Editor's introduction to the initial issue of the sixth volume of GaBI Journal

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This first issue of 2017 includes a range of manuscripts of interest to readers.

A Letter to the Editor from Professor Mohamed Izham Mohamed Ibrahim and Nada Moustafa Abdel Rida proposes steps that governments and international organizations have taken or need to do, especially with respect to pricing of pharmaceuticals, to make 'Essential Medicines' more widely available globally. They include a plea for, 'more research … to ascertain the successes and shortcoming of … policies' that have been instituted or proposed to deal with unequal access to effective medications. Such research is important because the effectiveness and practicality of the steps they propose are both unlikely to be equally successful in different counties or regions as well as generally unproven or even untested.

The Original Research manuscript, by Dr Harry L Gewanter and Mr Michael S Reilly, presents the results of a web-based questionnaire concerning 'physicians' perspectives' on the 'naming and labelling of biologicals'. Two thirds of the physicians who completed the survey supported the use of distinct, non-proprietary name for every approved biological product and the majority preferred that the name include the manufacturer rather than a random suffix. These findings are of interest despite the many, well-documented problems with the validity, reliability and generalizability of such data. These issues are beyond the scope of my comments but readers who are interested in publishing, doing, or evaluating the meaning of such studies would be well served by reading any of the many resources available such as the review of this topic recently published by Professor L Leung (J Family Med Prim Care. 2015;4:324-7).

The Review Article by Gore et al. presents an in-depth review of an ocular non-biological complex drug (NBCD) and is part of GaBI's previously announced decision to publish manuscripts focusing on NBCDs. This case study of an NBCD 'delivered to a complex organ to treat a complex disease,' is used, 'to illustrate current gaps in knowledge that create difficulties in the design of a robust regulatory path to establish bioequivalent NBCDs'. While long, very detailed, and perhaps most useful to NBCD developers, it also provides information of interest to the clinicians who prescribe, and the patients who use, these and related products. Readers are invited to submit similar 'tales' of the development and testing of other similar products.

The Perspective paper by Claus et al. describes the 'current practices and future challenges' for the Ghent University Hospital pharmacovigilance programme. This is an extremely important aspect of the clinical use and post-marketing surveillance of all drugs. As the authors state, the paper provides 'an example of the contribution hospitals can make to the improved pharmacovigilance of biologicals'. I would add that such programmes should not involve only biologicals; rather they should include generics and NBCDs as well. However, as discussed, much remains to be done to develop the best and most efficient ways to collect and evaluate the data collected including ways to more accurately identify which specific follow-on products and batches were administered to patients with a specific adverse effect. Product names are important to consider, as discussed in the manuscript by Dr Gewanter and Mr Reilly, since this can have major effects on the usefulness of such pharmacovigilance data. Other aspects of pharmacovigilance are discussed in the meeting report by de Abajo et al. see below.

The Special Report presents estimated patent expiry dates for a number of the best-selling biologicals. Such information is not easily obtained and can be very useful to identify drugs for potential development or for pharmaceutical budget planning.

The first Meeting Report by de Abajo et al. describes the Roundtable on biosimilars: pharmacovigilance, traceability, immunogenicity held on 15 November 2016 in Madrid, Spain. The meeting was designed to address concerns raised by physicians and pharmacists that have limited the uptake of biosimilars in Spain. Issues addressed included topics covered in other papers in this issue including physicians' concerns and opinions concerning clinical use and outcomes, as well as regulatory review, approval and post-marketing pharmacovigilance; including traceability and the use of registries. The meeting participants and faculty concluded that there 'is a need for more interactions between regulators, pharmacists, physicians and the medical societies (including patients) that they represent' if this uptake is to be increased.

The second Meeting Report describes another multi-stakeholder workshop on the topic of 'Biosimilar Labelling'; the workshop was funded in equal shares by European Biopharmaceutical Enterprises (EBE) and EuropaBio. Participants included representatives of the European Medicines Agency who attended (by phone) the workshop as observers. As the meeting title indicates the workshop focused on Summary of Product Characteristics, the Patient Leaflet as well as labels on the outer product packaging. Discussions focused on the quantity and quality of information available on biosimilar labelling in Europe, the need for greater transparency and cross-referencing, as well as the need for greater understanding of the concepts of biosimilarity by all stakeholders and availability of educational materials covering these issues.

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The meeting reports are followed by an Opinion by Dr Christoph Baumgärtel discussing the attitudes of the Austrian Medicines and Medical Devices Agency where he works towards biosimilar interchangeability. This generally positive, officially stated, position on both interchangeability and switching stands in contrast to the more skeptical views expressed by some other regulatory bodies, practitioners and patient groups but, as Dr Baumgärtel points out, is evidence based.

A Pharma News summarizes and provides references for a number of important developments in biosimilars during 2016 including naming, US substitution legislation, guidances, clinical trials, extrapolation, switching, labelling, reimbursement, collaborations, as well as a look at the general issues.

Again, I close with a plea to our readers to submit their comments or concerns about any of our manuscripts as well as their manuscripts.

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