Biological and Biosimilar Medicines: What patients’ organizations can do
Contents

Introduction 3
1. Are biological and biosimilar medicines available in your country? 3
2. How are biological and biosimilar medicines regulated in your country? 3
3. Is there a pharmacovigilance system in your country? 4
4. What is your organization’s position on biological and biosimilar medicines? 5
5. What is your strategy? 5
6. How to develop an action plan for your strategy 6
7. How do you increase awareness of and education about biological and biosimilar medicines? 7
8. IAPO member case studies
   The need for regulation and monitoring to ensure patient safety
   Eva Maria Ruiz de Castilla, Esperantra, Peru 8
   Physician notification of biosimilar medicines substitution
   Andrew Spiegel, Global Colon Cancer Alliance, USA and former CEO of Colon Cancer Alliance, USA 9
   Generating a buzz: actions and next steps following IAPO’s Workshop on Biosimilar Medicines
   Stephen Murby, Consumers Health Forum of Australia 10
9. Appendix 1
10. Appendix 2

With our thanks
IAPO would like to thank all those involved in preparing and developing this document. A full list of acknowledgements can be found at the end of the Briefing Paper, which is part of IAPO’s Information and Advocacy Toolkit on Biological and Biosimilar Medicines.

IAPO’s project on biosimilars medicines has been made possible thanks to educational grants from Amgen and Lilly USA, LLC (for the Toolkit) and Merck Serono and the Pharmaceutical Research and Manufacturers of America (PhRMA) (for IAPO’s Workshop on Biosimilar Medicines, 2013).

© November 2013 IAPO. All rights reserved.
IAPO is registered as an Association in The Netherlands.
Registration Number: 30201854

This publication is the property of IAPO and no part may be reproduced without its prior permission. Opinions expressed by participants in this Toolkit are their own and not necessarily those of IAPO. Reference to any person or organization in this Toolkit does not imply that such a person has been approved or recommended by IAPO.

Designed and produced by Postscript Communications Ltd
www.wearepostscript.co.uk
Introduction

This booklet provides patients’ organizations with information about how they can advocate for patient access to safe, high-quality, affordable and modern medicines. Countries across the world are at different stages in terms of the availability of biological medicines, their regulation and pharmacovigilance.

Sections 1 to 4 in this booklet provide a series of steps to help patients’ organizations address the following key questions in their work on biological and biosimilar medicines:

- Are biological and biosimilar medicines available in your country?
- How are biological and biosimilar medicines regulated in your country?
- Is there a pharmacovigilance system in your country?
- What is your position on biological and biosimilar medicines?
- What is your strategy?

Sections 5 to 7 provide tips on raising awareness and knowledge about biological and biosimilar medicines; an action plan template, including an example developed by a participant at IAPO’s Workshop on Biosimilar Medicines in 2013; and advocacy examples from three IAPO members to help you develop your own work. This booklet should be read in conjunction with the other sections in IAPO’s Information and Advocacy Toolkit on Biological and Biosimilar Medicines. For definitions of terminology please see the Glossary in the Briefing Paper in this Toolkit.

1. Are biological and biosimilar medicines available in your country?

The first step in developing your work on biological and biosimilar medicines is to determine whether or not they are available in your country.

- Find out if biological and biosimilar medicines are available in your country and, if they are, for which disease areas:
  - get a list of approved and marketed medicines in your country from your government/Ministry of Health
  - check on the internet
  - ask the patients that you represent, and speak to doctors, healthcare professionals and other patients’ organizations.

2. How are biological and biosimilar medicines regulated in your country?

Next you need to find out if and how biological and biosimilar medicines are regulated in your country.

