

● PATIENTS

● QUALITY

● VALUE

● SUSTAINABILITY

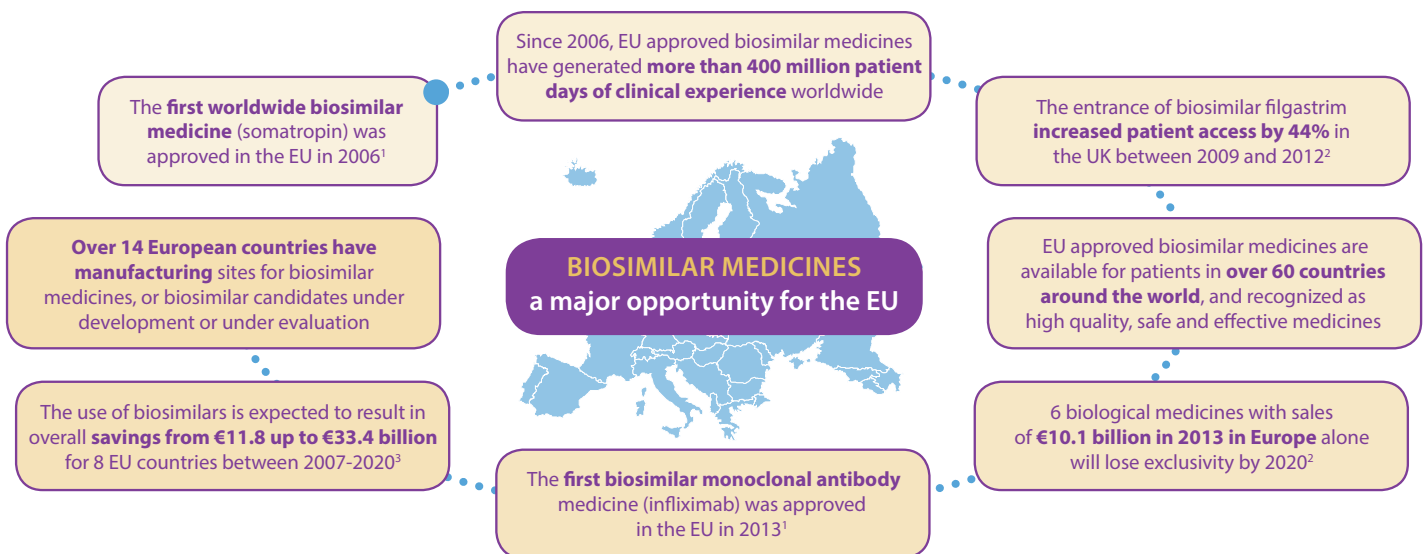
● PARTNERSHIP

WHAT IS A BIOSIMILAR MEDICINE?

A **biosimilar medicine** is a biological medicine that is developed to be highly similar to an existing biological medicine (the 'reference medicine').

The pharmaceutical company needs to show that the biosimilar medicine does not have any meaningful differences from the reference medicine in terms of quality, safety or efficacy.

BIOSIMILAR MEDICINES: KEY FACTS



Sources: ¹EMA European public assessment report; ²IMS Midas 2013; ³IGES Study, 2012.

