

Official Journal of the
GENERIC AND BIOSIMILARS INITIATIVE

GaBi Journal

Generics and Biosimilars Initiative Journal

Building trust in cost-effective treatments

The Generics and Biosimilars Initiative is proud to release the *GaBI Journal*—Official Journal of the Generics and Biosimilars Initiative—the reliable information source on generic and biosimilar medicines for healthcare professionals.



GaBI Journal is unique as an independent, peer reviewed academic journal—it encompasses all aspects of generic and biosimilar medicines development and use, from fundamental research to clinical application and policies.

GaBI Journal (Generics and Biosimilars Initiative Journal - ISSN 2033-6403), an open access journal on generic and biosimilar medicines, is published quarterly, available in both print and electronic format. For more information, visit www.gabi-journal.net

GENERICIS AND BIOSIMILARS INITIATIVE (GaBI)

GaBI OVERVIEW

Sustainability and equal access to health care for all are at risk due to rapidly increasing costs. The reasons for this are diverse: increased standard of living and life expectancy, but also the high cost of new drug innovations. Today's society is looking for inexpensive solutions to its ever-increasing demands. Healthcare systems endeavour on the one hand to provide groundbreaking, novel solutions to a greater than ever demand for therapeutic assistance; and on the other hand, to achieve this in the most cost-efficient way.

The availability of low cost pharmaceutical products through generic medicines and the ability to make medical care affordable to everyone are high on the social and political agenda of almost every nation in the world. The Generics and Biosimilars Initiative (GaBI) has been set up to support these demands.

VISIONS AND AIMS/MISSION OF GaBI

The mission of GaBI is to foster the worldwide efficient use of high quality and safe medicines at an affordable price, thus advancing and supporting the idea of accessible, affordable and sustainable health care. GaBI aims to raise the scientific status of generic and biosimilar medicines, and to provide comprehensive, high quality, scientifically sound, reliable, well-documented, and up-to-date information about generic and biosimilar medicines both in print and electronically in an open access format.

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MISSION OF GaBI JOURNAL

The mission of *GaBI Journal* is to provide an independent, high quality, authoritative, and peer reviewed platform for the publication of scientific articles concerning any aspect of the research into and development of cost-effective medicines, irrespective of their source.

This Open Access journal will thus make information on pharmaceutical innovation and developments in generic and biosimilar medicines accessible to everyone, including physicians, pharmacists and nurses, patients/consumers, drug developers, third-party payers, legislators and assessors.

This is achieved by:

- independent peer review
- collaboration with all relevant stakeholders (physicians/prescribers, regulatory authorities, industry, third-party payers and governments)
- publishing via open access channels, both in print and electronically

SCOPE AND PROFILE

The scope of *GaBI Journal* is broad and of interest and relevance to professionals active in clinical practice, pharmaceutical science and policy. Materials published in *GaBI Journal* include high quality research reports, literature reviews and case studies, all of which are peer reviewed.

Manuscripts on all aspects of generic and biosimilar medicines, covering areas in clinical, fundamental, technical, manufacturing, bio-processing, economic

Generics and Biosimilars Initiative Journal

and social aspects of pharmaceuticals and therapeutics are welcome. In addition, high quality work submitted in other formats, for example, scientific and evidence-based commentaries, may also be considered. In all cases, the emphasis is on quality, originality and knowledge contribution to those involved in health care.

All manuscripts submitted to *GaBI Journal* are subject to a rigorous peer review process. *GaBI Journal* is published in English and plans to be indexed in PubMed.

GaBI Journal is published quarterly, with a circulation exceeding 5,000 copies targeting healthcare professionals in clinical practice and healthcare policies, pharmaceutical experts, and scientists worldwide.

JOURNAL EDITORIAL OBJECTIVES

GaBI Journal aims to educate and raise trust in safe and cost-effective use of medicines for healthcare professionals.

To achieve this, *GaBI Journal* publishes high quality, peer reviewed and independent scientific articles on all aspects of generic and biosimilar medicines, including but not limited to the development of formulations, production, testing including equivalence-*in vivo* and *in vitro*, model development, regulatory issues, supply chain management, and pharmacoeconomics, through the support of experts who are highly motivated to share their knowledge and professional experience.

In addition, *GaBI Journal* endeavours to publish regulatory guidelines and legislation in an abbreviated, simplified format as short reports, facilitating an easier and wider understanding of the technical and complicated official documentation.

JOURNAL EDITORIAL SECTIONS

GaBI Journal strives to satisfy the needs of a wide readership, offering high quality relevant reports, studies, analyses and updates on issues of interest to healthcare practitioners, policymakers and drug developers.

The editorial content is structured in a variety of editorial sections:

- 1. Editorial** – article from the Editor-in-Chief or selected members of the Editorial Board, covering issues directly relevant to the journal or related to the editorial content of the journal issue
- 2. Commentary** – invited article, usually a thought-provoking idea or opinion on selected topics or brief report from members of the Editorial Board, International Editorial Advisory Board or reviewers. The article is usually one or two pages covering issues surrounding medical ethics, policies and recently published papers/reports/guidelines
- 3. Review article** – invited article, containing the current state of the research of a particular topic
- 4. Meta-analysis** – covering results of several studies that address a set of related research topics
- 5. Original research** – scientific papers investigating all aspects of generics and biosimilars development (including manufacturing and production technology) and usage (including clinical research and risk management)
- 6. Short communications** – short report in 1-page format providing key messages with elaborate background information or with the full report available on the website: www.gabi-journal.net
- 7. Letters to the Editor** – established as a proactive discussion platform, allowing readers' responses or reactions to articles published in *GaBI Journal*
- 8. Perspective** – articles cover a wide variety of topics of current interest in health care, medicine, regulatory and the intersection between patients/stakeholders and society
- 9. News** – providing updates on advances in generics and biosimilars development from diverse sources as well as regulatory, clinical, scientific and industry news updates
- 10. Legal/Regulatory/Guidelines** – including patents, discussions on bioequivalence and biosimilar guidelines
- 11. And more** – including conference, meeting or special reports, interviews, education, abstracted scientific content, patient-oriented information (For patients) and a lighter look at what is happening worldwide in the *Rhythm*

