Improving medicines value for money in the NHS and the role of biosimilars - assessing progress so far

Prepared by Professor Brian Godman

1. Introduction

2. Current situation biosimilars

3. Conclusion

Biosimilars are essential to help contain medicine costs and treat patients well with biologicals

- There is growing expenditure on medicines worldwide, estimated to reach US$1.5 trillion by 2023, with implications for affordability even in high income countries. This increase will be driven by biological medicines for complex diseases including cancer and orphan diseases exacerbated by their high costs, which are becoming unaffordable

- The costs even for the anti-TNFs has resulted in their limited prescribing among Central and Eastern European countries, which is difficult to sustain

- Biosimilars offer a way forward to improve the care of patients with proven similar effectiveness and safety between originators and biosimilars, e.g. NOR-SWITCH study in Norway. As a result:
  - ❑ More patients can be treated with biologicals as lower co-pays - especially important for CEE countries
  - ❑ More patients can be treated within the same overall expenditure
  - ❑ Services can be enhanced with realised savings, e.g. employing extra staff in rheumatology as seen with adalimumab in Scotland
  - ❑ Lower cost biosimilars puts pressure on patented biologicals that used the originator to help justify premium prices

There are concerns with rising prices of new oncology medicines and their value, e.g. the median annual cost for new oncology medicines exceeded US$150,000 per person per year in 2017 compared with US$79,000 in 2013, with continuing increases in costs/ LYS driven by the emotive nature of the disease area. Biosimilars can help

Journal of Economic Perspectives—Volume 29, Number 1—Winter 2015—Pages 139–162

Pricing in the Market for Anticancer Drugs†

David H. Howard, Peter B. Bach, Ernst R. Berndt, and Rena M. Conti

Biosimilars can enhance the use of biological medicines in RA and IBD among CEE countries

- There has been variable use of biological medicines to treat patients with rheumatoid arthritis across Europe in recent years driven by their higher costs versus traditional disease modifying therapies

- Putrik at al in 2014 showed considerable variation in the use of biologicals across Europe depending on issues including socioeconomic status, co-payments and disease severity

- Overall, low use of anti-TNFs to treat patients with rheumatoid arthritis among Central and Eastern European (CEE) countries versus Western European countries

- Biosimilars can help redress the balance and increase the ability of patients with rheumatoid arthritis to access biologicals to improve their care

Ref: Putrik et al 2014

Biosimilars can enhance the use of biological medicines in RA and IBD among CEE countries (cont.)

- There was also considerable variation in the use of biologicals to treat patients with inflammatory bowel disease (IBD) across Europe
- This ranged from appreciable use in France and Spain to limited or no use in Latvia, Poland and Romani (Pentek et al - 2017)
- Kostic et al (2017) also found limited use of biologicals to manage patients with IBD in Serbia due to high patient co-payments
- Biosimilars can again help enhance access to biologicals for patients with IBD among CEE and other countries

Ref: Kostic et al 2017; Pentek et al 2017; Baumgart et al 2019

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There is increasing use of biosimilars across countries with increasing evidence and measures

- NOR-SWITCH study organised by Ministry of Health in Norway was seen by many as a game changer to enhance acceptance of biosimilars among key stakeholder groups across Europe and wider. In addition increasing realisation that originator companies often change their manufacturing processes
- Studies such as these have typically resulted in more rapid uptake of biosimilars in the UK enhanced by quality indicators and benchmarking
- Demand-side measures essential else limited use biosimilars, e.g. Korea. This is not an issue in countries such as the UK
- Increased competition helps drive down prices as seen with infliximab in Norway and adalimumab in Denmark and the UK
- There have been issues with biosimilar insulin glargine with different devices and originator company activities to reduce biosimilar use/availability although not universal

The NOR-SWITCH study sponsored by the Norwegian Government helped cement biosimilars

Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial

Kristin K Jørgensen, Inge C Olsen*, Guro L Goll*, Merete Lorentzen*, Nils Bolstad, Espen A Haavardsholm, Knut E A Lundin, Cato Mørk†, Jørgen Jahnsen†, Tore K Kvien†, on behalf of the NOR-SWITCH study group*

Summary

Background TNF inhibitors have improved treatment of Crohn's disease, ulcerative colitis, spondyloarthritis, rheumatoid arthritis, psoriatic arthritis, and chronic plaque psoriasis, but are expensive therapies. The aim of NOR-SWITCH was to examine switching from originator infliximab to the less expensive biosimilar CT-P13 regarding efficacy, safety, and immunogenicity.

