Ongoing activities across countries to increase the utilisation of biosimilars and their implication

Prepared by Professor Brian Godman

Brian Godman – research activities

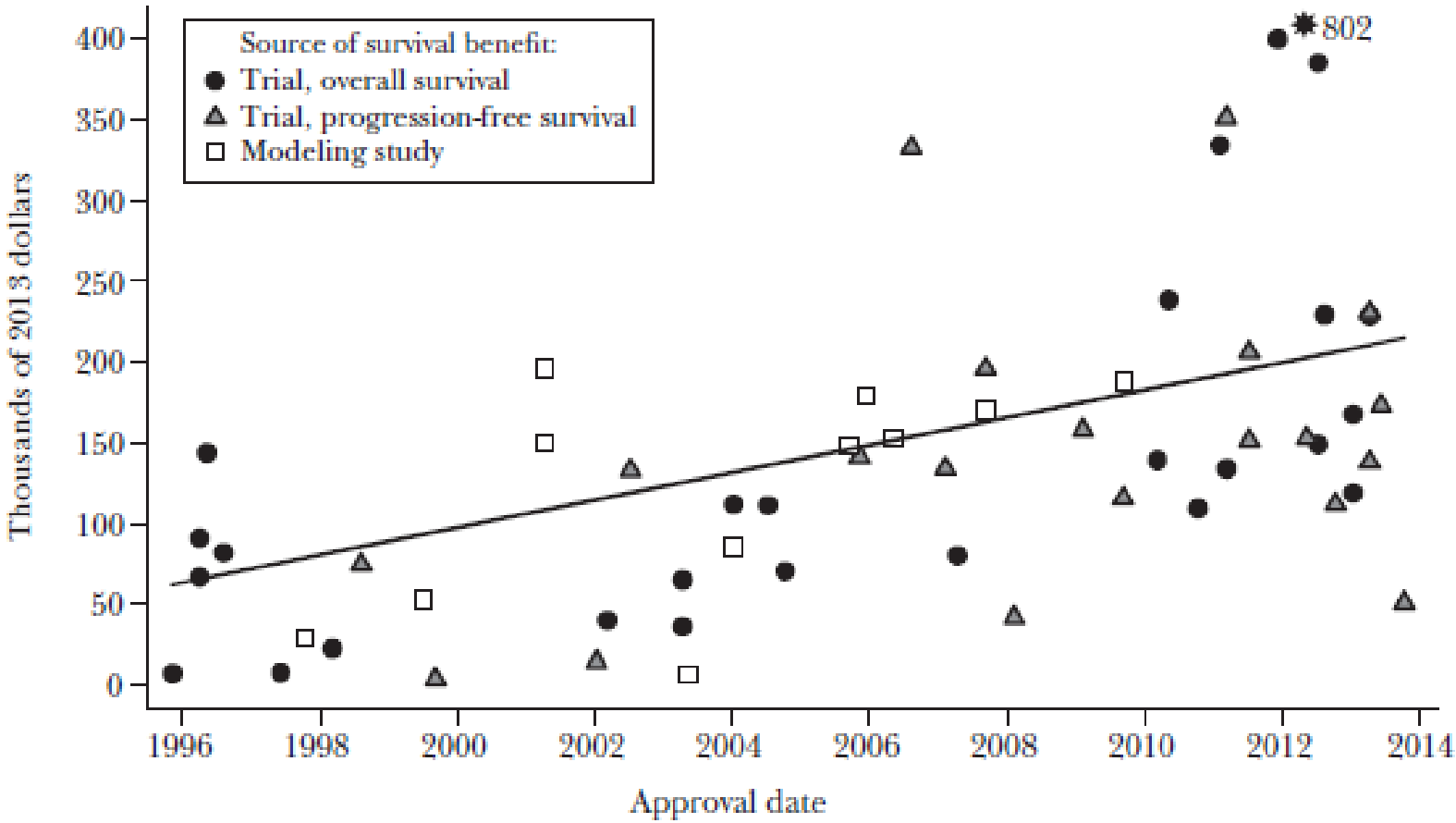
- PhD research activities (starting in 2006) initially in 7 EU countries to:
  - Increase the prescribing of generics first line and drive down their prices to enhance prescribing efficiency
  - Optimise reimbursement/ funding decisions for new medicines and their subsequent utilisation leading to the development of new models starting pre-launch
- Research interests subsequently extended globally and include activities to improve the quality and efficiency of prescribing/ dispensing of new and established medicines across multiple disease areas/ product classes including infectious and NCDs. This includes biosimilars
- Co-Founder of Piperska (Europe - 2008) and MURIA (2015)
- Over 350 peer reviewed publications in the past 15 years with payers/ advisers/ academics across multiple continents/ countries including Asia – with most listed in Pub Med
- Several publications involving Korea (solely or part of multi-country publications)

