GENERICS AND BIOSIMILARS INITIATIVE
Building trust in cost-effective treatments

Comments on FDA's guidance on naming biologicals
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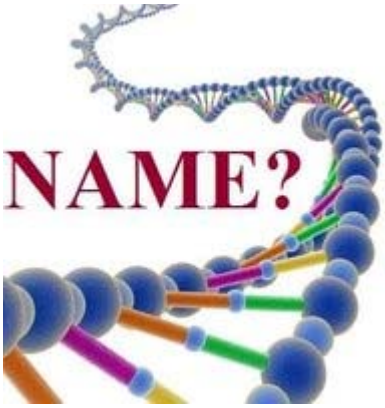

The US Food and Drug Administration (FDA) issued a draft guidance on the non-proprietary naming of biological products on 27 August 2015 [1], but not everyone is happy with the proposals made by the agency.

FDA is proposing that all biologicals and biosimilars have non-proprietary names and that a four-letter suffix be added to the names to distinguish them from each other. Biosimilars makers, however, would prefer to use the same non-proprietary names as the brand-name biologicals without any suffix, while originator manufacturers would prefer completely different names.

The Biologics Prescribers Collaborative (BPC), which has strongly advocated for distinguishable names, stated that the FDA's guidance will 'enhance transparency, help create physician confidence in biosimilars and support a robust biosimilar market'. While the American College of Rheumatology (ACR), has also announced its support for the guidance, saying that it supports the ACR's position statement [2],

The US-based Alliance for Safe Biologic Medicines (ASBM), although supporting that all biologicals should receive distinct non-proprietary names [3], and supporting a four-letter suffix proposal, is concerned that using a 'suffix deliberately designed to be 'devoid of meaning' creates an unnecessary barrier to the use of distinguishable suffixes'. The ASBM believes that the use of four-digit codes that are memorable and logical would better promote manufacturer accountability, giving Zarxio (filgrastim-sndz) as an example.

The Generic Pharmaceutical Association (GPhA), on the other hand, thinks that the guidance warrants 'serious scrutiny' because of its potential 'to erect barriers to patient access to new, more affordable medicines, and jeopardize their safety'. They go on to point out that 'adverse events and product recalls for small-molecule and biologic[al] drugs already are successfully identified using the national drug code, and lot number and company name, and there is no compelling evidence that biosimilars should be handled differently'. While the Academy of Managed Care Pharmacy (AMCP) also issued a statement calling the draft guidance 'disappointing' and saying it could result in 'lower market adoption and cost-savings' from biosimilars.

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References
1. GaBI Online - Generics and Biosimilars Initiative. FDA issues draft guidance on naming biologicals [www.gabionline.net]. Mol, Belgium: Pro Pharma Communications International; [cited 2015 Sep 11]. Available from: www.gabionline.net/Guidelines/FDA-issues-draft-guidance-on-naming-biologicals
2. GaBI Online - Generics and Biosimilars Initiative. ACR position statement on biosimilars addresses naming and substitution [www.gabionline.net]. Mol, Belgium: Pro Pharma Communications International; [cited 2015 Sep 11]. Available from: www.gabionline.net/Biosimilars/General/ACR-position-statement-on-biosimilars-addresses-naming-and-substitution
3. GaBI Online - Generics and Biosimilars Initiative. ASBM publishes paper on biosimilar naming

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Source: ACR, AMCP, ASBM, BPC, GPhA

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