

Considering biosimilars in inflammatory diseases

Iain McInnes

Correspondence to

Iain McInnes, Institute of Infection, Immunity and Inflammation, University of Glasgow, Scotland, UK, iain.mcinnnes@glasgow.ac.uk

With the projected expansion of the biosimilars market, clinicians must assimilate many important issues. These include understanding biosimilar development, building strategies for biosimilar introduction, and developing robust systems for biosimilar pharmacovigilance. With ten tumour necrosis factor inhibitors, a first rituximab biosimilar now on the market, and many more biosimilars currently in development, controversial issues such as multiple biosimilar switching and indication extrapolation also require consideration.

In *'The Biosimilar Approval Process: How different is it?'*, Isaacs *et al* explore the sophisticated biosimilar manufacturing process and the regulatory requirements for approval. In theory, subtle differences could result in unexpected consequences. In practice, stringent regulatory processes have been designed to minimise the likely occurrence of these; there is now a move towards a more harmonised approach to biosimilar development. Biosimilar clinical trials have used various designs to look at switching between originator and biosimilar products, with some reassuring results for clinical practice. The results of these trials are presented and their implications considered in *'Biosimilars Approved, and in Development'* by Dörner *et al*, which provides an authoritative overview of the current evidence base. While not a replacement for definitive data built on long term follow-up, these reviews will at least prepare the practicing clinicians with the current state of knowledge in this rapidly evolving area. Shortened clinical

development programmes and consequent reduced patient exposure will require extra vigilance in terms of post-marketing surveillance and registries, issues brought to the fore in *'Biosimilars: Considerations for Clinical Practice'* by Azevedo *et al*. Pharmacovigilance is especially important given the approval of an increasing number of biosimilars and the prospect of multiple switching for which there are currently no criteria. Moreover, we need to consider having robust systems to record which product a patient is receiving at any one time, and to ensure that patients are adequately trained to use devices that they are given. Entering this new world of multi-biosimilars and multiple biosimilar switching re-ignites the question of whether we can confidently move across indications or diseases. *'Considering Biosimilar Policy'* by Casteñada-Hernández *et al* highlights the need to respect the prominence of clinical pharmacology regarding drug responsiveness across diseases and its importance in internal medicine.

Since biosimilar availability should serve to reduce overall healthcare costs and permit access to biologic agents for a much wider global patient population, all these issues are worthy of consideration. Furthermore, as biosimilar development continues, there may be innovations in formulation and drug delivery technology of far-reaching importance for clinical practice. This edition of *Considerations in Medicine* explores important topics in biosimilar development and biosimilar use in clinical practice, within a series of concise reports. I commend it to you in this spirit.

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