The potential role of biosimilars will increase with growing expenditure on biologicals

- Global expenditure on medicines will soon reach US$1.5trillion, with medicines for chronic, complex, or rare diseases such as cancer and orphan diseases, accounting for over 50% and growing with increasing prices for new medicines
- These growth rates are unsustainable alongside the need to fund increased volume of medicines for patients with chronic non-communicable diseases with ageing populations alongside new high priced medicines to treat areas of unmet need
- In addition, patients in an appreciable number of countries do not have access to biologicals including anti-TNFs for RA and IBD as well as trastuzumab/ rituximab for oncology due to their high costs/ high patient co-payments
- Biosimilars offer a way forward, e.g. adalimumab was the top selling medicine in Germany in 2017 and the anti-TNFs were one of the top selling medicines in the UK in 2018

Ref: Inoati et al 2017; Moorkens et al 2017, Godman et al 2018, 2019, and accepted

Drug Price per Life Year Gained versus Drug Approval Date



The cost of cancer medicines now averages US$207,000/ life year gained (2013$) – This is likely to be an underestimate as modelling and concerns between linking PFS (typical outcome measure) and overall survival (needed for LYG calculations) in solid tumours

Ref: Howard et al 2015; Godman et al 2015, 2018

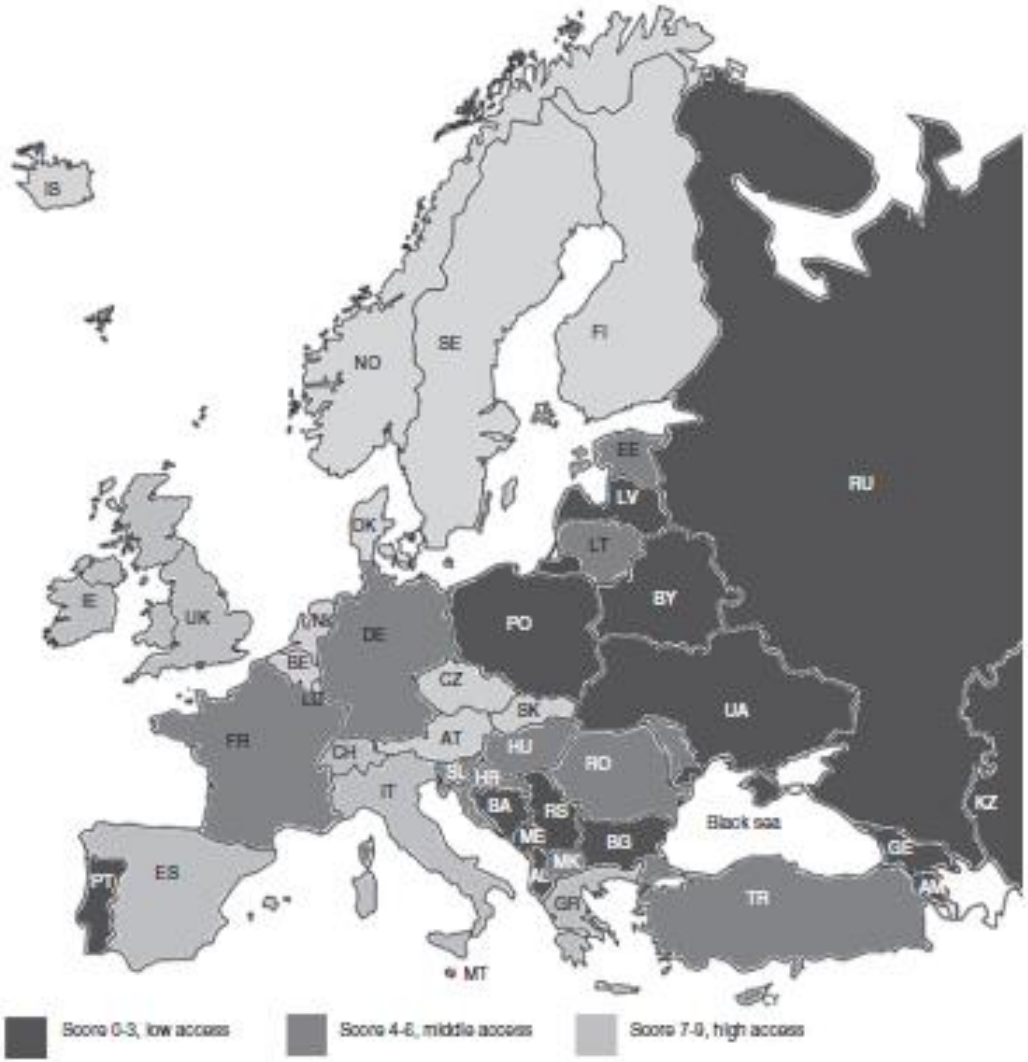
Concerns with ever increasing prices for new medicines for orphan diseases aided by the emotive nature of the disease area is resulting in publications such as Luzzatto et al in the Lancet in 2018, and limiting access to patients with orphan diseases across countries. Biosimilars may eventually help

Outrageous prices of orphan drugs: a call for collaboration

Lucio Luzzatto, Hanna I Hyry*, Arrigo Schieppati, Enrico Costa, Steven Simoens, Franz Schaefer, Jonathan C P Roos, Giampaolo Merlini, Helena Kääriäinen, Silvio Garattini, Carla E Hollak, Giuseppe Remuzzi, on behalf of the Second Workshop on Orphan Drugs participants*

