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

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This first 2015 *GaBI Journal* issue (fourth volume of the journal) is being published soon after the first US biosimilar approval and it contains a number of articles that illustrate how the development, marketing and acceptance of biosimilars differ globally including in North and South America and the Persian Gulf States.

An Editorial entitled **Biosimilars: patient and physician acceptability is the fifth hurdle to market competition** by Professor Alan Lyles discusses the original research article in this issue by Sandorff et al. on regulatory requirements in three Latin American countries. Professor Lyles proposes that in addition to safety, efficacy, quality data, country specific decisions about use of and payment for biosimilars now requires both cost-effectiveness (the 'fourth hurdle') as well as acceptability information (the 'fifth hurdle'). He discusses why uptake of biosimilars requires both significant savings and trust in the approval process as well as how evidence-based decisions are evolving for biosimilars.

In a Letter to the Editor entitled **Generic medicines policy in Qatar**, Professor Mohamed Izham bin Mohamed Ibrahim reviews the current state of generic drug use in Qatar and other Arab countries. Qatar 'has as a goal the development of world-class, patient-centered healthcare system' and it has made significant efforts towards this goal. However, the large income disparity and impact of poverty in Qatar are seen by Professor Ibrahim as major obstacles to the achievement of this goal. While many generic drugs and an increasing number of biosimilars are well established in many countries, there are still many countries where even well characterized, less expensive generic medicines are not widely used which has a disproportionate effect on the poor. This is not true only in Qatar where generics use may be increasing but where physician preferences, patient trust and lack of effective bioequivalence testing are still barriers in all six Gulf Cooperation Council states and elsewhere in the world. Professor Ibrahim suggests Qatar improves access by investing in companies to produce medications (both generics and biosimilars) locally for their populations and reduces reliance on imported medications.

In a Commentary entitled **The EU regulatory approach to generics and biosimilars is essentially similar**, van der Plas et al., three of whom are from the Dutch regulatory authority, explain why despite some scientific and regulatory differences, the European Medicines Agency/Committee for Medicinal Products for Human Use has consistently applied the 'same active substance' approach to both generics and biosimilars. They argue against use of biological modifiers in the naming of biosimilars and that product names should be based on 'regulatory and clinical' rather than a 'scientific' perspective. I will leave it to our readers to comment but I suspect that not everyone will agree that all 'biosimilars' or even some generics have 'no clinical differences'. As Professor Lyles comments about cost-effectiveness and trust suggest, there may be differences in what regulators, prescribers or payers in different countries define as 'no meaningful differences.'

In the Original Research by Sandorff et al. entitled **Payer and physician evidence and discount requirements for biosimilars in three Latin American countries**, the authors used a literature review and targeted interviews to examine the factors that influence uptake and use decisions in Argentina, Brazil and Mexico. Participating payers and physicians were selected by regional industry experts and literature review respectively. There are many limitations to what a small, selected population claims is true; still the data provide insights into the influence of factors such as budget impact, physician acceptance, scientific evidence, and trust in regulators have on the regional use of biosimilars. While there were differences in the three countries, the authors conclude that if discounts adequate and trust exists there is potential for market share.

The Original Research by European Biopharmaceutical Enterprises (EBE) entitled **What pricing and reimbursement policies to use for off-patent biologicals? – Results from the EBE 2014 biological medicines policy survey** presents results of a 24-question survey conducted in 31 countries by the EBE group. The EBE survey covered five policy areas: Tendering, Health Technology Assessment, International Nonproprietary Name prescribing, Internal Reference Pricing, and Substitution. These respondents, all from countries with regulatory processes in place for biologicals, 'perceived' that there were many differences in how biologicals are being regulated. In contrast to the prior Commentary by van der Plas et al., these authors, perhaps not surprisingly given their industry focus, claimed that 'biologicals are not the same as generics' and present a tremendous amount of data on what their survey found. While there are clearly problems with such data, the opinions of the respondents 'matter' to legislators, payers and prescribers as well as to regulators since they are likely to influence the uptake of biosimilars.

There are similar limitations of the data presented in a Review Article entitled **The refinement of the super generic concept: semantic challenge for product re-innovation**, Barei and Ross discuss the marketing implications of follow-on non-biological product names; whether the use of the term 'generic' when applied to hybrid or improved performance, i.e. super generic, older drugs reduces either liability or successful product promotion. There are challenges for the development of generic containing products that have improved performance, with or without lower costs. The authors discuss the regulatory, financial and marketing challenges and appeal of products that can have new dosage forms, different routes, new indications, or combinations of these characteristics.

They present the results of semi-structured interviews, using well described, predetermined, open-ended questions that were put to 10 managers, consultants, lawyers and researchers who agreed to be interviewed (it is not known how many were approached but refused) in Europe, India and USA. The methods used to identify those interviewed were not well described but included the use of LinkedIn and PubMed. The authors suggest that there is a need to avoid the 'generic' title for these 're-innovated

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products, value-added generics, new therapeutic entities' despite the marketing of some 'premium generics' and that 'the success of such products may require education of prescribers and patients'.

In a Perspective entitled **Biosimilars for prescribers** Professor Pekka Kurki reviews data on physician understanding, hesitation to use and its basis, and suggests that because the development of biosimilars is a new concept in drug development physicians prescribing biologicals need more neutral information on the quality, safety and efficacy of biosimilars. He suggests that as part of this educational effort regulators should distribute already available information. *GaBI Journal* is clearly in agreement with the need for education and hope that the journal is one of the 'already available' sources of such information. Education of all stakeholders is also a goal of the journal as illustrated by our past and planned educational workshops.

A Regulatory paper entitled **Health Canada's perspective on the clinical development of biosimilars and related scientific and regulatory challenges**, Pen et al. review the Canadian flexible, case-by-case approach to biosimilar regulation and discuss the importance of maintaining consistency in decision-making when using such an approach. The scientific and regulatory issues covered relate to clinical assessments including selection of reference product, comparative pharmacokinetic/pharmacodynamic studies, clinical trial designs, selection of sensitive populations, and study endpoints, safety, immunogenicity, and extrapolation. It is important for regulators, especially those like Health Canada that have successful regulatory programmes to present their methods for review and discussion by others.

Finally, in an Abstracted Scientific Content our editor Dr Bea Perks summarizes an article by Dr Alex Dodoo on the problems faced by developing countries such as Ghana in providing up-to-date treatments to cancer patients. In Ghana, unlike the situation described in Qatar, widely used generic drugs generate large savings, but the unavailability of high quality but inexpensive oncology drugs is still a major problem. Dr Dodoo suggests a role for the World Health Organization in identifying prequalified oncology drugs. The growing disparity between rich and poor, both nations and populations, is especially problematic with respect to access to life-prolonging if not life-saving medications and solutions must be found to at least improve this access. We at *GaBI Journal* hope to be able to contribute to the dialogue needed to start to find these solutions.

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