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Information for Patients " >

Biological medicines (or “biologics”) are innovative treatments that have transformed the lives of millions of patients with many disabling and life-threatening diseases[1].

When patents expire on original-brand biologics, different pharmaceutical companies are allowed to make these medicines, which have become known as biosimilars. An approved biosimilar is expected to match the original-brand biologic in terms of safety and efficacy, based on advanced laboratory studies, pre-clinical testing and clinical trials in patients[1,2] . Biosimilar medicines are approved by the same regulatory authorities and are manufactured following the same high quality standards as for existing biological medicines[2,3] .

Depending on the approaches of different healthcare authorities, biosimilar medicines have the potential to contribute to solving challenges around access to medicines for patients, physicians and payers[4].

Biosimilars – the results are the same

Think of an original-brand biologic and a biosimilar like an original key and another version that a locksmith makes. Both keys produce the same result, both will fit the same lock and open the same door, even if there are slight differences between the keys.

What are biologics?

Biological medicines (or “biologics”) are not like medicines such as aspirin or paracetamol, which are made with chemicals. Instead, biologics are protein-based medicines made in, or extracted from, living cells[1,5]. Scientists choose appropriate cells (animal or human cells are often used) and then modify them so that with skillful manufacturing they can be made to reproduce indefinitely. These cells become “factories” that endlessly produce a particular substance, usually a protein, which targets a specific illness[6].

Biological medicines are innovative treatments that have helped to transform the lives of millions of patients with many disabling and life-threatening diseases such as cancer, rheumatoid arthritis, anemia, inflammatory bowel disease, diabetes and skin conditions such as psoriasis[1,5].

One of the reasons biological medicines are so effective is that they are tailor-made to interact with specific targets in the body. This increases the potential that they will have the desired effect against the disease they are designed to treat.

Generics, biosimilars: What’s in a name?

When patents expire on medicines made with chemicals (such as aspirin, paracetamol or prednisone) it is straightforward for different pharmaceutical companies to make identical versions (generics) of the original brand. This is because these medicines are made by combining specific chemical ingredients in a defined and ordered process, making them relatively simple to duplicate: Chemical A + Chemical B = Medicine C.

In contrast, biological medicines are made using complex living cells and the manufacturing process is extensive. That is why all biologics, including original-brand biologics, have some degree of variability. In fact, biological medicines are so complex that they can even vary from batch to batch. This inherent natural variability (called “microheterogeneity”) is tightly controlled by the manufacturer and the health authorities to ensure the same clinical outcome from the biological medicine.

When patents expire on original-brand biologics, different pharmaceutical companies are allowed to make these medicines, which have become known as biosimilars. Biosimilars have the same active ingredient as an existing, approved biologic[3]. To gain approval for use by regulatory authorities, a biosimilar has to match the original-brand biologic in terms of safety and efficacy, demonstrating no clinically meaningful differences so patients can expect the same clinical outcome[1,2,3].

To manage this natural variability in a particular biological medicine (in original-brand biologics and biosimilars), any variations have to stay within precise ranges to maintain clinical efficacy and safety. These ranges are set and tightly controlled by both the regulatory authorities and the pharmaceutical company, to ensure that all batches of any one biologic are similar[1,2,3].

In fact, the term biosimilar can only be used to describe a biological medicine that has gone through a thorough process of laboratory analysis, pre-clinical testing and clinical trials in patients comparing the biosimilar to the original brand. This process is designed to demonstrate that the biosimilar matches the original-brand biologic in terms of safety and efficacy in patients[1,8]. A product is designated a “biosimilar” by the regulatory authority, so this term is a validation of its quality and comparability. And of course, once approved, biosimilars are as closely monitored as original-brand biologics to ensure their continuing safety[3].

5 Facts about Biosimilar Medicines (PDF, 0.12 MB)

Biosimilars – Why now?

Patents on some brands of biological medicines have run out or are reaching the end of their term, which is why different pharmaceutical companies are making biosimilars of these medicines.

In fact, biosimilars have been around for longer than a decade. The first biosimilar was approved in Europe in 2006[1] and now biosimilars are in use in approximately 100 countries around the world including highly regulated ones such as those in Europe, as well as Canada, Japan and Australia, and the US[9,10,11]. Many more biosimilars are in development globally and so they are likely to play a growing role in patient care[4].

Why are biosimilars important?

Even though it takes many years to develop and gain approval for use of a biosimilar, it is likely that there will be a difference in price between them and

original-brand biologics. This means that once they are approved for use, depending on the approaches of different healthcare authorities, biosimilar medicines have the potential to[1,4]:

- Cause healthcare providers to reassess existing guidance about use of a particular biologic based on considerations around cost-effectiveness.
- Make treatment more affordable for patients in certain countries who co-pay for their medicines.
- Allow health systems to redirect funds so that more patients can be treated.
- Allow some healthcare systems to use these innovative treatments for their citizens for the first time.
- Release resources to help healthcare systems to keep pace with growing healthcare needs and fund new generations of innovative treatments so that access to treatments, patient care and patients' lives can all be improved with a sustainable approach.

Original-brand biologic or biosimilar – Who decides?

As with all decisions about managing their condition, patients should talk with their doctor (and healthcare team) about all of the available treatment options, their safety, benefits and risks before coming to a decision about the treatment that suits them the best.

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