www.thelancet.com Vol 392 September 1, 2018

Re: Luzzatto et al 2018

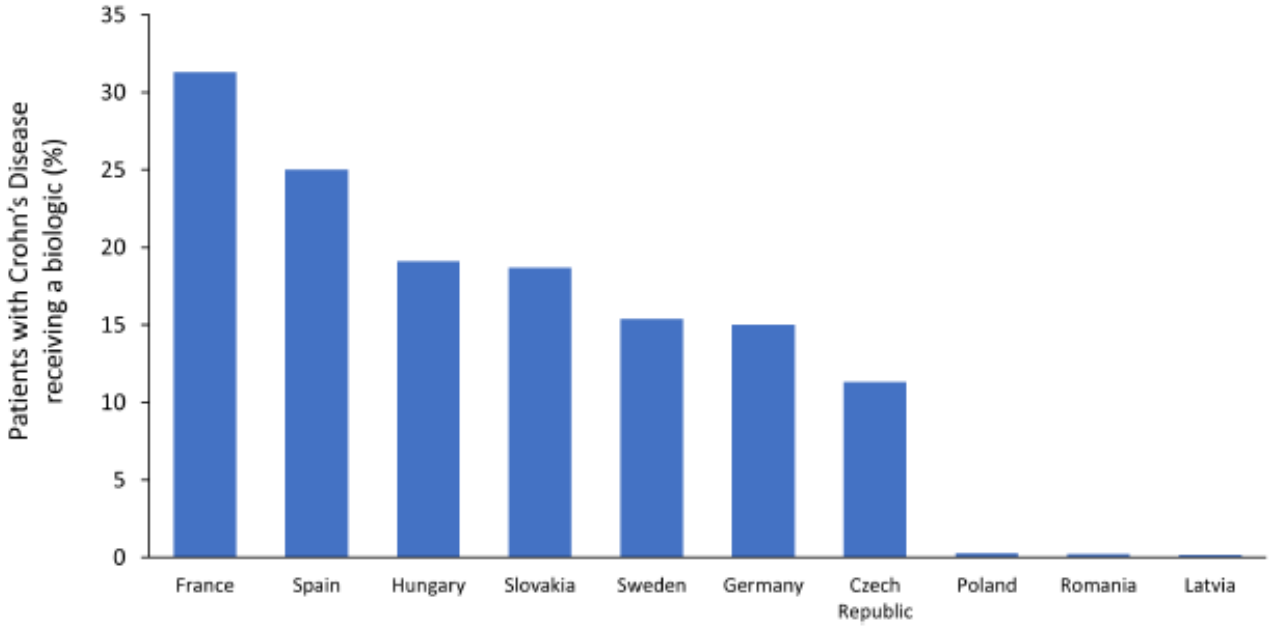


There has been variable use of biological medicines to treat patients with rheumatoid arthritis across Europe in recent years

Putrik at al in 2014 showed considerable variation depending on issues of socioeconomic status, co-payments and disease severity

High scores were associated with good access