- Find out who regulates medicines in your country. This will normally be a sector of the Ministry of Health.
- Find out how biological and biosimilar medicines are approved and made available to patients (e.g. what laws/guidelines/pathways are in place).
- Find out if there are separate regulatory laws/guidelines/pathways for biological medicines and chemical medicines.
- Find out if there are different regulatory laws/guidelines/pathways for biosimilar medicines and biological medicines.
- If so, do they follow the guidelines set by the:
  - European Medicines Agency (EMA)
  - World Health Organization (WHO)
  - US Food and Drug Administration (FDA).
If there are no laws/guidelines/pathways for the approval of biological and biosimilar medicines available in your country, follow these steps:

- Find out whether any other patients’ organizations in your country are working on the issue of regulation of biological and biosimilar medicines:
  - if they are, form a group or alliance with organizations that have the same objectives to strengthen your voice
  - if not, contact patients’ organizations that may be interested in this topic and organize meetings to share information and form a unified group as above.

- Once you have formed a network of patients’ organizations, create an action plan. Use the information about your country in this Toolkit and information you have gathered from patients, doctors and other patients’ organizations. Use the template on page 6 to write this action plan.

- Hold advocacy, information and discussion meetings with all relevant stakeholders (e.g. government, Ministry of Health, patients, doctors, regulators, academic researchers, health providers and pharmaceutical industry) to raise awareness and promote debate.

- Use your plan to advocate and lobby for laws/guidelines/pathways to be put into place to raise awareness.

In some countries, a law, guideline or pathway for approval of biosimilars may be in place, but may not have been implemented. In other cases, copies of biological medicines may have been approved before a law, guideline or pathway was put in place. In these cases, use the same steps as above to advocate for full implementation. An example of a letter written by Esperantra, a patients’ organization in Peru, to the Ministry of Health, can be found in Appendix 1. This letter highlights that in Peru, although a regulation for the approval of biosimilar medicines was created in 2009, it has not yet been fully implemented. Therefore, unregulated copies of biosimilar medicines are still being approved and made available for patients.

3. Is there a pharmacovigilance system in your country?

It is important to determine whether adverse effects of medicines are tracked and monitored in your country.

- Find out who is in charge of monitoring adverse effects in your country. This will normally be a sector of the Ministry of Health:
  - consult with your membership – who do the patients you represent report their adverse effects to?
  - ask doctors and healthcare professionals
  - consult with other patients’ organizations.

- Find out what sort of pharmacovigilance system is in place for tracking and monitoring adverse effects and for which types of medicines.

If there isn’t a pharmacovigilance system available in your country, or there is a weak system, follow the steps described in section 2 to advocate and lobby the government and relevant sectors of the Ministry of Health or your country’s equivalent health agency.

Tip: It is important to collaborate with doctors in your country as well as patients’ organizations to ensure a strong voice that emphasizes the value of pharmacovigilance in patient safety.

Tip: See IAPO’s toolkit on ‘Working with Partners and Stakeholders’, which offers guidance on partnerships and collaboration: www.patientsorganizations.org/partnersandstakeholders.

4. What is your organization’s position on biological and biosimilar medicines?

Once you have assessed the situation in your country, you need to develop your organization’s position on these medicines. It is important to understand the issues that affect the patients you represent and ensure your position reflects those issues.

- Undertake a consultation with your members by email, post, telephone or online via survey software. This will help identify:
  - the issues regarding biological and biosimilar medicines that are important to the patients you represent
  - the level of awareness of the issues.

- Conduct research on biological and biosimilar medicines, using the questions in sections 1 to 3, to determine what the situation is globally, regionally and nationally:
  - check the websites of the EMA, WHO and FDA for up-to-date information regarding regulation of medicines in your region.

- Look at current strategies, campaigns and policies in your country.

- Use both the results of the consultation and the research you have conducted to develop a policy position. A policy position sets out what the issues are and the actions that need to be taken to address them.

- Figure 1 shows the key stages that IAPO uses to develop policy positions. Please refer to IAPO’s Policy Framework for further information on this model and policy formulation at: www.patientsorganizations.org/policyframework.

STAGES 6 & 7

STAGE 1

STAGE 2

STAGE 3

STAGE 4

STAGE 5

ISSUE

A. Notify Members

B. Information Gathering and Analysis

C. Posting References

CONSULTATION with:

A. Members

B. Other Stakeholders

Survey results will be posted onto IAPO website

POLICY

COMMUNICATION

ON GOING AND PERIODIC REVIEW AND EVALUATION OF POLICY AND PROCESS

Figure 1. IAPO’s Policy Formulation Model

Tip: Your position must reflect the issues that are important to the patients that you represent and their views. State how many members you have and how many people you represent in your statement.

