Switching Australian patients with moderate to severe inflammatory bowel disease from originator to biosimilar infliximab

To the Editor: The SAME study affirmed the safety and efficacy of switching between originator and biosimilars and the potential for cost savings.[1] Yet the global uptake of biosimilars has been relatively slow[2] due to a number of factors, including marketing suggesting that such drugs are less safe or efficacious than the originator.[3] Implicated in such marketing is confusion arising from the use of the word "interchangeable", which is a defined term under United States legislation. The word "substitution" is used in Australia, which raises the likelihood of further confusion.

Pfizer, which sponsors both biologics and biosimilars, petitioned the US Food and Drug Administration to avoid false and misleading statements about biosimilars.[3] Key to Pfizer's arguments is the definition of "interchangeability" in the *Biologics Price Competition and Innovation Act of 2009* (US). To establish interchangeability, further clinical data are needed to show that switching a patient back and forth between the reference product and biosimilar "can be expected to produce the same clinical result as the reference product in any given patient [and] … the risk in terms of safety or diminished efficacy of alternating or switching … is not greater than the risk of using the reference product without such alternation or switch" (§ 262(k)(4)). This represents a higher threshold than biosimilarity, and there are currently no approved interchangeable biosimilars in the US, although a Bill (HR 8190) is currently being considered by the US Congress on insulin products.

In Australia, case law has accepted the Therapeutic Goods Administration definition of a biosimilar as "a version of an already registered biological medicine" having "similar characteristics" to the biologic, with no explicit statement as to what "similar" means.[4] If the sponsor of the originator were to claim that a competitor biosimilar is not interchangeable, although this would be correct in a legal sense, such claims could be misunderstood by Australian audiences as meaning that it is less safe or not therapeutically equivalent, even when it is "a-flagged" and approved for pharmacist substitution.[5] Therefore, it is important to distinguish the use of "interchangeability" and "substitution", as these terms may be understood differently by doctors, pharmacists, other health professionals, and patients.

Describing a biosimilar as (only) "similar" obscures the reality that approved biosimilars are as safe and efficacious as the originator. In such circumstances, a switch is appropriate, especially if it will save the patient and Pharmaceutical Benefits Scheme considerable money.

David Lim[1,2]
Rhiannon Bandiera[3]
Elizabeth Handsley[1]

1 Western Sydney University, Sydney, NSW.
2 Flinders University, Adelaide, SA.
3 Maynooth University, Maynooth, Ireland.

david.lim@westernsydney.edu.au

Competing interests: No relevant disclosures. ■

doi: 10.5694/mja2.51295

© 2021 AMPCo Pty Ltd

1 Haifer C, Srinivasan A, An Y-K, et al. Switching Australian patients with moderate to severe inflammatory bowel disease from originator to biosimilar infliximab: a multicentre, parallel cohort study. *Med J Aus* 2021; 214: 128–133. https://www.mja.com.au/journal/2021/214/3/switching-australian-patients-moderate-severe-inflammatory-bowel-disease
2 Lim D. Is Australia positioned to take advantage of biosimilars? *GaBI J* 2014; 3: 184–187.
3 Pfizer. Citizen petition. New York: Pfizer; 2018. https://www.regulations.gov/document/FDA-2018-P-3281-0001 (viewed Mar 2021).
4 Therapeutic Goods Administration. Biosimilar medicines regulation. Canberra: Department of Health; 2018. https://www.tga.gov.au/publication/biosimilar-medicines-regulation (viewed Sept 2021).
5 Baldry R, Lim D, Lau E, Nissen L. Doctors', pharmacists' and patients' attitudes and perceptions about biosimilars: a systematic literature review. National Medicines Symposium 2016; Canberra, 19–20 May, 2016. Canberra: NPS MedicineWise; 2016. ■