Ref: Putrik et al 2014



There is also considerable variation in the use of biologicals in patients with inflammatory bowel disease across Europe driven again by issues of access and affordability

Kostic et al in Serbia also found limited use of biologicals for IBD due to high patient co-payments

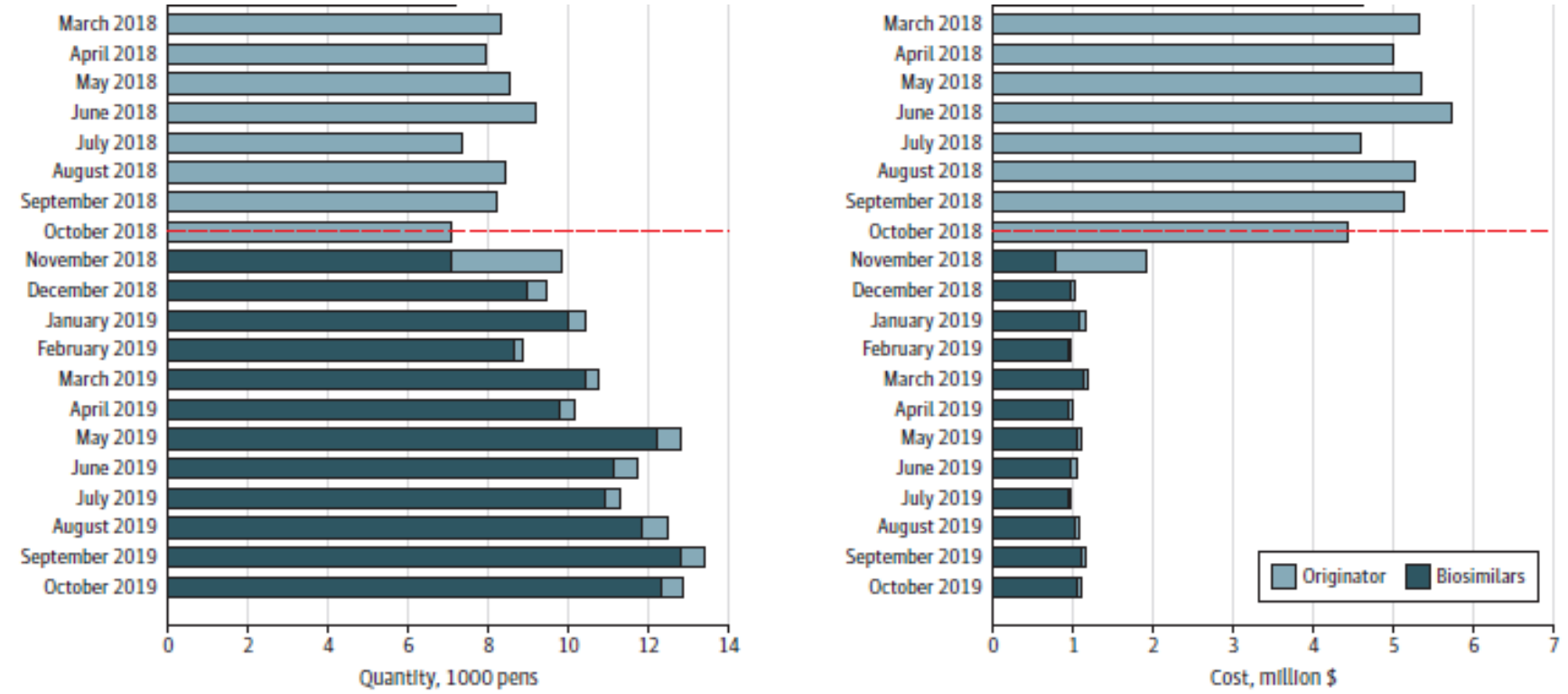
Ref: Kostic et al 2017; Baumgart et al 2019