Published Online
May 11, 2017
http://dx.doi.org/10.1016/S0140-6736(17)30068-5

See Online/Comment

We also know that originator companies do change their manufacturing processes, often multiple times, so each new batch is a 'biosimilar'. Suck knowledge helps enhance the acceptance of biosimilars

European Journal of Clinical Pharmacology (2018) 74:505–511
https://doi.org/10.1007/s00228-017-2397-x

PHARMACOEPIDEMIOLOGY AND PRESCRIPTION

Degree of prescriber's knowledge about variability in biological drugs "innovators" in manufacturing process

Lucía Jiménez-Pichardo[1] · Rocío Gázquez-Pérez[1] · Jesús Francisco Sierra-Sánchez[1]

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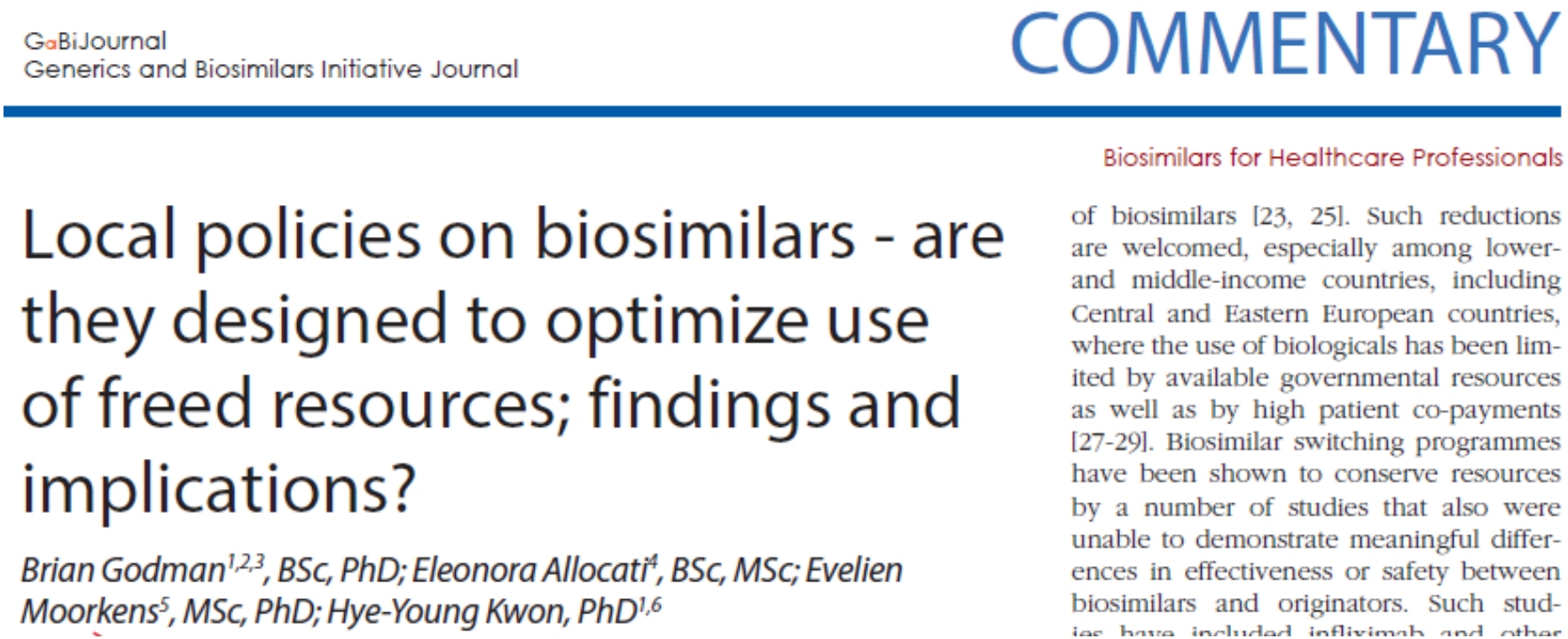
Originators do change their manufacturing process without the need to re-do clinical studies as commented on by us and others



GaBiJournal
Generics and Biosimilars Initiative Journal

COMMENTARY

Biosimilars for Healthcare Professionals

Local policies on biosimilars - are they designed to optimize use of freed resources; findings and implications?

