

# **Biosimilar Litigation Strategies**

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19 April 2021

# WHAT IS A BIOSIMILAR?

- By **biosimilar** medicine we refer to a medicinal product that contains a version of the active substance of an already authorised biological medicinal product (reference medicine), which has been proved to be highly similar in terms of quality, safety and efficacy.
- A **biological medicinal product** is a product, the active substance of which is a biological substance.
- A biological substance is a substance that is produced by or extracted from a biological source, such as:
  - micro-organisms,
  - cells or fluids (including blood or plasma) of human or animal origin,
  - organs and tissues of either plant or animal origin,
  - biotechnological cell constructs

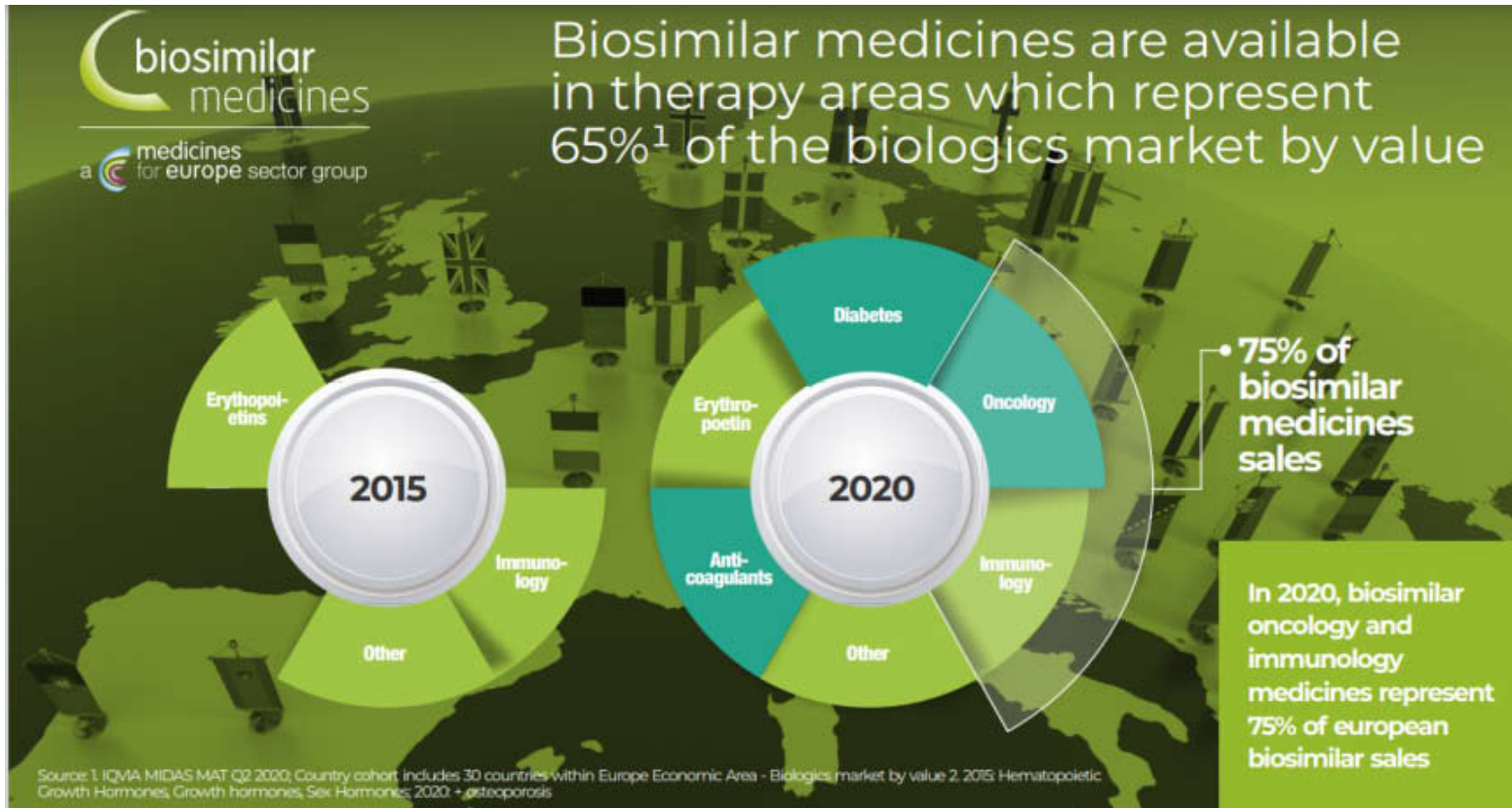
Directive 2001/83/EC, Annex I, Part I, 3.2.1.1.

# CATEGORIES OF BIOLOGICAL MEDICINES

- Immunological medicinal products
- Medicinal products derived from human blood and human plasma
- Advanced therapy medicinal products
- Medicinal products developed by means of one of the following biotechnological processes:
  - recombinant DNA technology,
  - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells,
  - hybridoma and monoclonal antibody methods.

Directive 2001/83/EC, Annex I, Part I, 3.2.1.1.

