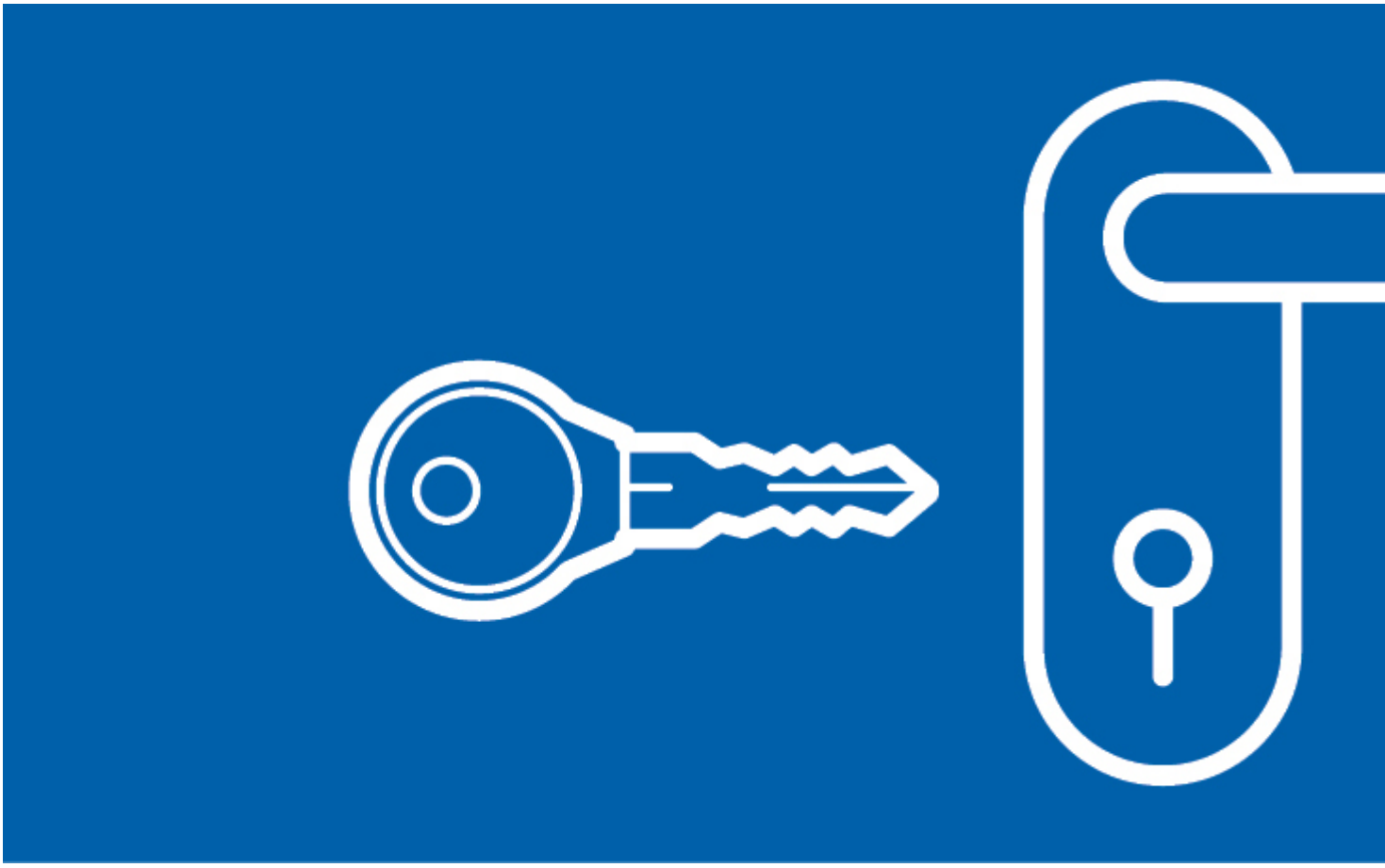
Information for Patients

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 branded biologics different pharmaceutical companies are allowed to make these medicines, which have become known as biosimilars. An approved biosimilar is expected to have the same safety and beneficial effects in patients as an existing biological medicine, based on advanced laboratory studies and clinical trials.[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 a branded biological and a biosimilar like an original key and a duplicate that a locksmith has made of it. There may be slight differences in appearance between the original key and the copy but the results are the same, both keys will fit the same lock and open the door.

Accordion:
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 = Drug C.

Because biological medicines are made in living cells and the manufacturing process is extensive it isn’t possible to make generics of these medicines. Think of it like making bread, cheese, wine or beer all of which are produced using fermentation, a natural process involving living cells. It is normal that even two batches of the same biologic from the same company that deliver the same therapeutic effect, are not identical and have inherent natural variability (called “microheterogeneity”).[7]

To manage this natural variability in a particular biological medicine, 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]

When patents expire on branded biologics different pharmaceutical companies are allowed to make these medicines, which have become known as biosimilars. Biosimilars have essentially the same active ingredient as an existing, approved biologic.[3] To gain approval for use by

regulatory authorities, every batch has to stay within the same precise ranges for variation as the existing, branded biological medicine; the ball has to go between the same goal posts.[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 study comparing the biosimilar to the original brand. This process is designed to demonstrate that the biosimilar is expected to deliver the same safety and beneficial effects in patients as an existing biological medicine.[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 existing biological medicines to ensure their continuing safety and efficacy.[3]

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 a decade. The first biosimilar was approved in Europe in 2006 and now, a decade later, there are 20 biosimilars of eight different biologics available for use in Europe.[9] Biosimilars have also been approved in other highly regulated countries including Canada, Japan and Australia, and in 2015 the first biosimilar was approved by the US Food and Drug Administration.[10] 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 existing 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 so that healthcare systems can keep pace with growing healthcare needs, and funding new generations of innovative treatments brought about by advances in medical science.

Existing brand or biosimilar – who decides?

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

Footnotes:

HQ/SDZ/16-0001(1)

1. European Commission. Consensus Information Paper 2013. What you need to know about Biosimilar Medicinal Products. http://ec.europa.eu/DocsRoom/documents/8242/attachments/1/translations/en/renditions/native [1]. Accessed March 14, 2016.
2. Information on Biosimilars http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/Ap [2]. Accessed April 27, 2016.
3. European Medicines Agency. Questions and answers on biosimilar medicines (similar biological medicinal products). http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2009/12/WC500020062.p [3]. Accessed March 14, 2016.
4. IMS Institute, Delivering on the Promise of Biosimilar Medicines: The Role of Functioning Competitive Markets. http://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/Documents/IMS_Insti [4]. Accessed April 27, 2016.
5. Information for Consumers (Biosimilars). http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/Ap [5]. Accessed April 27, 2016.
6. International Alliance of Patients' Organizations. Briefing Paper on biological and Biosimilar Medicines. November 2013. https://www.iapo.org.uk/sites/default/files/files/IAPO%20Briefing%20Paper.pdf [6]. Accessed March 14, 2016.
7. Biosimilars: what clinicians should know. Weise M et al. Blood, 2012; 120 (26): 5111-5117.
8. Guidelines on evaluation of similar biotherapeutic products (SBPs).World Health Organization (2010) http://www.who.int/biologicals/areas/biological_therapeutics/BIOTHERAPEUTICS_FOR_WEB_22 [7]. Accessed March 14, 2016.
9. European Medicines Agency. European Public Assessment Reports. http://www.ema.europa.eu/ema/index.jsp?curl=pages%2Fmedicines%2Flanding%2Fepar_search. [8]. Accessed April 27, 2016.
10.

FDA approves first biosimilar product.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.htm [9]

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