5. What is your strategy?

You must develop a strategy which outlines all the steps you are going to take in your work on biological or biosimilar medicines. When planning your strategy:

- Use your policy position to guide development of your strategy.

- Explore the current awareness around your disease area to determine what is the general awareness before focusing on biological and biosimilar medicines.

- Find out if there are any national, regional, global campaigns that exist already to avoid duplication of efforts and to present a unified voice on common issues. Existing campaigns provide an easy source of potential collaborators and stakeholders on common issues.

- Use the action plan outline on page 6 to put your strategy to work.

- Develop a campaign to promote your position and strategy, ensuring that it is widely read by all relevant stakeholders (e.g. disseminate via post, email, newsletter, website, webinars and social media).
6. How to develop an action plan for your strategy

For any issue that your organization wants to work on, it is essential that you develop an action plan which clearly identifies your objectives and expected outcomes before you begin your work. Your action plan should align to and be guided by your previously developed strategy. Use the template below to develop your action plan.

<table>
<thead>
<tr>
<th>Identify your issue(s)</th>
<th>E.g. slow process of registration by national regulation agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify your objective(s)</td>
<td>E.g. Ministry of Health commits to improving pharmacovigilance system</td>
</tr>
<tr>
<td>Identify your target audience(s)</td>
<td>E.g. patients' organizations, Ministry of Health, WHO department, regulators</td>
</tr>
<tr>
<td>Develop your key messages</td>
<td>E.g. pharmacovigilance is essential to ensure patient safety (Messages should be tailored to each audience)</td>
</tr>
<tr>
<td>Develop your actions</td>
<td>E.g. hold meetings, write letters, develop presentations, create information booklets</td>
</tr>
<tr>
<td>Identify your partners</td>
<td>E.g. other patients' organizations, WHO, healthcare professionals</td>
</tr>
<tr>
<td>Identify the channels of communication you will use</td>
<td>E.g. presentations, fact sheets, print and online media, press releases, social media</td>
</tr>
<tr>
<td>Develop a monitoring and evaluation plan</td>
<td>E.g. monitoring: number of people contacted and their reactions; evaluation: new pharmacovigilance system in place</td>
</tr>
<tr>
<td>What is your timeline</td>
<td>E.g. develop presentations: 29 January 2014 (This should be done for each step or activity, including an estimated completion date)</td>
</tr>
</tbody>
</table>

The action plan below was written by a patients’ organization representative at IAPO’s Workshop on Biosimilar Medicines in May 2013 in Geneva, Switzerland. It is not as detailed as a full action plan, but is a good example of a starting point for your own action plan.

7. How do you increase awareness of and education about biological and biosimilar medicines?

Whatever your objective, increasing awareness of and education about biological and biosimilar medicines among all stakeholders should be a key part of your strategy. For example, if you are trying to increase the availability of biological or biosimilar medicines, a key step is to ensure decision-makers understand what these medicines are, how they are different to chemical medicines, and their therapeutic value.

- Develop educational materials about biological and biosimilar medicines that are concise and easily understandable:
  - use the information in IAPO’s Information and Advocacy Toolkit on Biological and Biosimilar Medicines, country/region-specific research that you have conducted, and the results of consultations with your members
  - tailor materials to the different audiences they are intended for (e.g. patients, government, doctors);
  - stakeholders will have varying levels of knowledge of the topic
  - provide educational materials in both print and online formats
  - translate materials into local languages whenever possible.

- Distribute the materials you develop as widely as possible (e.g. by post, email, on your website) and use press releases and social media (e.g. Facebook and Twitter) to increase awareness of your resources.

- Share IAPO’s Information and Advocacy Toolkit on Biological and Biosimilar Medicines and any other important resources you find whenever there is an opportunity, e.g. at workshops and stakeholder meetings.

