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# What to look forward to in GaBI Journal, 2013, Issue 2

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The first of two [Letters to the Editor](#) is from Ms Gaspani and Ms Milani expressing their concerns about the lack of clear regulatory guidelines for approval of liposomal generic formulations. Liposomal products are only one and perhaps some of the best-characterized example of non-biological complex drugs (NBCDs). NBCDs while not having a biological source can still be as or even more complex than many biologicals. New NBCDs are handled by some regulatory authorities as are generic drugs whose chemical structures can be completely characterized by their physico-chemical characteristics but this is not true for most NBCDs. In future issues of *GaBI Journal* we hope to publish many additional manuscripts concerning the testing and approval of both liposomal products as well as a number of other more complex NBCDs.

The second [Letters to the Editor](#) concerns patient and provider attitudes in Yemen towards generics and biosimilars. Just as approval and marketing differs around the world, so do attitudes, prescribing and utilization of these products. We hope that by publishing similar manuscripts, we can provide readers with insights into the many divergent ways that generics, biosimilars and NBCDs are perceived.

While regulatory approval of products is necessary for their use approval alone is not sufficient to guarantee their actual use. [Original Research](#) by Dr Vogler and Ms Zimmermann describe how various Austrian sickness funds have tried to increase acceptance and use of approved drugs. An [Editorial](#) by Dr Godman, a member of our International Editorial Advisory Board and a frequent contributor to *GABI Journal*, offers some useful comments on the Austrian sickness funds' attempts to increase prescribing of generics and biosimilars.

This issue continues with a [Review Article](#) on the pharmacokinetics of antimicrobial drugs in obese children by Dr Sampson et al. Both what is known and what needs to be studied are emphasized. The

importance of this review is enhanced by a number of recent trends. First, the number of obese children (and adults) is increasing so rapidly that this increase is being characterized as an epidemic in the US as well as in a number of other countries. Secondly, antibiotic resistance can also be considered an epidemic and threatens to make infections by some organisms essentially untreatable. This is occurring at the same time that new antibiotic drug development has slowed dramatically. Finally, it has become increasingly obvious that antibiotic pharmacokinetics can differ greatly in critically ill patients as well as patients at both extremes of age compared to subjects used in most clinical trials. To be effective, antibiotic doses, administration regimens, and perhaps drug combinations need to be individually tailored to match both individual patient kinetics as well as infecting organisms' specific drug exposure targets. All of these facts make it imperative that clinicians understand how a number of specific patient characteristics including obesity can alter drug handling, the number of therapeutic failures, as well as drug toxicity.

There are four [Perspective](#) papers in this issue. The first two [Perspective](#) papers represent somewhat of a point/counterpoint discussion of the use and interchangeability of generic immunosuppressive drugs in transplant patients. Professor van Gelder presents a view as a clinician stating that the risks of interchanging these products is not justified by their benefit, especially if multiple products, each of which can differ by up to 20% from the originator product, are used in the same patient. However, Dr Maliepaard et al. present a regulatory opinion that they can be used interchangeably. They suggest this is true because these products can be well characterized and that regulators can make drug and disease specific decisions based on scientific data about when current bioavailability differences are acceptable or not. In my view both authors make legitimate points but also raise a number of difficult questions including: How

much of a difference between two generic drugs is too much to allow substitution between them when they each were tested against the innovator product and not against each other? What is the maximum risk (not the mean in a group) of rejection or toxicity increased by the use or substitution of generic immunosuppressants? Can these risks be minimized by the use of therapeutic drug monitoring? Should such products only be used when patients are first started on immunosuppressants or can they be used even in patients who are doing very well on a specific product? Should multiple switches be allowed without consent of the patients and their treating physicians? Should regulators, insurance companies, governments, or clinicians be able to decide for patients how much risk or cost saving is acceptable? Finally, are opinions or even well documented case reports adequate to answer all these questions for transplant or other patients where treatment failure can produce dramatic, even life-threatening consequences?

The other [Perspective](#) by Dr Aapro discusses the impact of availability and use of biosimilars in oncology and goes beyond the more focused issue of erythropoiesis-stimulating agents (ESAs) discussed in the updated clinical guideline report presented in this issue.

In the final [Perspective](#) paper Dr Chang et al. discuss biosimilars from a South American perspective; again extending the global perspective theme raised in another paper in this issue of the journal.

While there are many similarities the methods used to regulate drugs and devices differ around the globe. This issue of the *GaBI Journal* ends with a [Conference Report](#) from a presentation by Dr Toshiaki Sugita of the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). Dr Sugita summarizes how the PMDA reviews new drugs and biosimilars including its review of how ethnic differences in responses between Japanese are evaluated and how the PMDA is attempting to shorten the time it takes for products to be approved in Japan.

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