# Biosimilars: Outlook and Market Trends

Charbel Tengroth

2019-02-07

Drug Delivery & Packaging
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# Biosimilars

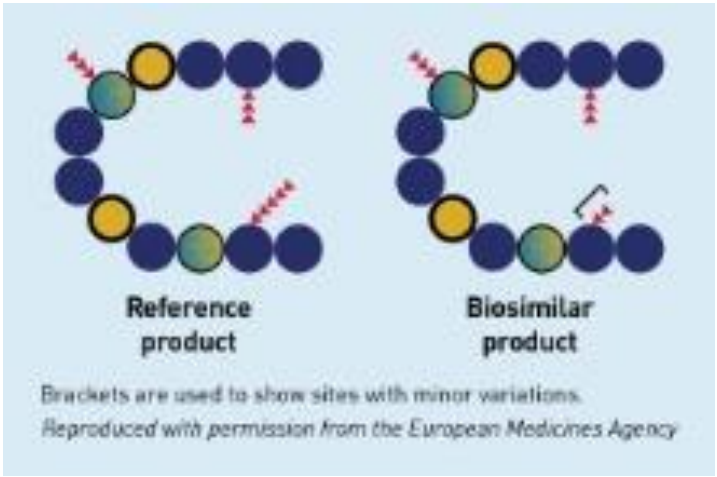
- Introduction
- Approved biosimilars
- Market segmentation
- Launch of biosimilars: success factors and obstacles
- What lies ahead?

# Introduction

- What is a biosimilar?
  - FDA: ”A biosimilar is a biological product that is **highly similar** to and has no clinically meaningful differences from an existing FDA-approved reference product.”
  - EMA: “a biological medicine **highly similar** to another already approved biological medicine (the 'reference medicine').”

# Introduction

- What is meant by **highly similar**?
  - FDA: Characteristics of the products (reference and biosimilar) wrt e.g. purity, chemical identity, bioavailability
  - EMA: In terms of structure, biological activity and efficacy, safety and immunogenicity profile



# Approved biosimilars - EMA

- EMA approved its first biosimilar in 2006, omnitrope (somatropin)
- As of August 2018, 50 biosimilars are approved for use by EMA (three withdrawn)
- Approvals cover various TA's/molecules, e.g.
  - hGH
  - Insulin
  - FSH
  - TNF inhibitor
  - mAb

# Approved Biosimilars - Therapies

- Drugs with high sales are also those most targeted for biosimilar products
  1. Neulasta (Neupogen) 3.6 $bn
  2. Humira (Adalimumab) 20 $bn
  3. Mabthera (Rituximab) 6.4 $bn
  4. Remicade (Infliximab) 6.3 $bn

# Approved – Not (necessarily) launched

- Several drugs have been approved by the FDA – but are still not available
  - 2 Humira biosimilars approved, not yet on market in the US (2023)
  - 2 Remicade biosims available in the US posting modest numbers of about 5% of total sales
  - Remicade biosimilars in Europe accounts for 53% of sales

# Drug savings

- NHS England spent £400 million on Humira each year before striking a biosimilars deal
- After accepting bids from Amgen, Biogen, Mylan/Fujifilm Kyowa Kirin and Sandoz on their biosimilars, and a cut-price bid from AbbVie itself, the NHS may save up to £150 million a year
- Savings equivalent to e.g. 11,700 community nurses

# European Market

- Sales close to 4 $bn (2.5 $bn 2017)
- Rituximab similars covering 70 to 80 % of the Nordics and the UK, respectively
- In France, Infliximab biosims now comprise 30% of sales compared with less than 5% three years ago
- Uptake slower for self-injected products