# THERAPEUTIC FIELDS



# BIOSIMILAR VS GENERIC

*Key  
technical &  
Scientific  
differences*

## BIOSIMILAR

Biological product

Large, complex molecules

Produced by modifying and reproducing biological material obtained from living organisms

Greater immunogenicity potential

SIMILAR, but never identical, to reference medicine

## GENERIC

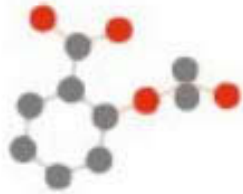
Chemical product

Relatively small, simple molecules

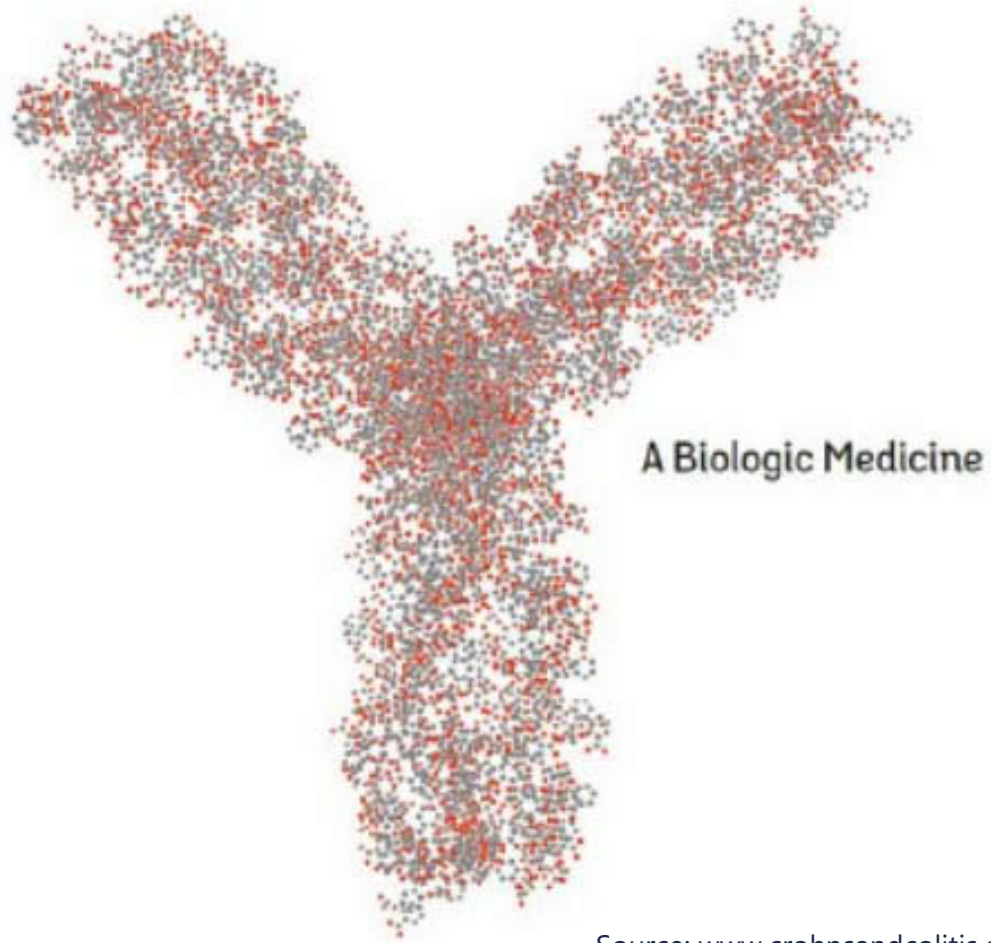
Typically produced by chemical synthesis

Lower immunogenicity potential

Potentially IDENTICAL to reference medicine



Aspirin



A Biologic Medicine

Source: [www.crohnsandcolitis.org.uk](http://www.crohnsandcolitis.org.uk)

# BIOSIMILAR VS GENERIC

*Key  
economic &  
regulatory  
differences*

## BIOSIMILAR

5 - 8 years development

10 - 300 M € development

Generally can only be authorised through EMA centralised procedure

Require comprehensive comparability (biosimilarity) studies, including clinical studies, prior to authorization. Additional monitoring (☐) post authorisation

Prescribed by brand name

Relatively new phenomenon (first biosimilar – somatropin- authorised in EU in 2006)

## GENERIC

2 - 3 years development

1 - 3 M € development

Can be generally authorised by Member States through different procedures

Just bioequivalence (mainly PK) studies prior to authorization. No special monitoring post authorisation

Can be prescribed by active ingredient (INN)

Used (and litigated) for decades

**Impact on patent litigation strategies?**





**I WANT YOU TO VOTE**

# TOPICS FOR DISCUSSION

## LAUNCH: PIs & CLEARING THE PATH

PIs available?

Irreparable harm required? Do local (non-) interchangeability / (non-) replaceability / (non-) switching rules or practices impact on establishing irreparable harm?

Balance of interests considered?

Clearing-the-path strategies?

## REMEDIES: INJUNCTION AND DAMAGES

Are injunctions an "automatic remedy"?  
Even against bio-betters?

Do local (non-) interchangeability / (non-) replaceability / (non-) switching rules or practices impact on establishing damages?

## EVIDENCE GATHERING

Proof of infringement

# PANEL MEMBERS

## MODERATOR



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# TOPICS FOR DISCUSSION

## LAUNCH: PIs & CLEARING THE PATH

**Are you likely to be able to get a Preliminary Injunction to prevent launch of a biosimilar?**

# TOPICS FOR DISCUSSION

## LAUNCH: PIs & CLEARING THE PATH

**Can you deploy a public interest defence to avoid an injunction (preliminary or final)?**

# TOPICS FOR DISCUSSION

## LAUNCH: PIs & CLEARING THE PATH

**What options do biosimilar manufacturers have to clear the path to avoid PI threats?**

# TOPICS FOR DISCUSSION

## REMEDIES: INJUNCTION AND DAMAGES

**Are there any special considerations for Biosimilars  
with regard to injunctions?**

# TOPICS FOR DISCUSSION

## REMEDIES: INJUNCTION AND DAMAGES

**Are there any special considerations for Biosimilars  
with regard to damage calculation?**



# TOPICS FOR DISCUSSION

## EVIDENCE GATHERING

**Are there any legal tools or options to facilitate proof of infringement in biosimilar cases?**



**I WANT YOU TO VOTE**

**Thank you.**