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

Professor Philip D Walson, MD

This issue begins with a Letter to the Editor by Professor Fabio V Teixeira from the Brazilian Inflammatory Bowel Disease (IBD) Society that deals basically with the issue of extrapolation of indications. The letter states that 'vigilance remains essential' for the use of this agent in IBD patients.

Professor Teixeira's letter is in response to the approval in April 2015 of the biosimilar infliximab (Remsima or CT-P13) monoclonal antibody product in Brazil for use in all indications granted to the innovator biological, Remicade. This biosimilar was approved for similar use by the European Medicines Agency (EMA) in 2013 and has been recommended for similar approval by the US Food and Drug Administration (FDA) in February 2016.

The basic question raised by the IBD Society and by Professor Teixeira concerns the appropriateness of extrapolating all indications for a biosimilar based on a consideration of mechanism of action rather than on separate clinical trials done in all patient populations.

The two Brazilian Remsima clinical trials conducted to gain approval were in rheumatology rather than IBD patient populations. Professor Teixiera points out the concerns raised by clinicians, investigators and Brazilian disease specific societies about this approach. He also points out that Canadian regulators had also voiced concerns and that a (possibly controversial) study done in Ireland appeared to show differences in clinical performance between the biosimilar and originator versions of this monoclonal antibody.

He makes a non-controversial call for post-marketing (pharmaco)vigilance so that clinicians and patients will be able to judge whether this decision was or was not in the best interest of patients. The question is whether, who and how such 'vigilance' can be done in an unbiased, scientifically valid, economically feasible way.

The first Commentary by Dr Joshua D Brown raises an issue that is important for the validity of post-marketing generic pharmacovigilance data coming from the US. Dr Brown explains how US low-cost generic drug programs (LCGPs) interfere with the collection of valid data for generic drugs. When these programmes provide generic drugs to patients without involvement of the patients' insurance companies, i.e. payers, their insurance claims data do not include these drugs. Yet, claims data are often used to generate pharmaco-epidemiologic information. Dr Brown points out that this 'loss of information' can lead to 'underestimation of overall quality' and discusses the implications of this underestimation as well as the effects on both cost estimations and 'signal detection of harmful medications'.

I wrote the second Commentary about the need to obtain a prior consent for chart review studies. Chart reviews can also produce important pharmaco-epidemiologic data. They are also very useful as hypothesis generating tools. However, such studies have to obtain prior approval by the local institutional review boards/ethics committees (IRBs/ECs) in order to be published by medical journals that conform to ethical, medical publishing standards. Investigators should not, and cannot, be responsible for deciding whether a given study, including chart reviews, adequately protects patients' welfare or privacy. Only properly constituted and run IRBs/ECs can do this. As explained in the Commentary, investigators are responsible for submitting their studies, including chart reviews, to their local IRB/EC for approval in order for their work to be accepted for publication.

The Original Research manuscript by Karampli et al. presents information gathered during interviews with a small number of Greek physicians and patients about their 'views' on generic medicines after the introduction by the Greek Government of a number of methods to promote the use of generics. While 'qualitative' in nature and based on small numbers, the interviews generated a number of concerns that, if generalizable to a sufficient number of Greek physicians or patients, will need to be dealt with if the use of generics are to increase.

The Review Article by Mr Tim Steele is a review of hybridoma technology. The author explains why he feels that this technology still holds promise as an 'ideal for commercial applications in the drug discovery, drug development and drug manufacturing paths'.

In a Regulatory paper, Alhomaidan et al. explain how biosimilars are priced in Saudi Arabia, one of a number of countries where price is a consideration in the approval of generics and biosimilars. The authors also discuss factors that influence pricing as well as various approaches to price control of these products both in Saudi Arabia and worldwide.

The two following Regulatory and Special Report manuscripts discuss non-biological complex drugs (NBCDs). First, Dr Falk Ehmann and Dr Ruben Pita describe in some detail the current EU legislation concerning all aspects of NBCDs. Then, Professor Gerrit Borchard discusses the pharmacopeial issues involving monographs for this important class of agents.

The issue ends with two Abstracted Scientific Articles and Pharma News written by the GaBI editorial staff covering 'Promoting a competitive generics market in the US' and 'The case for reforming drug naming'; as well as 'Top developments in biosimilars during 2015'.

I close this letter with a repeat plea for readers to submit their research as well as comments or concerns for publication in the journal.

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

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