- Hold educational meetings, roundtables, conferences, workshops and webinars for patients, doctors, government representatives, regulators and other stakeholders. Ensure plenty of time is available for questions and discussion.

- Collect patients’ case studies, in which they share their experiences, and disseminate them through the channels described above to increase awareness and understanding. Personal stories and testimonials can provide powerful examples of the messages you are trying to communicate. Define your story; keep it short, poignant and with clear key messages.

- Ensure that you provide information regarding how patients can contact support teams, and where to report adverse effects. Include information about the importance of pharmacovigilance.

Tip: Use social media such as Facebook and Twitter to spread your messages.
8. IAPO member case studies

This section provides three different advocacy case studies provided by IAPO member patient representatives detailing how they have worked on certain issues on biological and biosimilar medicines, or to increase awareness. Please note that all opinions expressed by patients’ organization representatives in these case studies and the following appendices are their own and do not necessarily reflect those of IAPO.

---

The need for regulation and monitoring to ensure patient safety
Eva Maria Ruiz de Castilla, Esperantra, Peru

Esperantra has been working in Peru to help ensure health authorities (principally the Dirección General de Medicamentos, Insumos y Drogas, DIGEMID [Directorate General of Medicines, Supplies and Drug], under the Ministry of Health) are able to monitor the safety and efficacy of biosimilar medicines as highly-specialized, complex medicines requiring an updated regulatory process for approval and marketing authorization.

Peru passed an important new general law on medicines in 2009, which included language on proposed requirements for the regulation of biosimilars. In response to this, we convened a series of meetings to inform and empower patients on the law’s implications, with regard to the risks and benefits of biosimilars on health and patient access. These sessions focused mostly on the difference between biosimilars and generic medicines, and why specific regulations in Peru were necessary.

Unfortunately, the 2009 law has been implemented slowly and an important regulatory vacuum has ensued, in which several supposed biosimilars (i.e. copies of biological medicines) have been reviewed and approved by DIGEMID using the same regulatory pathway as for regular medicines. These medicines will not have been through an approval process equal to that of a highly regulated country, i.e. one that follows the World Health Organization or European Medicines Agency guidelines. It is almost impossible to tell if these copies of biological medicines are working for patients. There is virtually no pharmacovigilance on these products and, therefore, there have been no means to accurately identify adverse events or other unwanted or unforeseen consequences.

Because of these copies, at Esperantra we advocated more directly with the health authorities to ensure the draft language on the regulation of biosimilars could be strengthened and brought forward for implementation. Esperantra and patient advocates argued that safety and efficacy were the priority, but also that successful regulation would ensure greater patient access to these types of advanced treatments (perhaps at a lower cost) in the future.

Peru’s language on biosimilars regulation is in line with international standards as recommended by the World Health Organization. In addition, according to a November 2012 directive from the Ministry of Health, DIGEMID should be applying new standards for any new biosimilar application. However, because details are lacking on both the definition of a biosimilar as well as the exact pathway for approval, we remain concerned and will continue to advocate for the regulatory pathway to be fully implemented and ensure patient safety.

---

Physician notification of biosimilar medicines substitution
Andrew Spiegel, Global Colon Cancer Alliance, USA and former CEO of Colon Cancer Alliance, USA

The Colon Cancer Alliance (CCA) was one of the founding members of the Alliance for Safe Biologic Medicines (ASBM), an organization that has been working for more than two years to ensure that patient safety remains the guiding principle for the US Food and Drug Administration’s efforts to bring biosimilars to patients in the USA. Through webinars, forums and other activities and events, the CCA has joined ASBM to provide information that will help educate patients, physicians and policymakers on the safety and quality of biologics, to advocate for policies that keep medical decisions between patients and physicians, and pursue solutions that ensure affordability and accessibility of biologic medications without compromising patient safety.