There is potential for appreciable savings with biosimilars given high sales of biologicals

- Humira had global sales of US$19.9 billion in 2018; with rituximab, infliximab, and etanercept having global sales of US$7.9billion, US$ 5.9 billion and US$ 5.8 billion in 2017 respectively – all now reducing with biosimilars launched
- Global sales of trastuzumab were stable in 2019 at US$7billion due to increasing use of biosimilars with biosimilars already capturing 45% of the European market and growing
- The insulin glargine market was valued at US$3.88 billion in 2018 envisaged to reach US$9.26 billion by 2025 with growing rates of diabetes worldwide. Biosimilars can help here as well
- Can be considerable savings with biosimilars without affecting care, especially with more biosimilars becoming available, e.g. expenditure on adalimumab in the UK was estimated to fall by 75% following the availability of biosimilars and among Danish hospitals, expenditures decreased by 82.8% following biosimilars with almost total replacement (95.1% utilisation)

Ref: Godman et al 2019, and accepted, Jensen et al 2020

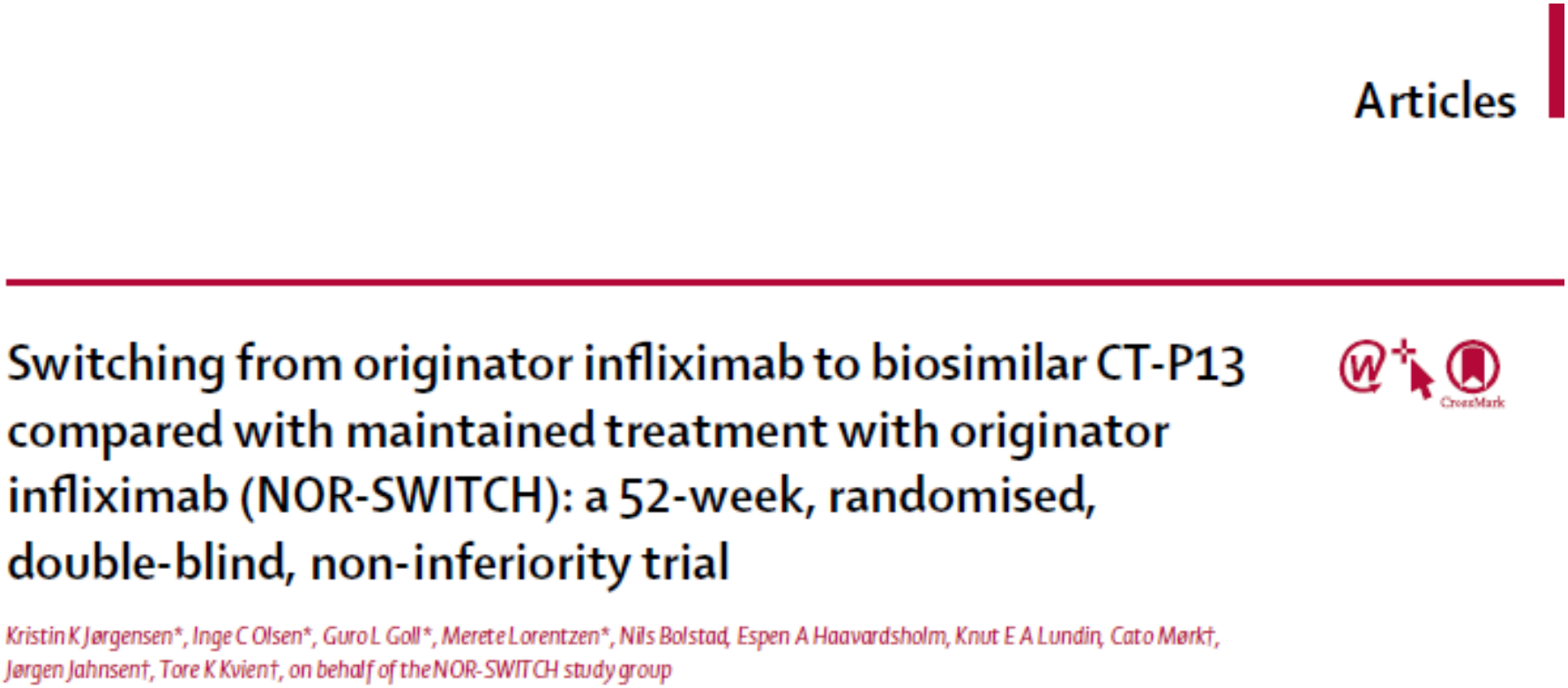
There were considerable savings for adalimumab among Danish hospitals following biosimilars with almost total use of low cost biosimilars (82.8% reduction in expenditure)



Red line indicates when biosimilars became available

Ref: Jensen et al 2020

There have been concerns with the effectiveness and safety of biosimilars – addressed by studies such as NOR-SWITCH study sponsored by the Norwegian Government ....



Ref: Jorgensen et al 2017

… as well as growing realization that originator companies often change their manufacturing process without having to undertake further studies – so in effect biosimilars as well

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]

Received: 27 July 2017 / Accepted: 5 December 2017 / Published online: 15 December 2017

Ref: Jimenez-Pichardo et al 2018, Godman et al 2019

There can be concerns with some biosimilars. Both demand and supply side measures needed

- However – there can be occasions where savings are more limited with biosimilars as currently seen with insulin glargine across countries with limited price reductions and concerns with switching with different pens and familiarity
- Typically, both supply- and demand side-measures are needed to maximise savings from biosimilars
- Supply-side measures include encouraging competition through tenders, e.g. Danish Hospitals and UK with adalimumab
- Demand-side measures include education, engineering, economics and enforcement (4Es)
- Without both – limited savings. In fact in Korea – when biosimilar infliximab introduced there was limited use of the biosimilar alongside appreciably increased use of the originator – NOT the desired aim

Ref: Wettermark et al, 2009, Godman et al 2019 and accepted; Kim et al 2020

This was our recently published study involving Korea – available Open Access

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]**

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OPEN ACCESS

Demand-side measures can be collated under the 4Es and include education and economics

