biosimilar medicines
better access. better health.

Factsheet | On Biosimilar Medicines

What is a Biosimilar Medicine?

A **Biosimilar Medicine** is a biologic medicine that is developed to be highly similar to an existing biologic 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

BIOSIMILAR MEDICINES
A major opportunity for Europe

- Since 2006, EU approved biosimilar medicines have generated **more than 400 million patient days of clinical experience worldwide**
- The entrance of biosimilar **filgrastim increased patient access by 44%** in the EU between 2006 and 2013[2]
- EU approved biosimilar medicines are available for patients in **over 60 countries around the world**, and recognised as high quality, safe and effective medicines
- 12 biological medicines with global sales of **€ 78 billion in 2014** will lose exclusivity by 2020 **in Europe**[2]
- The **first biosimilar monoclonal antibody** (infliximab) was approved in the EU in 2013[1]
- The use of biosimilars is expected to generate overall **savings from €11.8 up to €33.4 billion** for 8 EU countries between 2007 - 2020[3]
- **Over 15 European countries have manufacturing sites** for biosimilar medicines or biosimilar candidates under development/evaluation
- The **first worldwide biosimilar medicine** (somatropin) was approved in the EU in 2006[1]

Sources: [1]EMA European public assessment report;
[2]IMS Midas 2015; [3] IGES 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)	Anemia | Consequence of chronic kidney failure | Follow-up of cancer treatment
Filgrastim (2008)	Neutropenia | Follow-up of cancer treatment | Hematopoietic stem cell transplantation
Infliximab (2013)	Rheumatoid arthritis | Crohn's disease | Ulcerative colitis | Psoriasis | Psoriatic arthritis | Ankylosing spondylitis
Follitropin (2013)	Anovulation
Insulin Glargine (2014)	Diabetes mellitus
Etanercept (2016)	Rheumatoid arthritis | Psoriatic arthritis | Plaque psoriasis | Ankylosing spondylitis

Key Therapeutic Areas Covered by Future Biosimilar Medicines

Active substance	Therapeutic area
Adalimumab	Crohn's disease | Ulcerative colitis | Rheumatoid arthritis | Psoriatic arthritis | Plaque psoriasis | Ankylosing spondylitis
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

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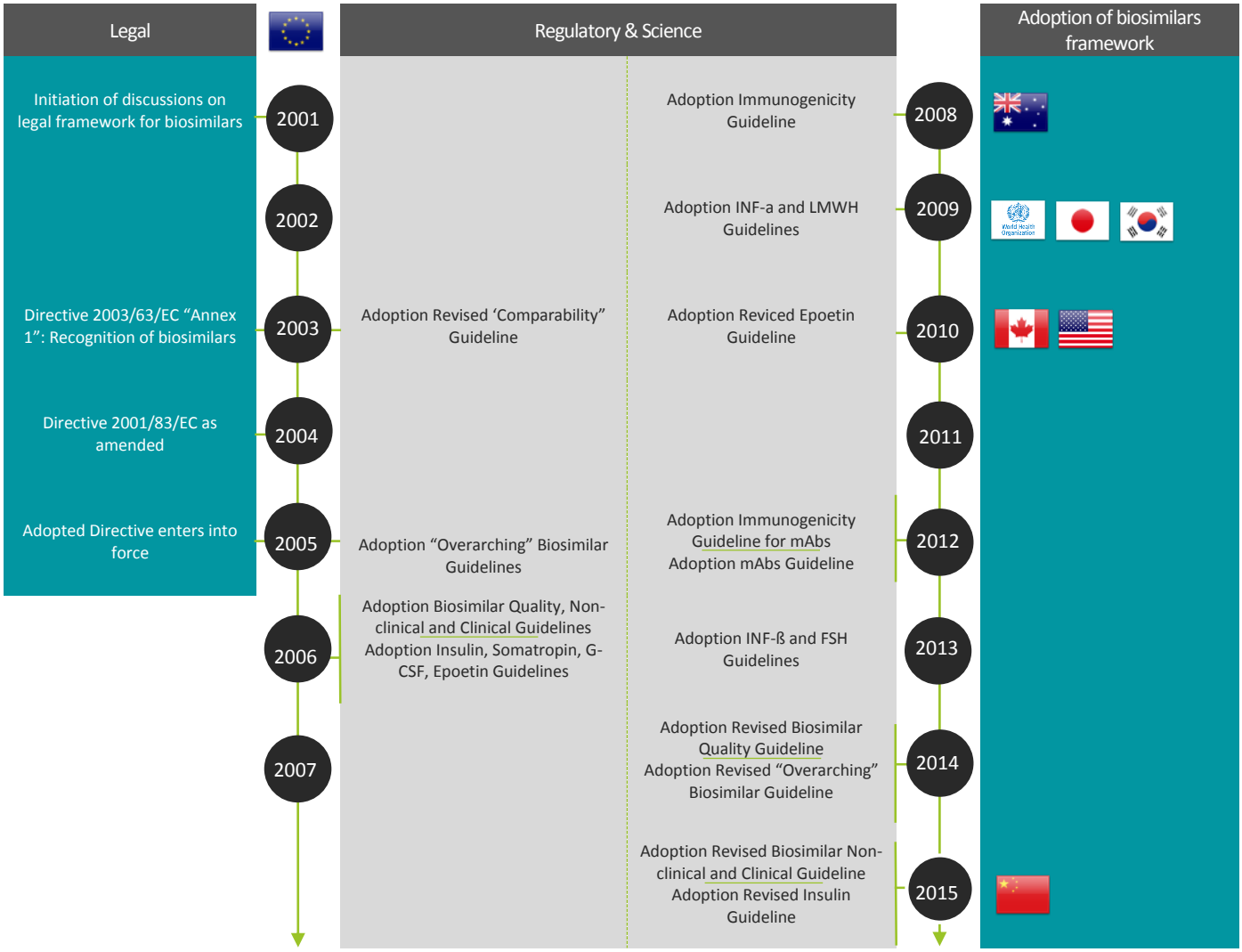
Biosimilar Medicines: EU legal, scientific & regulatory framework inspiring the world



About the Biosimilar Medicines Group

The Biosimilar Medicines Group, a sector group of **Medicines for Europe**, represents the leading companies in the biosimilar medicines space. Biosimilar Medicines Members bring competition to the biologic 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.

Medicines for Europe represent the European generic, biosimilar and value added medicines industries, which provide access to high-quality cost-competitive medicines to millions of patients in Europe and worldwide. Medicines in Europe's vision is to provide sustainable access to high quality medicines for all patients, based on 5 important pillars: patients, quality, value, sustainability and partnership.

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