23 June 2019 ICMRA Plenary San Diego Agenda Item 6 b
Confidence in biosimilars for patients and public

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

ICMRA/WHO present this statement on biosimilars to provide assurance on the robust regulatory processes for the approval and monitoring of these medicines, and to highlight the benefits biosimilars can provide for patients and healthcare systems in terms of increased treatment alternatives, access and cost competitiveness.

What are biosimilars?

Biosimilars [1] are biological medicines that are highly similar to an already-approved originator biological medicine[2], with no meaningful differences in efficacy and safety. Biological medicines (including biosimilars) are often large and complex molecules (usually proteins) that can be produced by living cells using biotechnology. They are used to treat diseases such as diabetes, inflammatory diseases and cancer. Examples include small proteins such as insulin and growth hormones, as well as larger and more complex proteins such as antibodies.

How do they compare to the originator biological medicine?

Biosimilars are approved after rigorous scientific evaluation by regulators. Biosimilars are manufactured to the same regulatory standards as other biological medicines. The foundation of evidence for biosimilar approval is provided by extensive laboratory studies that use state-of-the-art analytical technologies to show that the biosimilar is highly similar to the originator medicine. In addition, some clinical studies involving human participants are needed to show that there are no meaningful differences between how the biosimilar and originator medicines work.

Once studies have shown that the biosimilar is highly similar to the originator, the biosimilar may be used to treat the same medical conditions (indications) as the originator based on the efficacy and safety of the originator that has been established in each indication. It is not necessary to repeat all the clinical studies that were carried out with the originator medicine.

Are biosimilars safe to use?

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

What are the advantages of biosimilars?

Biosimilars increase competition among biological medicines and provide more treatment options for patients. More competition can reduce prices and 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:

Any questions about a biosimilar you are prescribed should be addressed to your healthcare professional.

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

[2] Originator (original brand product or medicine) is also referred to as a reference product or reference medicine.

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ICMRA

ICMRA brings together the heads of 29 medicines regulatory agencies[i] 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.

[i] 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 (URPLWMiPB), Russia Roszdravnadzor and Spain Agencia Española de Medicametos y Productos Sanitorios (AEMPS).