# Self-injection vs clinic administration

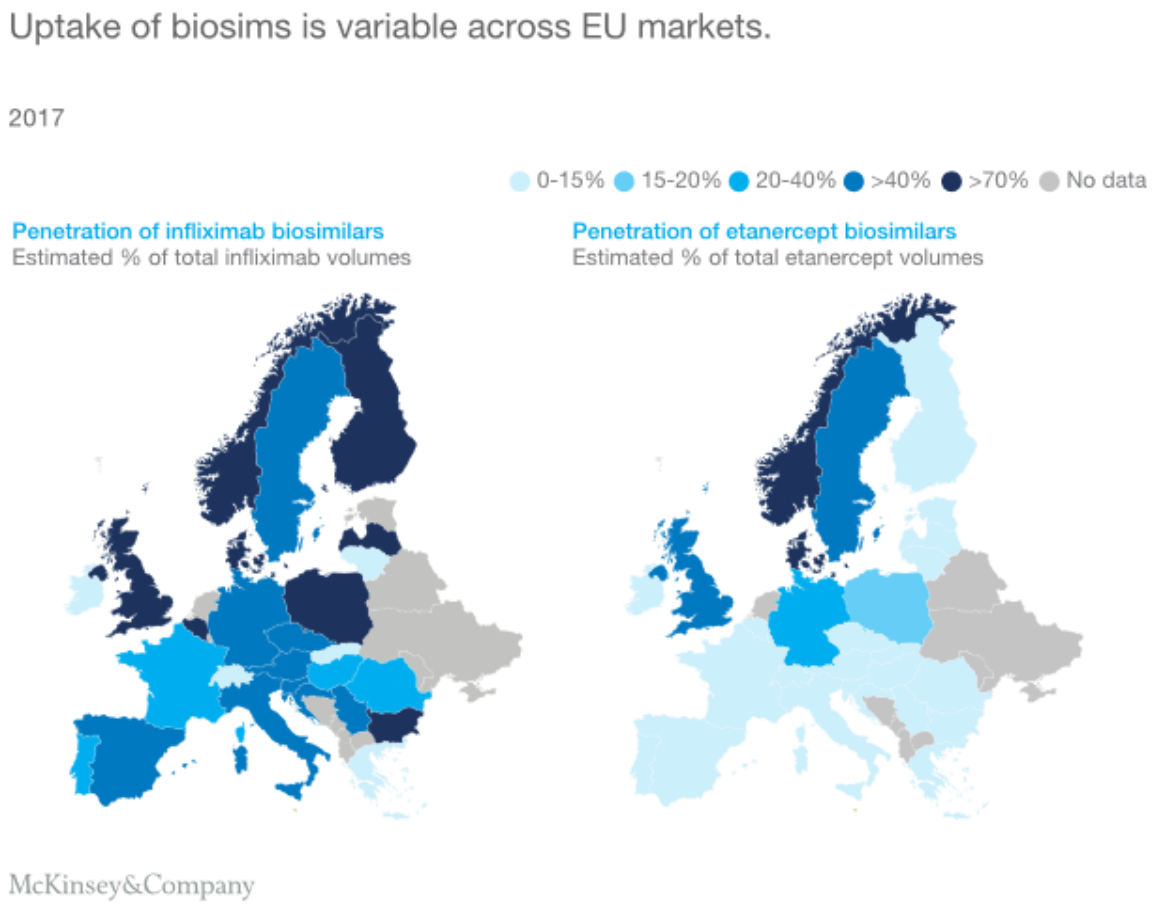
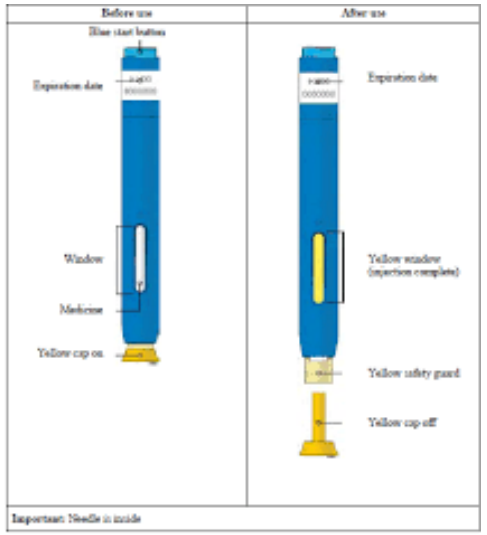