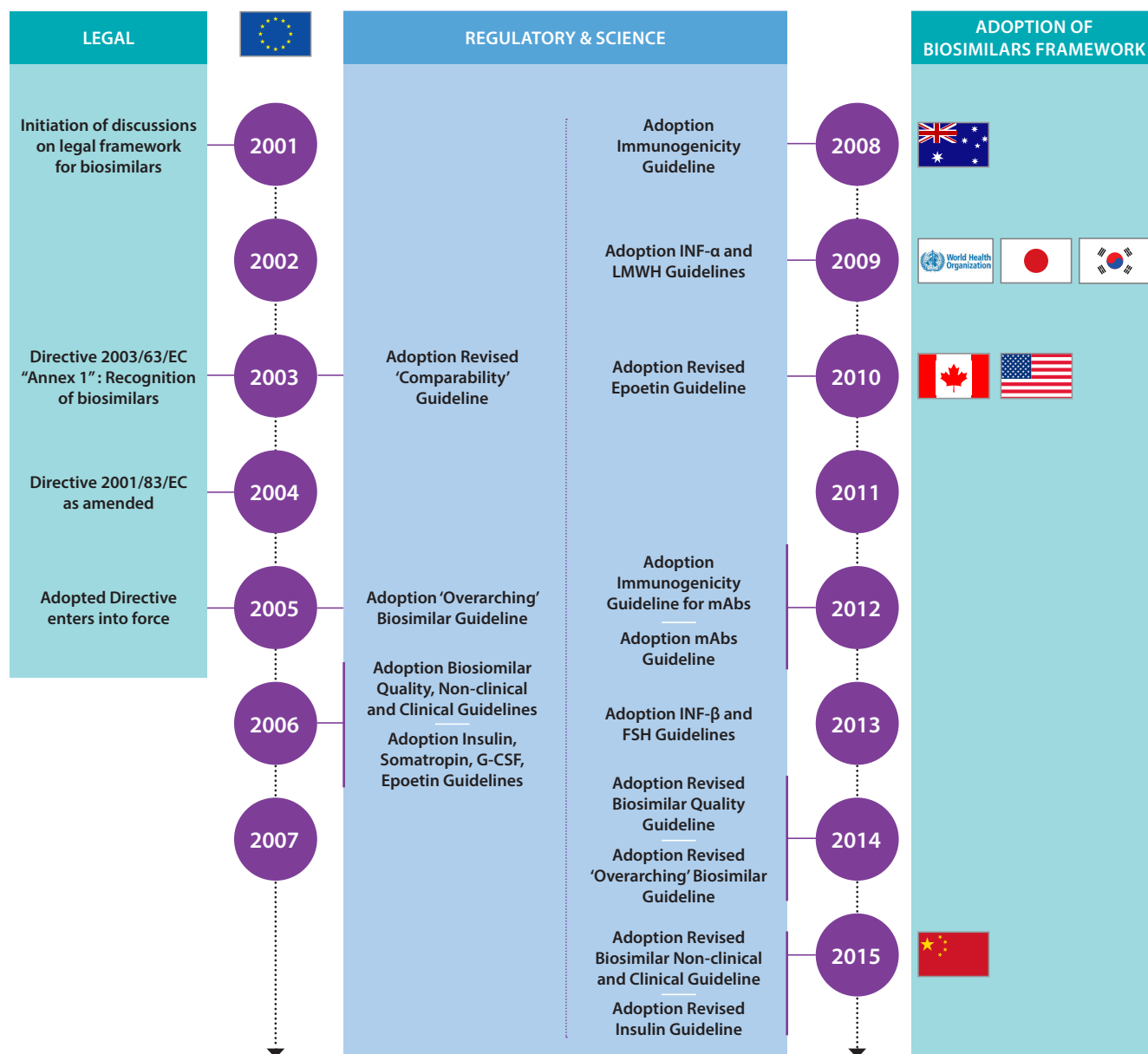
Key Therapeutic Areas Covered by Current Biosimilar Medicines

Active substance (year of first approval)	Therapeutic area
Somatropin (2006)	Pituitary dwarfism Prader-Wili syndrome Turner syndrome
Epoetin (2007)	Neutropenia Follow-up of cancer treatment Hematopoietic stem cell transplantation
Infliximab (2013)	Rheumatoid arthritis Crohn's disease Ulcerative colitis Psoriasis Psoriatic arthritis Ankylosing spondylitis
Foliotropin (2013)	Anovulation
Insulin glargine (2014)	Diabetes mellitus

Key Therapeutic Areas Covered by Future Biosimilar Medicines

Active substance	Therapeutic area
Adalimumab	Crohn's disease Rheumatoid arthritis
Bevacizumab	Colorectal cancer Lung cancer
Cetuximab	Colorectal cancer Head and neck cancer
Insulin Aspart	Diabetes mellitus
Insulin Lispro	Diabetes mellitus
PEG-filgrastim	Neutropenia Follow-up of cancer treatment Hematopoietic stem cell transplantation
Ranibizumab	Macular degeneration
Rituximab	B-cell non-Hodgkin's lymphoma
Trastuzumab	Breast cancer

EU BIOSIMILARS LEGAL, SCIENTIFIC & REGULATORY FRAMEWORK INSPIRING THE WORLD



ABOUT THE EBG

The **European Biosimilars Group (EBG)**, a sector group of the EGA, represents the leading companies in the biosimilar medicines space. The EBG Members bring competition to the biologicals market, thereby increasing access to highly innovative medical treatments to patients, in Europe and around the world, and supporting the sustainability of the European healthcare systems.

The EGA represents the European generic and biosimilar medicines industries, which provide high-quality cost-competitive medicines to millions of Europeans. The EGA vision is to provide sustainable access to high quality medicines for all European patients, based on 5 important pillars: patients, quality, value, sustainability and partnership.

Follow us on



EGA | EUROPEAN GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION

Rue d'Arlon 50 B-1000 Brussels, Belgium

T: +32 (0) 2 736 84 11 | F: +32 (0) 2 736 74 38

www.egagenerics.com | info@egagenerics.com