Editor's introduction to the wide range of topics in the initial issue of the second volume of *GaBI Journal*

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We start off the second year of *GaBI Journal* with articles covering a wide range of issues.

In Letters to the Editor, Dr Christian K Schneider discusses and expands on a previously published article by a bioethicist [1] on the ethics of biosimilars. Dr Schneider applauds the inclusion of ethicists in the debates concerning biosimilars but points out some problems created by questioning the safety or efficacy of properly approved biosimilars. He discusses the biosimilars approval processes in Europe and asks 'How ethical is it to question their safety, and can we afford questioning it?' Unfortunately, he does not discuss the very real problems posed by inadequately studied copies of biological products that are being produced in many countries such as the problems discussed in an article by Professor Abdol Majid Cheraghali from Iran. In another Letters to the Editor, Dr Christoph Baumgärtel is in response to two previously published articles by Dr Julie Clayton, *GaBI Journal* Science Editor; asking for increased physician involvement in the use of biosimilars [2, 3], Dr Baumgärtel discusses attempts by the Austrian Regulatory Authority to do this.

Biosimilars are discussed both from a payer's perspective by Mr Gustaf Befrits Hälsoekonon in a Commentary as well as by Dr Brian Godman in an Editorial on health authority's perspective.

Original Research by Dr Fereshteh Barei et al. discuss their view of how generics manufacturers can move from incremental innovation to 're-innovation', and on the future of biosimilars.

Three Review Articles are presented discussing how biosimilars are approved for use or interchangeability in different countries. Professor Shein-Chung Chow and Ms Christine Ju discuss US review processes included in the US Biologics Price and Competition Act. In contrast to the rigorous US processes, Professor Abdol Majid Cheraghali discusses the use and monitoring of biological products in Iran, including inadequately controlled biological copies. A related discussion of how 'similar biologics' are approved and marketed in India is included as a news item. In the third review, Professor Joan Rovira et al. discuss the biosimilars development processes used in 24 European Union Member States, plus Norway and Switzerland.

A Perspective by Dr Richard O Dolinar discusses concerns that he, the Alliance for Safe Biologic Medicines – the group that funds the organization he works for, and various other 'stakeholders' including treating physicians and patients have about the use of biosimilars. Some concerns expressed about biosimilars also apply to originator products whenever any production method changes are made. This suggests, at least to this reader, that even new batches of originator products perhaps should be subjected to expanded retesting or restricted use. Unfortunately, neither this nor the possibility that biosimilars can actually be 'biobetters' was adequately covered.

Diverse Regulatory and practice Guidelines articles are presented as well. Dr Toshiyoshi Tominaga, Dr Tatsuya Kondo, and Ms Yuki Ando present a less detailed discussion of the Japanese Pharmaceuticals and Medical Devices Agency. Dr Robin Thorpe and Dr Meenu Wadhwa review the European Medicines Agency's Committee for Medicinal Products for Human Use 'Guideline on immunogenicity assessment of monoclonal antibodies intended for *in vivo* clinical use'. One very relevant cancer treatment practice guidelines from the European Organisation for Research and Treatment of Cancer concerning the use of biosimilars is reviewed by our editors.

A For Patients paper by Ms Yasemin Dil directed at patients discusses relevant patient-centred healthcare indicators. Finally, in Abstracted Scientific Content, a paper describes some publications concerning the use of generic anticonvulsant medications was abstracted by Dr Julie Clayton, *GaBI Journal* Science Editor.

The wide range of topics presented in this issue emphasizes the complexity of the use of generics and biosimilars. Readers are encouraged to submit both comments on these and other published articles as well as their own relevant manuscripts.

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References

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