# Viewpoint: The biosimilars breakthrough (3 min read) [1]

Access to Medicines [2]

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**1 – Safety**
In Europe, with more than 10 years on the market, 35 biosimilars in nine categories and more than 700 million patient days[1] of positive clinical experience, I think this says biosimilars have been a success. They are a triumph for pharmaceutical science. Of course, it is principally patients who benefit and who we are here to serve. Based on the vast knowledge we have about their safety and efficacy, it is time we stop treating biosimilars with suspicion. We should move to endorsing their use.

**2 – Economics**
Biosimilars contribute significantly to increasing patient access to biologic medicines and have the potential to save national health systems hundreds of millions every year.[2] Their advantage is economic, but they deliver the same medical benefits and match the reference biologic in terms of safety, efficacy and quality. Biosimilars can stimulate competition that steadily drives down prices, which frees up healthcare funds. And the results would be that more people receive therapy.

**3 – Efficacy**
With the introduction of biosimilars, treatment can be given to patients with diseases considered “lower risk” or in earlier stages. In New Zealand, when physicians used biologics only as “rescue” medications, about a third of women having chemotherapy for breast cancer were hospitalized. When biosimilars were launched there and access to these new treatment options was significantly improved, hospitalization among these patients fell to seven in 100.[3] This demonstrates that patients do benefit.

**4 – Switching**
In Europe, switching means that a patient’s treatment with a reference medicine can be continued with a biosimilar because it achieves the same medical result. All this is done under the direction of a physician. Biosimilars are as effective and safe as the reference medicine, and doctors should consider biosimilars as a valuable treatment option. Studies with over 3,000 patients in Europe who switched from reference biologics to biosimilars showed that these medicines were as effective as the reference medicine.[4]

**5 – Extrapolation**
Some doctors are still anxious about switching patients from the reference medicine to a biosimilar until they see data in the specific indication. For a biosimilar to receive approval in this indication, one clinical confirmatory Phase III study in a sensitive patient population is part of the development program. Extrapolation means that a biosimilar can be prescribed in other indications without additional clinical trials. It is based on proof in analytical, preclinical and clinical studies that both molecules – reference and biosimilar – behave the same way in the same patient populations.

**6 – Essential medicines**
The latest World Health Organization’s List of Essential Medicines, a list of the most important medication needed in a basic health system, includes three biologic medicines for treating cancer. These WHO

recommendations are only achievable from an economic standpoint when doctors embrace biosimilars. Access to innovation has one key rule: The only treatment that sustainably works is the one that we can afford to give.


1. http://www.medicinesforeurope.com/news/oncology-the-new-era-for-biosimilar-medicines/ [3]
2. http://www.medicinesforeurope.com/wp-content/uploads/2016/03/infographic-biosimilars.pdf [4]
3. https://www.pharmac.govt.nz/about/annual-review/2014/biosimilar-filgrastim/filgrastim-sidebar/ [5]
4. 10 years of biosimilars - who benefits? Presentation to ESO Task Force Advisory Board on Access to Innovative Treatment in Europe - European School of Oncology, by Paul Cornes.


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**Links**
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