FACT SHEET 6

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[2]. 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%).[3] 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.[1]
>
> **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)[4 5] 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.