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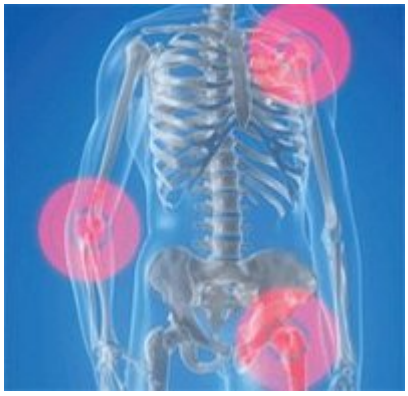
US rheumatologists in favour of distinct names for biosimilars Posted 22/04/2016



Following the approval of the infliximab biosimilar Inflectra (infliximab-dyyb) the American College of Rheumatology (ACR) has issued a statement supporting the use of distinct names for biosimilars.

The US Food and Drug Administration (FDA) approved the country's second biosimilar Inflectra on 5 April 2016 [1]. Inflectra is the first biosimilar to receive approval in the US for the treatment of rheumatic diseases, including rheumatoid arthritis and psoriatic arthritis.

The ACR welcomes the introduction of biosimilars to the US healthcare system, saying that 'the safe adoption of biosimilars into the US marketplace remains a top priority'. In addition, it states that it 'is hopeful that the decrease in cost resulting from the availability of safe and effective biosimilars in the US will increase patients' access to life-changing therapies and improve their overall health'.

The group, however, adds that while they support the development of new biosimilars, patients' safety remains their highest priority. They therefore 'encourage the FDA to continue to apply distinct names for future biosimilars, and to maximize clarity in the labelling of biosimilars, specifically with respect to their interchangeable status and the origins (reference drug versus biosimilar) of clinical data upon which FDA approval is based.'

They conclude by stating that 'the ACR supports distinct naming and transparent labelling for all biosimilar products to ensure correct prescribing and dispensing, post-marketing surveillance, prescriber confidence and enhanced market uptake.'

The issue of naming for biologicals is a contentious one. Advocates for distinct names include the Biologics Prescribers Collaborative (BPC) and the Alliance for Safe Biologic Medicines (ASBM). The Generic Pharmaceutical Association (GPhA), on the other hand, believes that different names could 'erect barriers to patient access to new, more affordable medicines, and jeopardize their safety'. While the Academy of Managed Care Pharmacy (AMCP) said distinct names could result in 'lower market adoption and cost-savings' from biosimilars [2].

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References
1. GaBI Online - Generics and Biosimilars Initiative. FDA approves infliximab biosimilar Inflectra [www.gabionline.net]. Mol, Belgium: Pro Pharma Communications International; [cited 2016 Apr 22]. Available from: www.gabionline.net/Biosimilars/News/FDA-approves-infliximab-biosimilar-Inflectra
2. GaBI Online - Generics and Biosimilars Initiative. Comments on FDA's guidance on naming biologicals [www.gabionline.net]. Mol, Belgium: Pro Pharma Communications International; [cited 2016 Apr 22]. Available from: www.gabionline.net/Biosimilars/General/Comments-on-FDA-s-guidance-on-naming-biologicals