Biological and Biosimilar Medicines
Fact Sheet 5: What can patients' organizations do?

International Alliance of Patients' Organizations
A global voice for patients

This Fact Sheet provides tips on how patients' organizations can further develop their work on biological and biosimilar medicines, for example through the development of a strategy and action plan.

When developing your work on biological and biosimilar medicines consider the following three questions. This will help you to advocate for patient access to safe, high-quality, affordable and modern medicines:

1. **Are biological and biosimilar medicines available in your country?**
2. **How are biological and biosimilar medicines regulated in your country?**
3. **Is there a pharmacovigilance system in your country?**

Once you have answered these questions, it is essential that you develop your organizational **position** on biological and biosimilar medicines, and your **strategy**, which should outline all the steps you will take.

Developing your position:

- undertake a consultation with your members/patients to identify relevant issues and concerns
- conduct research to determine the situation regarding biological and biosimilar medicines in your country, regionally and globally
- look at current strategies, campaigns and policies in your country
- use the information you have collected to develop your policy position
- share your policy position with your members and other stakeholders as widely as possible.

A **policy position** sets out what the relevant issues are and the actions that need to be taken to address them

Tip: Your position must reflect the issues which 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.

Developing your strategy:

- develop an action plan
- relate your policy position to your action plan
- explore the current awareness around your disease area
- determine if there are any existing national, regional and/or global campaigns that your organization can join to avoid duplication of efforts and to present a unified voice
- develop a campaign to promote your position and strategy (if no others exist)
- distribute your position to all relevant stakeholders (e.g. disseminate via post, email, newsletter, website, webinars, social media)
- develop links with other relevant patients' organizations and stakeholders who you may be able to collaborate with.

Tip: Your action plan should clearly identify your objectives and your expected outcomes. It should be guided by your strategy.

IAPO member case study

The following case study provides an example of how an IAPO member organization has been working to improve regulation of biosimilar medicines in a country where biosimilar medicines are not being robustly regulated (their guidelines do not follow those of the European Medicines Agency or World Health Organization). These products cannot be called biosimilar medicines and are often called non-comparable follow-on biological products.

The need for regulation and monitoring to ensure patient safety

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Esperantra has been working in Peru to help ensure health authorities (principally the Direccion General de Medicamentos, Insumos y Drogas, DIGEMID [Directorate General of Medicines, Supplies and Drugs], 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.

For more information on advocacy, action plan templates and case studies see the 'What patients' organizations can do' booklet in the Information and Advocacy Toolkit on Biological and Biosimilar Medicines.