Brian Godman[1,2,3], BSc, PhD; Eleonora Allocati[4], BSc, MSc; Evelien Moorkens[5], MSc, PhD; Hye-Young Kwon, PhD[1,6]

of biosimilars [23, 25]. Such reductions are welcomed, especially among lower- and middle-income countries, including Central and Eastern European countries, where the use of biologicals has been limited by available governmental resources as well as by high patient co-payments [27-29]. Biosimilar switching programmes have been shown to conserve resources by a number of studies that also were unable to demonstrate meaningful differences in effectiveness or safety between biosimilars and originators. Such stud-

Can local policies on biosimilars optimize the use of freed resources – experiences from Italy
Generics and Biosimilars Initiative Journal (GaBI Journal). 2020;9(4):183-7.

Quality targets for new and switched patients plus benchmarking has accelerated biosimilar uptake in UK

- In England:
  - Biosimilar infliximab took 28 months to reach 80% penetration (total infliximab)
  - Biosimilar rituximab took 10 months to reach 80% of total rituximab
  - Biosimilar trastuzumab took 8 months to reach target penetration rates (80%)
- In Scotland:
  - Etanercept and infliximab biosimilars reached 84% and 94% of total utilisation of these biologicals by December 2017
  - Rituximab 74% - its first year of availability
  - By December 2019, biosimilars for trastuzumab had accounted for 92% of all trastuzumab and biosimilar adalimumab 87% of all adalimumab and growing

Ref: Godman et al submitted/ re-submitted

This compares with Korea where limited use of biosimilars with limited demand-side measures

frontiers in Pharmacology

ORIGINAL RESEARCH
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Uptake of Biosimilar Infliximab in the UK, France, Japan, and Korea: Budget Savings or Market Expansion Across Countries?

Yujeong Kim[1], *Hye-Young Kwon*[2,3*], *Brian Godman*[2,4,5], *Evelien Moorkens*[6], *Steven Simoens*[6] *and SeungJin Bae*[1*]

Increasing competition is helping drive down the prices of biosimilars – this will continue

AJMC | THE CENTER FOR BIOSIMILARS

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After Biosimilar Deals, UK Spending on Adalimumab Will Drop by 75%

November 26, 2018
Kelly Davio

This morning, the United Kingdom's National Health Service (NHS) announced that it has completed negotiations over using the best-value adalimumab product, and it has arrived at a plan whereby it will save £300 million (approximately $386 million) of its current £400 million-per-year (approximately $514 million) spending on adalimumab.

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These substantial savings, said the NHS, will allow the health system to pay for an additional 11,700 community nurses, or 19,800 more treatments for

Ref: Davio 2018

Costs of adalimumab decreased by over 82% among hospitals in Denmark following successful tendering – benefitting both patients and the healthcare system

Letters

RESEARCH LETTER

Shift From Adalimumab Originator to Biosimilars in Denmark

Brand-name adalimumab (Humira, hereinafter originator) is being paid by patients and payers when much cheaper biosimilar drugs are available outside the US.

Denmark, a member of the European Union with 5.8 million inhabitants, has benefited from substantial discounts owing to a well-planned implementation of adalimumab biosimi-

Methods | Monthly data (January 2017 to October 2019) on drug sales to all Danish Hospital departments from Amgros, the purchaser of all hospital drugs, were used to assess the biosimilar uptake proportion and subsequent changes in cost. Institutional review board approval was waived because the data used did not have information on individual drug use. Owing

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Concurrent with this, Abbvie decreased the price of HUMIRA by 89% in some European countries to try and reduce biosimilar use/ availability – not universal though

frontiers in Pharmacology

ORIGINAL RESEARCH
published: 08 January 2021
doi: 10.3389/fphar.2020.591134

Check for updates

The Expiry of Humira® Market Exclusivity and the Entry of Adalimumab Biosimilars in Europe: An Overview of Pricing and National Policy Measures