In 2013, there was a proliferation of biosimilar physician notification bills introduced in more than a dozen states across the USA. These bills would require the prescribing physician to be notified when a patient’s medication is changed at the pharmacy. The ASBM and the CCA supported these bills by writing letters to policymakers, testifying at hearings, submitting editorials and articles to media outlets, and participating in and leading teleconferences with policymakers.

The CCA worked closely with ASBM in support of the bills because of its commitment to increase access for life-saving and life-enhancing medicines for those we represent. We found it very troubling that opponents of the physician notification bills were actively working to defeat legislation that ensured that doctors were informed when their patients were switched from the prescribed biologic to a biosimilar. It is important to note that biosimilars are not yet available in the USA but in the countries where they are available, automatic substitution is generally prohibited because of safety concerns. Patients and their physicians deserve to know when a biologic that has been working to keep them alive is being substituted.

The result of our efforts is somewhat mixed as legislation was passed in two states, North Dakota and Virginia, with most of the remaining 15 states having adjourned without acting on the legislation. This means that ASBM and its members, including CCA, will continue this battle over the next few years.

"As a patient advocate, I believe that patients have the right to expect the same quality in drugs, whether they receive the biologic or imitative version, irrespective of price. They also have the right to leave personal medical decisions to their doctor, without interference from regulators and bureaucrats whose primary focus is to cut corners to save costs during their time in office."

Andrew Spiegel, Global Colon Cancer Alliance

---
Generating a buzz: actions and next steps following IAPO’s Workshop on Biosimilar Medicines
Stephen Murby, Consumers Health Forum of Australia

My objective following IAPO’s Workshop on Biosimilar Medicines in May 2013 was to ensure closer dialogue on biosimilars among patients, health providers, the pharmaceutical regulators and the government in Australia through three steps:

1. Report to senior members of Consumers Health Forum of Australia (CHF)
2. Update patients and health providers
3. Invite patients, government/regulators and industry to a ‘three-cornered’ (at least) roundtable discussion

I carried out a number of actions following this workshop to meet my objective, the first of which was to report to the CHF Board and senior patient representatives. Following IAPO’s Workshop on Biosimilar Medicines I prepared a summary report which contained information about the participants, the sponsors, the programme, the key information inputs, the key issues as they were covered and as they emerged, and the need for further action. The report was distributed to members of the CHF Board and CHF senior patient representatives on various government and industry committees and working groups.

Subsequently, I took the report and rewrote it as an article for information and interest among the membership of CHF. This article did not include the formal and process information about the IAPO Workshop on Biosimilar Medicines and, being for a wider consumer readership, I was able to focus on the key concepts and issues relevant to patients associated with biosimilars. This article was published in CHF Consumer Update under the heading ‘Biosimilars: Please don’t call me a Koala Bear!’ and it focused on the concepts and concerns relating to biosimilars with particular emphasis on the need to treat biosimilars very differently from ‘generic medicines’. The reference to the children’s song ‘Please don’t call me a Koala Bear!’ is, apart from koalas being uniquely Australian, that koalas are not bears at all – even though they look like they might be.

Then the real work began – honing the previous article for wider, popular publication. This required a lot more background research and checking than the previous two factual reports. Any new information that I wished to introduce had to be triangulated from other sources to ensure that it was fit for wider public publication. The resultant article was entitled ‘Biosimilars are not the bio-same’ and the public relations and media specialist at CHF canvassed a number of prospective publishers.

I have made this article available for others to use or adapt and use provided the original source is cited at CHF canvassed a number of prospective publishers.

Then the real work began – honing the previous article for wider, popular publication. This required a lot more background research and checking than the previous two factual reports. Any new information that I wished to introduce had to be triangulated from other sources to ensure that it was fit for wider public publication. The resultant article was entitled ‘Biosimilars are not the bio-same’ and the public relations and media specialist at CHF canvassed a number of prospective publishers.

What are my next steps? Timing is everything in many areas and none less so than in the political landscape. With a change of Prime Minister and a Federal Election in Australia in the wind, perhaps there is no better time than now for CHF to attempt to convene a three (or four) cornered roundtable between government/regulator, consumers, industry and health providers in order to ensure that biosimilars are both on the radar and the agenda for Australia – moving forward!