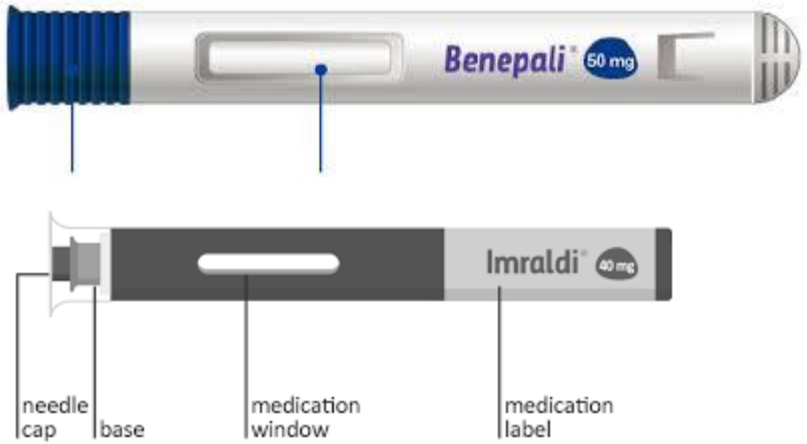

Image from https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/five-things-to-know-about-biosimilars-right-now

# Available presentations

- Presentation differs mainly depending on the therapy area and expected use
  - Oncology products are often filled in vials
    - IV delivery in clinic
    - Lyo formulation
  - Sub-cutaneous delivery filled in PFS (across TA's)
  - Diabetes products can also be filled in cartridges (for use in pens)
  - Only biosimilars where reference product is available in an autoinjector have device presentations

# Biosimilars injection devices







# Does primary packaging matter?

- No clear indication that it does
- In Europe available products are evenly distributed across vials, PFS, and Autoinjectors or injection pens
- For Amgen, the Onpro device could be seen as a competitive advantage for Neulasta (reference product)

# Market Technology Evolution

- Expecting to see more biosimilars in devices from companies with access to an existing device platform
- Contrary to innovative products biosimilars will always be under competitive pressure – cost of device development likely prohibitive
- Continued launch of biosimilars in PFS due to advantages of a simpler combination product
  - Less technical and regulatory burden
- May be opportunity to use devices for self-injected products to stimulate market penetration

# Biosimilars drug outlook

- Current biosimilar drugs mostly in the areas of
  - Oncology
  - Autoimmune diseases (RA, Psoriasis, etc)
  - Hematology (Epogen)
- Expecting to see more biosimilar drugs in the areas of
  - Diabetes
  - Rare diseases (but not too small)

# Biosimilars drug outlook

- EU/EMA continuing to be the major market for several years
  - Market/user acceptance
  - Acceptance/incentive of substitutions from payers
  - Significant market penetration of biosimilars
- US likely needs policy changes/adjustments to see accelerating numbers in available biosimilars

# Biosimilars drug outlook

- Biosimilars will drive increased availability of (bio) drugs across the world
  - Competition will allow payers to negotiate price vs market access
  - Will likely be most successful for drugs with broad applicability and/or large patient base (oncology, diabetes, RA)
  - May drive development of alternative formulations
    - Lyo formulation to avoid cold chain
    - Increase stability or shelf life

# Summary

- EU/EMA the major market for biosimilars
  - Number of approved drugs
  - Market penetration
- Self-injected products see slower uptake
- Drug delivery drives the choice of presentation
- US expected to grow significantly once barriers are removed or reduced

# Summary

- Growth from increased market access
- Savings will be significant, thus increasing incentives for substitution
- Expect more biosimilars in TA’s with great patient populations (large volume products vs high value)