Biological and Biosimilar Medicines
Fact Sheet 1: Introduction and key definitions

International Alliance of Patients' Organizations
A global voice for patients

This Fact Sheet provides an introduction to why biological and biosimilar medicines are important, and why IAPO has developed this Information and Advocacy Toolkit on Biological and Biosimilar Medicines. The back of this Fact Sheet provides the reader with key definitions that will be useful while using this Toolkit.

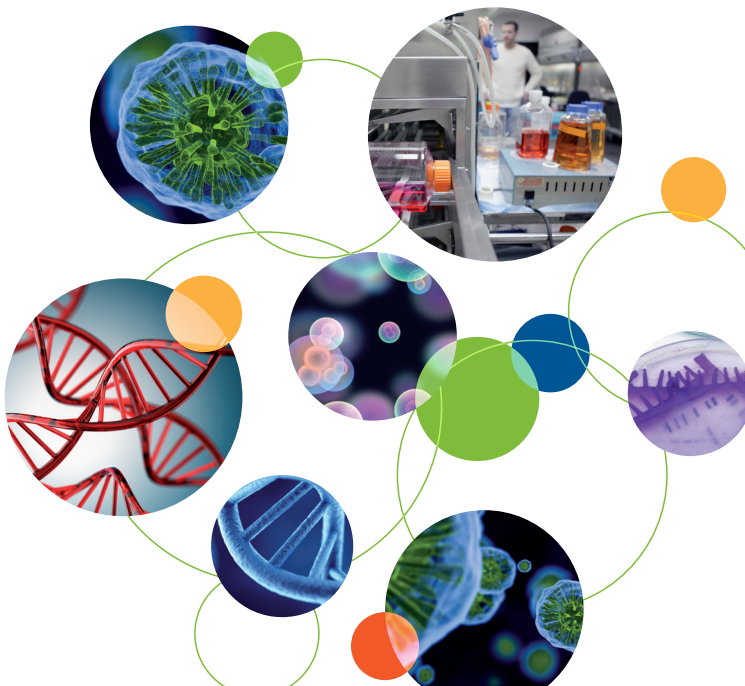
At a time when the burden of chronic diseases is increasing across the world, ensuring that patients can access safe, quality, affordable and modern medicines such as biological medicines is vital to improving health.

Biological medicines are made from living organisms using biotechnology techniques. Since their introduction in the 1980s they have revolutionised the treatment of many diseases such as cancers, diabetes, autoimmune diseases (for example rheumatoid arthritis), heart attacks, stroke, multiple sclerosis, as well as a number of rare disorders. They have benefited millions of patients worldwide. As many of these original biological medicines reached the end of their patents, other manufacturers were able to produce highly similar versions of these medicines. These highly similar versions of biological medicines are commonly called **biosimilar medicines**.

There are many barriers to patient access to new medicines. In the coming decade we expect a great number of biosimilar medicines to become available for patients worldwide. These will provide alternative medicines for patients, usually at a lower cost, making these lifesaving medicines more accessible, and will increase options for doctors, patients and healthcare systems in general.

As with all medicines, patients need to be able to make a fully informed decision about whether to take a biological medicine or not, and to be fully involved in deciding what treatment to pursue together with their healthcare team. It is therefore essential that patients have access to clear and impartial information about what biological and biosimilar medicines are, and what their growing availability will mean for them.

IAPO believes patients should be aware of what these important medicines are and what the implications of their increasing availability will mean to them. IAPO's Information and Advocacy Toolkit on Biological and Biosimilar Medicines aims to provide patients' organizations with up-to-date, evidence-based information on the science, technology and regulatory information relevant to biological and biosimilar medicines, as well as tips on advocacy. IAPO expects these resources will help patient advocates to make informed judgements on the value of biological and biosimilar medicines and actively engage in debate and discussion with other stakeholders involved in healthcare.



Key definitions

Chemical medicine/drug (also called small molecule medicine): A medicine which is manufactured without the involvement of living organisms. These contain chemical compounds with defined structures and characteristics.

Generic medicine: A generic medicine contains the same active pharmaceutical ingredient as, and is bioequivalent to, an original branded medicine. Generic medicines are identical in the active pharmaceutical substance, dose, strength, route of administration, safety, efficacy and intended use, and can therefore be substituted for the original branded medicine.

Biotechnology: The United Nations Convention on Biological Diversity defines biotechnology as "any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use".

Biological medicine (also called biopharmaceutical medicine, biotechnology medicine or biotherapeutic medicinal product): The active substance of a biological medicinal product is a biological substance. A biological substance is a substance that is produced by, or extracted from, a biological source. A combination of physico-chemical-biological testing, knowledge of its production process and control is needed to characterise it and determine its quality.

Biosimilar medicine: A biosimilar medicine is a highly similar version of an already-approved biological medicine, in terms of quality, safety and efficacy.

World Health Organization definition (also called a similar biotherapeutic product): A biotherapeutic product which is similar in terms of quality, safety and efficacy to an already-licensed reference biotherapeutic product.

European Medicines Agency definition: A biological medicine that is developed to be similar to an existing biological medicine. When approved, its variability and any differences between it and its reference medicine will have been shown not to affect safety or effectiveness.

US Food and Drug Administration definition: A biological product that is highly similar to a US-licensed reference biological product, notwithstanding minor differences between the biological product and the reference.

Originator product (also called innovator product): A medicine which has been licensed on the basis of a full registration dossier, i.e. that the approved indication(s) for use were granted on the basis of full quality, safety and efficacy data.

Reference product: A biological medicine that has already been approved on the basis of a full registration dossier (full quality, pre-clinical and clinical data), which is used in a comparability exercise with a biosimilar medicine in order to show similarity in terms of quality, safety and efficacy.