Appendix 1
Letter from Esperantra, Peru, to Directorate-General of Medicines, Supplies and Drugs (DIGEMID), Ministry of Health, Peru

TRANSLATION:
Lima, July 1, 2013

Doctor Peter Yarasca
Directorate-General of Medicines, Supplies and Drugs (DIGEMID)
Ministry of Health
Peru

Dear Dr Yarasca,

We are writing to you on behalf of Esperantra Association, an institution that represents and brings together cancer patients, to express and ensure that you know our concerns about the potential risks to which we are exposed to due to the approval of copies of biological products that have not fulfilled the required quality standards to be prescribed for the treatment of chronic diseases.

It is important to remember that biotechnology products are obtained from living modified organisms which undergo complex biotechnological processes. These products are modern pharmaceutical therapies, helping to improve the quality of life of many patients who are threatened with serious chronic diseases. Given that they come from living organisms, they can vary, hence any modification to the manufacturing process, transportation or storage conditions, may cause changes to the safety and efficacy of the final product, and could result in therapeutic failures.

In this sense, it is necessary that the regulatory authorities carefully monitor the quality of these types of products; since they are derived from complex and highly specialized technology, and they require sufficient quality standards to prove their safety and efficacy.

Currently, the Directorate General of Medicines, Supplies and Drugs (DIGEMID) of the Ministry of Health is giving approval to pharmaceutical biotechnology products without demanding the compliance with the approved standards by the DS 016-2011-SA Regulation for Sanitary Registry, Control and Surveillance of Pharmaceuticals Products, Medical Devices and Sanitary Products. In particular, products are not undergoing full safety and efficacy tests.

We believe that the lack of guidelines is not an excuse, because it is a deficiency of the DIGEMID itself. This month marks two years from the adoption of this Regulation, which is enough time for having undertaken such an important issue.
Furthermore, the Regulation establishes the obligation to perform the evaluation of the registration of biotechnology products, taking into account the documents and recommendations issued by the World Health Organization (WHO), and requiring compliance with, at least, the following regulatory standards:

1. The submission of appropriate and unique studies that demonstrate the product safety and efficacy is required. This is needed because each active substance obtained by biotechnology is the result of a unique validated process. The process of any molecule produced by a certain company will inevitably differ from that of another company. Any difference, however subtle it may be, between products of biological origin and from different manufacturers can result in a different product.

2. We understand that the Registry Regulation provides the ability to register biosimilar products; however, the authority must grant the sanitary registry (approval) of a biosimilar product only when this product has proved the similarity with the product of reference, as stated in article 107.

3. Justification must be demanded for differences in quality between the biological product of reference, and the potential implications on the safety and efficacy of the biosimilar.

4. The consistency of the final product characteristics, the manufacturing processes, formulation and storage conditions must be ensured, because any modification, variation or change in any of the aforementioned processes can give rise to therapeutic failures in the product and therefore adverse effects.

5. The health authority must undertake strict and proper monitoring of adverse effects in order to ensure product safety to the patients.

We appeal to the authorities to make special emphasis on the evaluation criteria used for the authorisation and the registration of biotechnology products, by evaluating registration and re-registration procedures using international standards such as those provided by WHO. This is needed due to the importance and complexity involved, taking into consideration that the safety and life of the patients could be damaged if there is not an appropriate evaluation and control by the authorities.

Finally, on behalf of our members, we request to the authorities that they issue appropriate guidelines as soon as possible, applying them to the pending registrations and to those registrations already granted requesting their reassessment, in light of the aforementioned and according to the authorities’ legal powers.

We appreciate the attention you give to this letter and we put ourselves at your disposal in case that additional information is needed.

Sincerely,

Eva María Ruiz de Castilla, Director, Esperança

Appendix 2

Article written by Stephen Murby, Consumers Health Forum of Australia

Biosimilars are not the bio-same
Stephen Murby

The power of biological medicines to ape nature and combat disease is about to present a new cost and safety challenge to patients and governments worldwide.

