



ICMRA statement about confidence in biosimilar products (for patients and the public)

ICMRA present this statement on biosimilars to:

- give assurance that regulators have robust processes in place for the approval and monitoring of biosimilars
- highlight the benefits biosimilars can provide for patients and healthcare systems in terms of increased treatment options, access and cost competition

What are biosimilars?

Biosimilars¹ are biological medicines that are highly similar to an already-approved originator biological medicine², with no meaningful differences in efficacy and safety.

Biological medicines, including biosimilars, are often large and complex molecules that can be made by living cells using biotechnology.

They are used to treat diseases such as:

- diabetes
- inflammatory diseases
- cancer

Examples of biosimilars include:

- small proteins such as insulin and growth hormones
- larger and more complex proteins such as antibodies

How do biosimilars compare to originator biological medicines?

Biosimilars are approved after rigorous scientific evaluation by regulators. They are manufactured to the same regulatory standards as other biological medicines.

Extensive laboratory studies give the foundation of evidence for biosimilar approval. These studies use state-of-the-art technologies to show that the biosimilar is highly similar to the originator medicine. In addition, regulators require some clinical studies involving human participants to show that there are no meaningful differences between how the biosimilar and originator medicine work.

Once studies have shown that the biosimilar is highly similar to the originator, the biosimilar may be used to treat the same specific diseases as the originator, based on the efficacy and safety that has already been established for the originator. This avoids repeating the same clinical studies that were done with the originator medicine.

Are biosimilars safe to use?

Biosimilars have been used safely for many years. Regulators monitor the safety of all medicines on the market, including biosimilars, to protect the health and safety of patients. Biosimilars have been marketed in many different countries for over a decade. Regulators have not identified any important differences in side effects between biosimilars and their respective originators.

¹ Biosimilars are also called biosimilar products, biosimilar medicines, similar biological medicinal products or similar biotherapeutic products (SBPs).

² Originators (original brand products or medicines) are also called reference products or reference medicines.



What are the advantages of biosimilars?

Biosimilars:

- increase competition among biological medicines, which reduces their prices
- provide more treatment options for patients
- can improve access to biological medicines for patients

Globally, regulators' rigorous science-based standards for review and approval mean that healthcare professionals and patients can have confidence in the use of a biosimilar in each approved indication.

NOTE:

If you have any questions about a biosimilar you are prescribed, you should speak to your healthcare professional.

ICMRA

ICMRA brings together the heads of 29 medicines regulatory authorities¹ from every region in the world, with the WHO as an observer. Medicines regulators recognize the important role we play in facilitating the provision of access to safe, effective, high-quality products that are essential to human health and well-being. This includes advancing the biology needed to set standards and inform decision-making, as well as maintaining efficient regulatory processes that support the development and delivery of innovative medicinal products while ensuring the benefits of these products outweigh the risks.

¹ ICMRA is an international executive-level coalition of key regulators from every region in the world. It provides a global strategic focus for medicines regulators and gives strategic leadership on shared regulatory issues and challenges. Priorities include coordinated response to crisis situations. Members of the ICMRA include: Therapeutic Goods Administration (TGA), Australia; National Health Surveillance (ANVISA), Brazil; Health Products and Food Branch, Health Canada (HPFB-HC), Canada; China National Medical Products Administration (NMPA), China; European Medicines Agency (EMA) and European Commission - Directorate General for Health and Food Safety (DG - SANTE), European Union; French National Agency for Medicines and Health Products Safety (ANSM), France; Paul-Ehrlich-Institute (PEI), Germany; Health Product Regulatory Authority (HPRA), Ireland; Italian Medicines Agency (AIFA), Italy; Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), Japan; Ministry of Food and Drug Safety (MFDS), Korea; Federal Commission for the Protection against Sanitary Risks (COFEPRIS), Mexico; Medicines Evaluation Board (MEB), Netherlands; Medsafe, Clinical Leadership, Protection & Regulation, Ministry of Health, New Zealand; National Agency for Food Drug Administration and Control (NAFDAC), Nigeria; Health Sciences Authority (HSA), Singapore; Medicines Control Council (MCC), South Africa; Medical Products Agency, Sweden; Swissmedic, Switzerland; Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom; Food and Drug Administration (FDA), United States and the World Health Organization as an observer. Associate members include Austrian Medicines and Medical Devices Agency (AGES), Danish Medicines Agency, Israel Office of Medical Technology, Health Information and Research (MTHIR), Poland Office of Registration of Medicinal Products and Biocidal Products (URPLW MiPB), Russia Roszdravnadzor and Spain Agencia Española de Medicamentos y Productos Sanitarios (AEMPS).