPC).

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