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Fourth and final issue of GaBi Journal's fourth volume

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This last issue of 2015 starts with a [Commentary](#) by Drs Christoph Baumgärtel and Brian Godman concerning the approval of generic versions of narrow therapeutic margin products; including immunosuppressant drugs. The authors explain why they find concerns that have been raised by some clinicians concerning the bioavailability margins needed for approval of narrow therapeutic drugs are not justified. The authors include the lack of reported adverse effects of use of these products as one proof of the adequacy of the approval processes as well as the safety of the products. Unfortunately, the fact that adverse events are rarely reported and the failure of many reports to identify which product was actually used limits the ability of adverse event report statistics to support such claims. However, the tolerability and efficacy of such products has clearly been improved both by more strict bioavailability margins being used by regulators as well as by the fact that the concentrations of such drugs should often, if not always, be monitored. When properly done such concentration monitoring should identify generic drug product bioavailability issues as well as even more common problems such as poor adherence, as well as unusual drug clearance, drug-drug and drug-diet interactions. The authors claim to have no potential conflicts of interest (COI) but financial interests are not the only type of COIs. One of the authors works for an agency that makes marketing decisions. Others and I might argue that such employment constitutes a potential if not obvious COI.

An [Original Research](#) manuscript by Mr Michael S Reilly and Dr Harry L Gewanter describes a study that used an Internet-based questionnaire to examine knowledge and opinions of physicians who prescribe biological medicines from four Latin American countries, Argentina, Brazil, Columbia and Mexico. Mr Reilly is the Executive Director of the industry-sponsored Alliance for Safe Biologic Medicines (another potential COI). The peer review of this manuscript suggests that we should repeat prior attempts to describe the minimum requirements for submitting such questionnaire studies. At a minimum, authors must describe how

questionnaires were developed, and (if appropriate) validated for use in the population and languages used. They must also describe how those who received the questionnaire were identified, who performed and funded the study, what the response rate was, what incentives were used to obtain responses, and whether or not a single or multiple attempts were made to obtain responses. It would also be useful to at least attempt to compare the characteristics of those who answered the questionnaire to those who did not so that readers can judge how likely the responses are to be representative of the entire population who were sent the questionnaire. While the study was funded and performed by investigators who are likely to have potential COI, the reviewers and myself felt that the manuscript still should be published because it presents useful information. The data presented suggest that, at least in the relatively small number of physicians who completed the questionnaire, there are some major gaps in knowledge concerning the approval, use and monitoring of biosimilar products. The manuscript also presents useful information on the opinions these physicians held concerning important aspects of the use, naming, switching/substitution and post-marketing surveillance of biosimilar products.

A [Perspective](#) paper by de Vlieger et al. explains why a separate section of the *GaBi Journal* has been developed to cover non-biological complex drugs (NBCDs). These products were described previously in a meeting report [1].

An [Opinion](#) paper by Professor Mohamed Azmi Hassali and Zhi Yen Wong discusses the challenges that some low- and middle-income countries have in 'developing effective generics substitution policies' that are acceptable to practitioners and patients.

Another [Meeting Report](#) by myself and *GaBi Journal's* Deputy Editor-in-Chief Dr Robin Thorpe describe GaBi's first MENA (Middle East and Northern Africa) educational workshop on similar biotherapeutic products. The meeting format and conclusions were similar for this region as described in



the report of prior meeting held in Mexico City [2]. The rapid pace of development of both innovator and follow-on biological drugs has outpaced medical therapeutic education and therefore resulted in large knowledge gaps throughout the world.

The MENA meeting report is followed by two [Special Reports](#), the first by Dr Michelle Derbyshire from our editorial staff provides an updated list of patent expiry dates for best-selling biologicals. The second special report by Dr Bea Perks from our editorial staff discusses the need for clearer guidelines on 'establishing biosimilarity and approving subsequent extrapolation' of indications.

There are also two [Abstracted Scientific Content](#) papers from our editorial staff of papers published elsewhere. The first by Dr Michelle Derbyshire discusses the results of a World Health Organization (WHO) implementation workshop held in Seoul, Republic of Korea, in May 2014 that focused on the immunological assessment of monoclonal antibodies. The second by Ms Maysoon Delahunty reviews a paper entitled 'Measuring performance in off-patent drug markets: a methodological framework and empirical evidence from twelve EU Member States' published in *Health Policy* in 2014 by Associate Professor Panos Kanavos who proposes a five component methodological framework for evaluating the effectiveness of generic drug policies.

This issue ends with some important comments from our readers concerning a paper on pro-generics policies and registration backlogs in South Africa [3] that was

previously published in the journal. These comments and the responses of the authors are an excellent example of the kind of interaction that we at *GaBI Journal* want to encourage. Please send your questions or comments about relevant papers, whether published in our journal or elsewhere.

Finally, as the year draws to a close we want to thank our readers for their interest and participation in disseminating information about generics and biosimilars

and wish everyone a productive, healthy, more peaceful and happy New Year.

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References

1. Walson PD, Mühlebach S, Flühmann B. First Asia-Pacific educational workshop on non-biological complex drugs (NBCDs), Kuala Lumpur, Malaysia, 8 October 2013. *Generics and Biosimilars Initiative*

Journal (GaBI Journal). 2014;3(1):30-3. doi:10.5639/gabij.2014.0301.010

2. Walson PD, Thorpe R. First Latin American educational workshop on similar biotherapeutic products Mexico City, Mexico, 20 January 2015. *Generics and Biosimilars Initiative Journal (GaBI Journal)*. 2015;4(3):143-8. doi:10.5639/gabij.2015.0403.031
3. Leng HMJ, Sanders D, Pollock AM. *Generics and Biosimilars Initiative Journal (GaBI Journal)*. 2015;4(2):58-63. doi:10.5639/gabij.2015.0402.014

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