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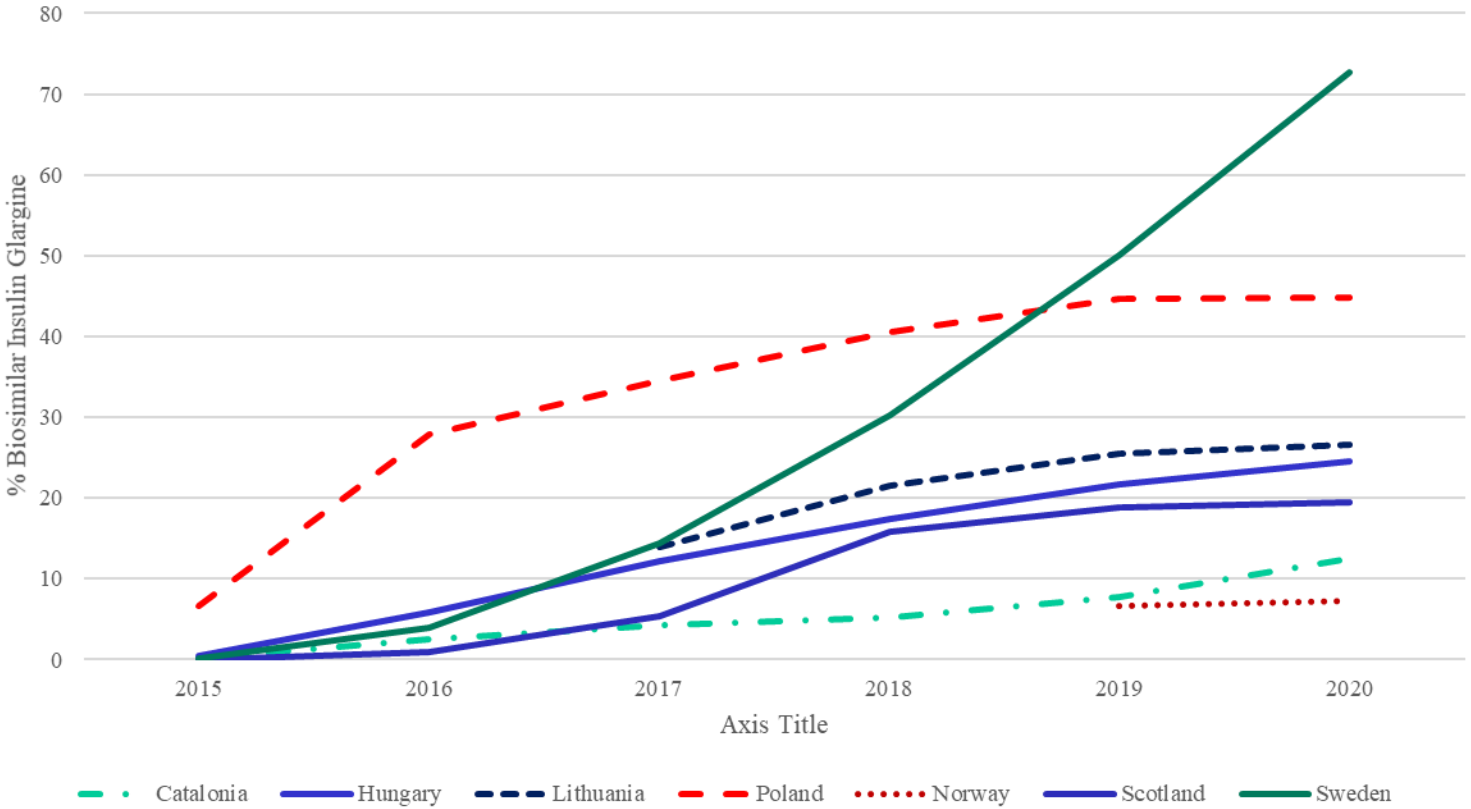
Specialty section:

There has been variable use of biosimilar insulin glargine across Europe exacerbated by concerns with different devices and the originator company decreasing its price/ promoting higher strength patented formulation



NB: No or very limited biosimilar insulin glargine in Austria, Albania, Estonia, Kosovo, Latvia, Malta or Romania. This situation may deter biosimilar companies from developing biosimilars for other long-acting insulin analogues unless addressed

Ref: Godman et al submitted/ re-submitted

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In conclusion:

- More biosimilars at lower prices especially for oncology and immunological diseases are essential to help with increasing medicine expenditure with ageing populations

- There are concerns if biosimilars are not launched in a class – especially as competition helps drive down prices without compromising care to the benefit of key stakeholders

- Quality indicators/ other demand-side measures can alleviate discussions especially in US that originators should automatically drop their prices once patent loss negating the need for biosimilars (only short term gains). UK is showing the way

- Under VBP principles – countries should see greater discounts/ price reductions for existing patented biologicals that used a biological that is now a biosimilar for price justifications to help with access and affordability – limited examples to date

Thank You

Any Questions!

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