

## FACT SHEET 6

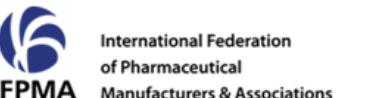
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# TALKING TO PATIENTS ABOUT BIOSIMILARS: ROLE OF HEALTH PROFESSIONAL



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# SOURCES

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## TALKING TO PATIENTS ABOUT BIOSIMILARS

**Providing clear information to patients**  
about the treatment they are receiving is  
an underlying principle of good, modern  
healthcare – and is of vital importance in the  
case of all biologics. Patients need to have  
understandable and reliable information to  
participate in informed decisions about whether  
to take a biologic medicine, which biologic  
medicine to take, and how to monitor how it is  
working. Health professionals play a significant  
role in providing this information and engaging  
patients in an open dialogue about the risks  
and benefits of their treatment choices.

**Engaging patients with shared knowledge**  
and decision-making has been recognised  
worldwide as one of the founding principles  
of patient-centred healthcare<sup>2</sup>. The IAPo  
Patient-Centred Healthcare principles  
promote transparent and mutually attentive  
communication among all stakeholders in a  
health system, and place critical importance in  
allowing patients to make informed decisions.

**Most patients' current level of knowledge**  
about biologic medicines is insufficient.  
A recent survey in high-income countries  
found that only 6% of the general population  
had a general understanding of biosimilars;  
awareness was only slightly higher among  
diagnosed patients (9-11%) and improved only if  
they received support from patient groups (20-  
30%).<sup>3</sup> The information gaps are likely much  
greater in low-and-middle-income countries.

As more and more biosimilar medicines  
become available, patients and patient  
organizations need to consider issues  
such as the importance of regulatory  
transparency, the clarity and content of  
patient information, and shared decision-  
making by patients and health professionals  
in assessing treatment options.<sup>1</sup>

The International Alliance  
of Patients' Organizations  
Biosimilars Toolkit

Today's patients are bombarded with  
information on medicines from valid  
high quality sources, as well as some  
questionable sources. Health professionals  
have a duty to give accurate, relevant,  
and timely information to eliminate  
misconceptions. Moreover, they have a  
duty to discuss everything in a participatory  
manner to restore the balance between  
the real risks based on evidence and  
the patient's perception of risks held  
genuinely due to poor information, advice  
and support. This is a patient-centric way  
we recommend to all. Information must  
be given in a culturally, age, gender and  
linguistically sensitive manner. This can  
only happen face-to-face in an open  
participatory and transparent dialogue.

Kawaldip Sehmi, the  
International Alliance of  
Patients' Organizations

The ability of health professionals to convey clear, accurate information to their patients about the biologic medicines they are receiving is also the key to establish meaningful patient-doctor communication.

Patients often rely on their health professionals, particularly doctors, to guide and inform their treatment options. Patients expect their doctors to be aware of treatment options available, be knowledgeable about each option, and be willing to engage in an honest discussion at an equal level with them.

However, evidence suggests that many doctors are also not fully up-to-date on research, treatment options, and best practices in the rapidly expanding field of biologic medicines, including biosimilars. A key emerging issue is providing evidence-based advice on the switching from an original biologic to a biosimilar.

A physician survey from Argentina, Brazil, Colombia, and Mexico (2015)<sup>4,5</sup> found that:

**6%**

of the doctors were able to differentiate a true biosimilar from an intended copy (not true biosimilar).

**54%**

assumed all biosimilars go through the same regulatory requirements as the original biologics.

**34%**

believed that switching between two biologic medicines with the same INN had no impact on patient safety or efficacy.

**44%**

of them believed that if two biologic medicines had been given the same INN, they were interchangeable.

Professional training on biologics including biosimilars, and clear communication of this information to patients, is needed to promote patient confidence in all biologics.

Interviews with stakeholders suggested that due to the complex nature of biologics the perceived risk among patients is often higher than the real risk in terms of safety or side effects. This perception is heightened in the case of biosimilars.

The lack of balanced, reliable information from credible sources undermines their potential benefit for patients and contributes to erosion of public confidence in their evolving role in modern healthcare.

**A biosimilar is approved as a “close copy” of an original reference biologic, but it is not identical nor is it approved as interchangeable with the reference.**

The decision to switch from an originator to a biosimilar or between biosimilars should be a medical decision, and as such, the role of the physician in the decision to prescribe a biosimilar is essential. The benefits and risks of switching between an originator to a biosimilar or between biosimilars may vary by disease, severity and stage, therapeutic intent, potential impact of immunogenicity, the availability of alternatives, and other considerations unique to a specific clinical setting or patient. For instance, the benefits and risks of switching may vary between a patient taking a biologic for rheumatoid arthritis (RA) and a patient taking a biologic for metastatic breast cancer, or between an RA patient who may have other conditions, and/or be on other therapies, or whose disease is well managed with a current biologic versus an RA patient experiencing a relapse of disease. The benefits and risks to the patient should be carefully assessed by the prescribing

physician, and decisions to switch patients should be informed by clinical practice on a case-by-case basis unique to each patient.

For these reasons, it is important that physicians maintain the freedom to prescribe the medicine they deem appropriate in consultation with the patient. Therefore, procurement practices should allow the physician to choose what medicine to prescribe in consultation with a patient (whether an originator or a biosimilar), based on what is in the best interest of the patient. Practices such as “winner take all” tenders do not maintain this flexibility, and can result in “forced switching”, which effectively removes the prescribing choice from the physician. This practice is not in the best interests of the patient because, as noted above, switching should take into account patient history, e.g. the number of previous switches, the patient’s other medications and/or other conditions, and the therapeutic options available, and only the prescriber can do this.

For this reason, physician organizations that represent specialties that use biologics should consider development of recommendations for the use of biosimilars in common clinical scenarios.