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What to look forward to in GaBI Journal, 2017, Issue 2

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The use of both generics and biosimilars offers the potential to increase availability of medicines through decreases in cost that should occur when an expensive product (drug) loses patent protection and lower cost alternatives are marketed in countries with a 'free-market' economy. As the manuscripts in this issue of *GaBI Journal* emphasize, it is clear however that while this principle works very well for the majority of consumer products, it is not working very well for either generic or biosimilar drugs. There are a number of apparent reasons for this failure. Innovator companies have been very successful in raising concerns that limit their acceptance by prescribers, consumers and even governments. In some cases this is justified based on legitimate quality or biologically justified concerns. In others, actions taken by prescribers, governments or regulators appear to simply be inadequate.

In the [Editorial](#), Mr Alessandro Curto discusses pricing and reimbursement policies and suggests that it is 'only a matter of time before progress in biosimilars matches that of generics worldwide'. Is this enough however? There is ample evidence that even very good or superior lower cost generics are providing much less cost savings than theoretically possible. This is true even in those countries such as Germany where there is extensive use of both generics and biosimilars.

This is also the topic of the [Commentary](#) by Godman et al. written in response to the article by Rida and Ibrahim [1] published in the prior issue of *GaBI Journal* discussing pricing strategies of pharmaceuticals in developing countries. Godman et al. suggest that developing countries might be more successful if they used some of the more aggressive, successful policies used in The Netherlands and Sweden.

The large variability in approaches being taken to the pricing of and reimbursement for biosimilars are demonstrated in the first [Original Research](#) by Reiland et al. This manuscript reports in detail the responses of national pharmaceutical trade associations in 32 countries, the

28 European Union Member States plus Norway, Serbia, Switzerland and Turkey to a questionnaire survey conducted by the European Biopharmaceutical Enterprises. The massive amount of data presented is most useful to understand how much approaches differ, that the policies 'take account of the specificities of biologicals', and that 'treatment decisions remain in the hands of physicians'. It is understandable that physicians (and their patients) want to maintain control of which medicines they can prescribe for their patients.

The second [Original Research](#) by Vogler and Schneider presents questionnaire data on the variability in the approach to pricing and usage enhancing generic and biosimilars policies being used in 40 European countries plus Canada and South Africa. The authors conclude that policymakers are still 'struggling' to identify the best approach to take; possibly because the 'best' approach is very likely to be different in different countries with different healthcare and reimbursement systems as well as different levels of physician and patient understanding, education and financial realities.

The pricing and reimbursement for generics and biosimilars has perhaps the most emotional impact when it relates to truly life-saving or extending drugs such as the oncology drugs covered in the first [Special Report](#) by Venkatesan et al. that reviews the 20 approved tyrosine kinase inhibitors. These novel oncology drugs have literally transformed the treatment of patients with a number of cancers who previously faced rather grim prognoses. These authors discuss some of the reasons for their high costs and long delays in making generics available, including their long patent lives.

It should also be noted that there is good evidence that differences in the efficacy and toxicity of some if not all kinase inhibitors are largely the result of the huge individual differences in their clearance and subsequent drug exposure, and that these differences can be effectively controlled through the use of kinase inhibitor concentration monitoring. Such monitoring might also allay any concerns that practitioners



might have, or innovator manufacturers might raise, about product performance differences.

The second [Special Report](#) reviews differences in the approach taken to the interchangeability of biosimilars in various countries. Until or unless physicians begin to make more evidence-based decisions, payers will have to consider pushing for more such involuntary methods to encourage the use of true biosimilars. However, harmonization of such approaches could do much to decrease the confusion these multiple approaches create for all stakeholders.

In an [Abstracted Scientific Content](#) at the end of this issue, our editorial staff summarized a related article published in *US Pharmacist*, Manigault et al. suggest that the UK could save as much as 71–99% of their large kinase inhibitor costs if they undertook national generic kinase drug production themselves. The magnitude of the savings might be less in other countries but the principle is sound and should definitely be considered. This might be the only way to control the unsustainable increase in drug costs for these and other generic, life-saving medications.

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Reference

- Rida NMA, Ibrahim M. Pricing strategies for pharmaceuticals in developing countries: what option do we have? *Generics and Biosimilars Journal (GaBI Journal)*. 2017;6(1):4-6. doi:10.5639/gabij.2017.0601.002
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