- Education – includes education of all key stakeholder groups including physicians, pharmacists and patients – especially with concerns with the nocebo effect. An increasing number of published studies showing no difference in the effectiveness and safety between originators and biosimilars should help here
- Engineering – includes setting goals for % of patients started on biosimilars as well as switching (where pertinent). In addition, benchmarking of physicians among each other for biosimilar prescribing rates and potential savings
- Economics – financial benefits for patients (e.g. lower premiums and co-pays) and physicians (directly as well as indirectly) from increasing use of biosimilars. In addition – sanctions including removing of licences
- Enforcement – compulsory INN prescribing; compulsory substitution

Ref: Moorkens et al 2017, Godman et al 2019 and accepted; Dutta et al 2020

The potential nocebo effect with biosimilars is discussed in this and other papers

frontiers in Pharmacology

REVIEW
published: 29 November 2019
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The Clinical Implications of Nocebo Effects for Biosimilar Therapy

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Potential demand-side policies in other countries are discussed in this publication (Europe) and others

RESEARCH ARTICLE

Policies for biosimilar uptake in Europe: An overview

Evelien Moorkens[1]*, Arnold G. Vulto[2], Isabelle Huys[1], Pieter Dylst[1,3], Brian Godman[4,5], Simon Keuerleber[6], Barbara Claus[7], Maria Dimitrova[8], Guenka Petrova[8], Ljiljana Sović-Brkičić[9], Juraj Slabý[10], Robin Šebesta[11], Ott Laius[12,13], Allan Karr[14], Morgane Beck[15], Jaana E. Martikainen[16], Gisbert W. Selke[17], Susan Spillane[18,19], Laura McCullagh[18,19], Gianluca Trifirò[20], Patricia Vella Bonanno[21], Asbjørn Mack[22], Antra Fogele[23], Anita Viksna[23], Magdalena Władysiuk[24], Helder Mota-Filipe[25], Dmitry Meshkov[26], Marija Kalaba[27], Simona Mencej Bedrač[28], Jurij Fürst[29], Corrine Zara[30], Peter Skiöld[31], Einar Magnússon[32], Steven Simoens[1]

Potential demand-side measures across countries is also discussed in this paper

GaBiJournal
Generics and Biosimilars Initiative Journal

Ever-evolving landscape of biosimilars in Canada; findings and implications from a global perspective

Brian Godman[1,2,3], BSc, PhD; Eleonora Allocati[4], BSc, MSc; Evelien Moorkens[5], BSc, MSc*

Other potential advantages from increasing use of biosimilars – apart from increasing access to therapy and physician numbers to treat more patients – include simulating research into the next generation of biologicals through making savings available to fund them

BioDrugs (2020) 34:159–170
https://doi.org/10.1007/s40259-019-00395-w

REVIEW ARTICLE

Check for updates

Identifying Key Benefits in European Off-Patent Biologics and Biosimilar Markets: It is Not Only About Price!

Binita Dutta[1] · Isabelle Huys[1] · Arnold G. Vulto[1,2] · Steven Simoens[1]

Published online: 2 December 2019

Biosimilars are increasingly necessary. Both demand- and supply-side measures important

- In conclusion, biosimilars offer considerable advantages to healthcare systems struggling to cope with increasing demands – made worse by the current COVID-19 pandemic. In addition help patients where high co-payments
- However both appropriate supply- and demand-side measures are necessary to fully realise the potential of biosimilars. This is important especially if originator companies are looking to aggressively lower prices to stave off competition (e.g. AbbVie with HUMIRA in the Netherlands)
- Savings will grow as more biosimilars become available across disease areas especially in oncology
- In time – may well see re-evaluation of the prices of existing patented medicines that used a biological medicine that has now become available as a biosimilar for referencing in negotiations. This becomes important with some of the considerable price reductions seen with biosimilars (80 – 90%)

Thank You

Any Questions!

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