What to look forward to in GaBI Journal, 2015, Issue 2

Professor Philip D Walson, MD

This entire issue of the *GaBI Journal* could be titled 'World News' since it contains manuscripts describing global generics and biosimilar activities.

The Commentary by Leng et al. describes regulatory events in South Africa that led to claims of delay in marketing approval of generic drug products. The authors discuss the relationship between regulatory policies and resource limitations and conclude that while changes in the fast track approval process and staffing levels are needed that there really has not been undue delay. Their experience suggests that possible unintended consequences of policies caused by differences in regional marketing practices need to be more carefully considered before fast track systems are implemented.

The first Original Research paper by Fuhr et al. evaluated the theoretical effects of product naming from the perspective of manufacturers, patients, providers and payers; and concluded that because of governmental and third-party payers incentive schemes, naming is unlikely to have a major impact on the uptake of follow-on biological products in the US.

The second Original Research paper by Jeske et al. used well designed, actual laboratory experiments using a primate model to evaluate and compare the effects of the originator (enoxaparin) and a follow-on low molecular weight heparin product. These authors demonstrated significant 'differences in pharmacodynamic (PD) behaviours, especially in the mean release of tissue factor pathway inhibitor.' The authors suggest that currently used *in vitro* methods, e.g. anti-factor Xa and anti-factor IIa, are inadequate to fully characterize potentially important differences in product performance. While there are some limitations of the studies as pointed out by the authors as well as a potential for bias since the funding for these studies were provided by Sanofi (the authors state 'had no role in the study design'), the results raise important questions about the adequacy of current pre-marketing comparability studies that should be examined in clinical settings such as suggested by the authors 'where higher dosages are administered' or where minor PD differences are likely to have measurable effects. The results also imply that epidemiological studies examining differences in outcomes should also be undertaken. This work is an example of the kind of 'hard' science that we at the *GaBI Journal* would like to see more of submitted for publication in our journal.

The third Original Research paper by Brkičić et al. examined the relationship between two different reference pricing systems in Croatia on the savings generated by generics. While the non-experimental methods used were not adequate to fully support all the claims made, the authors identified some interesting associations based on which the authors suggest that different pricing systems have differing effects on the amount of savings generated from the use of generic drug products.

In a Perspective Dr Asbjørn Mack discusses what has and has not worked to increase the uptake of biosimilars in Norway. He suggests that for the use of biosimilars to decrease expenditures to be successful, there will need to be a combination of approaches including education of providers and the public, instructions for use and the use of tenders but that there is a lack of adequate support for these.

In the first Regulatory paper Dr Jeewon Joung describes the current Republic of Korea's regulatory approach to approval and marketing of biosimilars as well as the number of biosimilar products on the market in his country.

The second Regulatory paper by our editor provides an update on the various legislative approaches to substitution of biosimilars enacted in various US states.

Finally, in World News, Mr Ian Ford describes a new online biosimilars resource directed at patients across Latin America that was developed and supported by the International Alliance of Patients' Organizations (IAPO). As with all online content the usefulness and quality of the information provided is not necessarily peer-reviewed and will need to be established by readers familiar with the content. Readers of *GaBI Journal* are encouraged to review this and other related websites and submit their comments.

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

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