TARGET AUDIENCE

GaBI Journal is circulated to healthcare professionals involved in all aspects of medicinal provision including:

- physicians
- pharmacists
- healthcare providers, e.g. nurses, scientists
- regulatory agencies (national and international)

- national pricing and reimbursement authorities, health technology assessment boards, healthcare purchasers
- policymakers, policy advisers, politicians
- insurance companies, healthcare payers
- generics/biosimilars/innovator pharmaceutical companies
- biotechnology companies
- members of relevant societies such as FIP, IAPO
- manufacturers of chemicals/raw materials (API)
- industry suppliers
- clinical research and manufacturing organizations

CALL FOR PAPERS

Manuscripts, prepared according to the instructions for authors, see www.gabi-journal.net, are invited on all aspects of pharmaceutical and therapeutic sciences, including:

- clinical trials
- comparative bioavailability/bioequivalence studies
- bioequivalence methodology (traditional and biopharmaceutical)
- drug safety and risk management
- general drug production
- biopharmaceutical production/analytical/manufacturing methodology
- drug/formulation development
- supply chain management
- biopharmaceutical and generics regulatory issues
- healthcare policies and medicines policies
- health economics
- special patient populations, e.g. children, elderly, obese
- OTC products, including herbal remedies and nutraceuticals

Original research, review articles, meta-analyses, perspectives, and letters to the editor will be considered for publication. Manuscripts should be in English and submitted electronically to *GaBI Journal* via the manuscript submission website or at editorial@gabi-journal.net

Authors who wish to discuss the submission of articles or related matters are invited to contact the Editor-in-Chief by email at editorial@gabi-journal.net

A message from the Editor-in-Chief, *GaBI Journal*

Dear Colleagues,

Research on the science of generics and biosimilars has matured and deserves its own platform for the exchange of research and opinions, to be shared amongst healthcare professionals globally. Such a platform does not exist at present and, as a result, most of the research performed in the field of generics and biosimilars is scattered in specialized journals, and therefore less readily accessible.

GaBI has created a solution to this dilemma by providing a journal dedicated to generics and biosimilars—the *GaBI Journal*. This journal is dedicated to strengthening the appropriate use of both patented and quality generic and biosimilar medicines in all patient-care settings.

Professor Philip D Walson, MD, USA



**ENHANCE YOUR KNOWLEDGE IN THE SCIENCE OF GENERICS AND BIOSIMILARS.
READ *GaBI JOURNAL* (OFFICIAL JOURNAL OF THE GENERICS AND BIOSIMILARS INITIATIVE).**

JOURNAL MANAGEMENT AND GOVERNANCE

GaBI Journal adheres to the standard of the ICMJE (www.ICMJE.org) – Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication.

I. Editorial Board

The Executive Editorial Board, the expert Associate Editors, and an International Editorial Advisory Board support the journal.

A. Executive Editorial Board

GaBI Journal's Executive Editorial Board comprises the Editor-in-Chief, Deputy Editor-in-Chief, two Associate Editors, and the Publisher.

1. Editor-in-Chief: Professor Philip D Watson, MD, USA
2. Deputy Editors-in-Chief: Dr Rob Janknegt, PharmD, PhD, The Netherlands
Dr Robin Thorpe, PhD, FRCPath, UK
3. Associate Editors:
Professor Huub Schellekens, MD, The Netherlands
Professor Steven Simoons, PhD, Belgium
4. Publisher: Ms Lasia Tang, Belgium

The Executive Editorial Board (EEB) comprises individuals with extensive knowledge of all topics related to generic and biosimilar medicines. Chaired by the Editor-in-Chief, this board defines the publication strategy, journal direction and editorial content of *GaBI Journal*. The EEB meets annually at a selected and relevant congress event to take executive decisions on strategic issues such as publication tactics and editorial direction, and to review past performance.

The Deputy Editor-in-Chief is elected from among the Associate Editors and will take over responsibilities from the Editor-in-Chief during his absence and in cases where the Editor-in-Chief declares a conflict of interest.

B. Expert Editorial Board with Associate Editors portfolios for:

1. Bioequivalence methodology (traditional and biopharmaceutical)
2. Biopharmaceutical production/manufacturing methodology
3. Regulatory issues around generics and biopharmaceuticals, including national medicines boards' perspective
4. Clinical trials
5. General drug development
6. Healthcare policies, medicines policies and health economics
7. Special patient populations such as children, elderly, obese
8. Drug safety and risk management

Members of the Editorial Board and the International Editorial Advisory Board have submitted a 'Conflict of Interest Disclosure' statement, which is available upon request.

II. International Editorial Advisory Board

This international board of reputable scientists acts independently and represents the interests of the different parties/stakeholders involved. This board is comprised of:

1. Scientists from academia
2. Representatives and individual specialists from professional research organisations
3. Regulators from regulatory organisations (drug/health/professional agencies)
4. Top global players in generic and biosimilar medicines industry

International Editorial Advisory Board

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