The first generation of these medicines, which have transformed treatments for diseases like rheumatoid arthritis, MS, HIV/AIDS and some cancers, are coming off patent. Patent expiry will attract more manufacturers to produce ‘copies of the original biologic’ so resulting cost-structures and competition may make these products, now costing as much as $1m or more per patient per year, somewhat cheaper. Welcome to the brave new world of biosimilars.

Alluring though it is, reproducing such “wonder” drugs carries significant risks. Unlike generic medicines, which are reproduced using precisely the same active chemical compounds as the original, biological medicines are based on living micro-organisms. They use therapeutic proteins and monoclonal antibodies prepared by rDNA-technology and so comprise the variables of nature.

At the simplest level we might consider the fundamental differences as being between the ‘chemical’ process of a cake recipe and the ‘biological’ processes of making yoghurt from a culture or beer from living yeast. Whilst recipes sometimes fail, by-and-large the same ingredients lead to the same result whereas, as any yoghurt maker or brewer will tell you, what appears to be the same ‘biological process’ doesn’t always yield the same result – for better or worse!

Biosimilars are not the bio-same

Biological medicines are not only produced differently, they are a whole lot bigger. The average antibody has about 1,000 times as many atoms as chemical aspirin and is around 1,000 times more massive. The size alone gives cause for more risk of complex immunological reactions. It isn’t just size though: minor manufacturing differences of the highly complex structures can cause adverse effects; as can light, heat, denaturing and a ‘simple drift’ of the biological over time. How the body may respond to the presence of a biotechnological medicine is completely different from how it is likely to respond to a chemical medicine. Such phenomena, may, for instance stimulate unwanted responses, including thrombosis and tumours.

Currently there are four biosimilars on the Australian Register of Therapeutic Drugs; however, worldwide the biological medicines market is currently growing at 20% pa. This means that over the next 10 to 20 years we can expect to see far more biological medicines being made available on- and off-patent for the treatment of some of the major life-shortening and debilitating conditions. The likely widespread manufacturing and availability of both biologics and their biosimilars is very much a new area and one that is likely to sow significant confusion and misunderstanding for some time to come, not just on the part of consumers and prescribers but also regulators and politicians as well as scientists and manufacturers.

‘Biosimilars’ are those biotech medicines that are manufactured within an internationally recognised regulatory framework and based on a (now off-patent) original biologic. The resultant biotech med is ‘similar’ to the biologic BUT not the same. The similarity will be largely in terms of efficacy. But because it involves a different manufacturer with different plant, equipment, cell lines and processes it can never be the same. Of even more concern are the uncertain and dubious ‘Copy Biologics’ which are manufactured outside the internationally recognised regulatory framework and/ or based on a biologic which may or may not be off-patent.

Under absolutely no circumstances should we consider biosimilars in the same way we think of generic medicines. We think of generics as the same active chemical drug as the original, brand only cheaper. But, when working with living micro-organisms, it is nowhere near the same concept or result. Simply put, a biosimilar can never be to a biologic what a generic is to a brand. We think of biosimilars as generics at our peril.

Generics are generally fast-tracked to market because it is relatively easy enough to demonstrate the similarity, the interchangeability and hence substitution between a generic and its original brand drug. This is not the case with biosimilars. First, it is not such a straightforward matter to demonstrate the ‘sameness’ which also goes to the reason why biosimilars are not going to be so much cheaper than the biologic at the outset. Secondly, the notion that a biosimilar might be interchangeable with a biologic or another biosimilar is just that – a notion – and a long way from being technically defined and determined. Interchangeability and, hence, possible substitution of biosimilars is a very topical issue around the world with some regulators being more cautious than others.

Consumers Health Forum of Australia has been proactively in consultation with the Therapeutic Goods Administration (TGA) and the Department of Health and Aging about biosimilars and the TGA’s draft guideline for evaluating biosimilars. Coming to terms with biosimilars, however, will only happen when health consumer organisations around the world are actively engaged in developing a system which ensures consistent regulation and adherence of the pharmaceutical industry and marketplace.