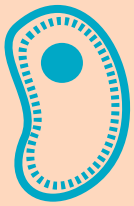
WHAT ARE BIOSIMILARS?



Because they are derived from living organisms, **no two batches are identical**[2]

Biosimilars are **biological medicines** (biologics). Biologics are **large, complex molecules** from natural sources – human, animal or microorganism[1]

Biosimilars are so-called because they are **highly similar** to already marketed biologics, known as **reference products**[3]

HOW ARE THEY REGULATED?

EUROPEAN MEDICINES AGENCY

In Europe all biosimilars are **approved** by the **European Medicines Agency (EMA)**[4]

Every part of the drug development process is **assessed prior to approval** to demonstrate that the biosimilar is **equivalent** to the reference product[5]

The **first biosimilar** was **approved in 2006** and there are now **20 approved biosimilars** in Europe[3,6]

There have been **no safety concerns** identified for approved and marketed biosimilars to date (2013)[7]

WHY ARE THEY NEEDED?

Biosimilars are typically made available at a **lower cost** than the reference product after the patents and Supplementary Protection Certificates protecting that product have expired[7]

One of the most significant new developments is **biosimilar monoclonal antibodies** which are **projected to save** European healthcare systems between

€1.8bn and €20.4bn

between 2007 and 2020[8]

The **cost savings** provided by biosimilars **can help improve patient access** to safe and effective biological medicines[7]

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4. FAQs About Biosimilar Medicines. European Generics Association http://www.egagenerics.com/index.php/biosimilar-medicines/faq-on-biosimilars Last accessed 6.10.14
5. Quick Guide on Biological and Biosimilar Medicines. IAPO November 2013 http://iapo.org.uk/sites/default/filesfiles/IAPO%20Quick%20Guide.pdf Last accessed 7.10.14
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7. What you need to know about biosimilar medicinal products. Consensus document, European Commission 2013 http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/biosimilars_report_en.pdf Last accessed 13.10.14
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