The International Federation of Psoriasis Associations' statement on biosimilars

The introduction of biologic medications like TNF-alpha inhibitors have revolutionized the treatment of psoriasis and psoriatic arthritis. They have been proven to provide reliable disease control with relatively few side effects, and have greatly improved the quality of life of many people living with psoriasis.[1] However, biologics can be expensive, which has placed a high burden on national health systems and created an access barrier to patients in need of these life-changing therapies.[2]

Several new medications called "biosimilars" have recently appeared in countries around the world. A biosimilar is developed to be functionally similar to an already-licensed biologic medicine, called an "originator" for the new biosimilar. It has become possible to create these new medications as the brand-name patents of some of the oldest biologic products have expired over the past decade. To date, there have already been biosimilars approved for adalimumab, etanercept, and infliximab.[3] Biosimilars are inexpensive to develop as compared to novel treatments and therefore tend to be more affordable than their originator counterparts. **IFPA welcomes the introduction of safe and effective biosimilars that have the potential to improve access to treatment and increase treatment options for people living with psoriasis.**

However, biosimilars are not exact copies or generic versions of their originators. Generic drugs can usually be substituted for their brand-name equivalents because they are chemically identical. Biologics are produced by living organisms, which means that batches of originator products can vary. Biosimilars are designed so that these are within the range of variation of the originator batches.[4] Biosimilars can substitute biologics, provided that substitution is done under certain conditions. It has been shown that switching from an originator to a biosimilar does not usually lead to worsening disease symptoms, compromised safety, or decreased tolerance,[5] so this may be presented as a valid treatment option.

IFPA continues to stress the importance of the patient-provider relationship when making any treatment decisions and that the patient should remain at the center of decision-making processes. The decision to switch from an originator to a new biosimilar should be made on an individual basis and only with the full, informed consent of both patient and provider. Such a decision should not be made by a payer or a pharmacy without the explicit agreement of the prescribing provider. If an adverse effect is observed after substituting a

[1] Campanati, A. et al. (2016). Biologic Therapy in Psoriasis: Safety Profile. *Current Drug Safety*, 11(1), 4-11. and Kerkhof, P. V. (2006). Consistent control of psoriasis by continuous long-term therapy: the promise of biological treatments. *J Eur Acad Dermatol Venereol*, 20(6), 639-650.

[2] Putrik, P. et al. (2013). Inequities in access to biologic and synthetic DMARDs across 46 European countries. *Ann Rheum Dis*, 73(1), 198-206.

[3] EMA. (2017). *European public assessment reports.* Retrieved from http://www.ema.europa.eu

[4] WHO. (13 June 2017). *Similar biotherapeutic products.* Retrieved from http://www.who.int/biologicals/biotherapeutics/similar_biotherapeutic_products/en/

[5] Veselý, R. and Richardson, P. (2017). The switch from infliximab to biosimilars. *The Lancet*, 389 (10086), 2266-2268.

IFPA Secretariat
Gustavslundsvägen 143
167 51 Bromma
SWEDEN

biosimilar, the option to revert to the originator should be openly offered. No patient should be made to switch to a biosimilar when adequate disease control is already being achieved with another treatment. When initiating biologic therapy for the first time, whether with a biosimilar or a brand-name biologic, patients should be informed of the associated risks and benefits. IFPA recommends initiating a biosimilar as the first biologic therapy when clinically indicated for an individual patient as assessed by his or her provider.

Moreover, **IFPA emphasizes that biosimilars must be proven to be as safe and as effective as their biologic originators with sufficient clinical and nonclinical testing before they can be used to treat patients**. WHO has issued guidelines on quality, nonclinical, and clinical parameters that should be examined when investigating whether a biosimilar is in fact "highly similar" to its originator.[6] Regulatory oversight is paramount in managing the potential risks posed by indiscriminate substitution of biosimilars for their originators.

[6] WHO, Expert Committee on Biological Standardization. (2009). *Guidelines on evaluation of similar biotherapeutic products (SBPs)*.