Latest features in GaBI Journal, 2012, issue 3-4

Professor Philip Walson, MD

This issue of the *GaBI Journal* uses a number of article formats to cover a range of issues related to generics and biosimilars.

In Letters to the Editor, Dr Carlo Petrini presents and defends the suggestion that the clinical use of biosimilars poses ethical concerns that differ from those of other pharmaceutical products. He even suggests that perhaps the 'advice' of an ethics committee should be sought before such products are used. In another Letters to the Editor Dr Kalle Hoppu presents an opposing, practitioner's view.

In Editorial, Mr Andy Gray challenges and extends some of the points made in the Pharmaceutical Pricing and Reimbursement Information (PPRI) Conference held in Vienna, Austria, and points out that the issues raised extend far beyond the European region; while Dr Sabine Vogler provides comments concerning the review by Dylst et al.

In a Commentary, Dr Christoph Baumgärtel discusses how data from a 2010 study abstract presentation were misleadingly used to suggest that an increased cardiovascular risk would result if patients were switched from an innovator brand lipid lowering 'statin' (atorvastatin) to a different but generic statin (simvastatin). In fact the theoretical risks were based not on a brand to generic switch of the same product but rather the switch from an effective dose of atorvastatin to a therapeutically non-equivalent dose of simvastatin. Unfortunately it is unlikely that this will be the last misleading analysis raising concerns about generic or biosimilar products. Another Commentary by Dr Sabine MJM Straus and Dr Thijs J Giezen presents a summary of a presentation these authors gave at the Conference of the Drug Information Association (DIA) in Copenhagen, Denmark, on the challenges, and possible solutions, associated with biosimilar pharmacovigilance programmes. They stress that such programmes will be both informed by data collected for innovator products and useful to evaluate events that are not likely to be uncovered during limited, pre-marketing, double-blind, randomized, and controlled trials.

Original Research by Haustein et al presents some biosimilar savings data. It would be interesting to see how these calculations would change if the price of innovator products decreased in an attempt by innovator sponsors to maintain market share.

The Review Article by Dylst et al presents a detailed description of the design, popularity, and effectiveness of reference price systems used in Europe.

A Perspective by Dr Robin Thorpe and Dr Meenu Wadhwa presents examples of the confusion that can and has resulted from inconsistent biosimilars terminology. The authors provide definitions they believe should be adopted to decrease this confusion. The other Perspective by Mr Luc Besançon discusses the role of health professionals in communicating the risks associated with counterfeit medicines. However, it is not clear how or even whether the use of generic drugs or biosimilars affect this risk or the content of such communications.

A Special Report by Dr Susanne Keitel describes the MEDCRIME Convention designed to deal with the growing, global criminal trade in falsified/counterfeit medical products.

In Guidelines, Mr Keith McDonald and Dr Kowid Ho use a question and answer format to provide readers with an overview of the background of the ICH Q11 guidelines on the development and manufacture of drugs and biologicals and the relevance of these guidelines for biosimilars and generic drugs.

Finally, in a Conference Report, Dr Sabine Vogler and Ms Nina Zimmerman provide a summary of presentations made at the 2011 PPRI Conference. They discuss the effects and unmet potential of generic policies in a number of European countries.

In the Abstracted Scientific Content, our editor summarizes a recently published science manuscript titled 'Effective pharmaceutical regulation needs alignment with doctors', Ebbers et al. discuss the role physicians should play in the development of biosimilars guidelines. It is hoped that these will stimulate discussion and perhaps submission of related manuscripts and letters from our readers.

Some of the formats in this issue are new and not all are routine in scientific journals. The editors, editorial staff and I would be interested in feedback from our readers on the usefulness and acceptability of these as well as the articles themselves.

Professor Philip Walson, MD
Editor-in-Chief, GaBiJournal