Western European markets for biosimilar drugs; worth differentiation

Prepared by Brian Godman

Brian Godman – research activities

- PhD research activities initially in 7 EU countries to:
  - Increase the prescribing of low cost generics first line to enhance prescribing efficiency
  - Optimise reimbursement/ funding decisions for new medicines and their subsequent utilisation
- Extended across Europe and globally researching:
  - New models to optimise the use of new medicines
  - Measures to improve the quality and efficiency of prescribing - based on 4Es – across multiple disease areas/ product classes including biosimilars
- Typically work with health authorities and their databases
- Over 100 peer reviewed publications/ acceptances in the past 8 years (over 80 listed in Pub Med) with payers/ advisers/ academics in Africa including South Africa, Asia, Australia, Canada, China, Europe, Fragile States, Middle East, Pakistan, New Zealand, S. America and US

1. Introduction

2. Activities with biosimilars in Europe

3. Conclusions

Scrutiny over pharmaceutical expenditure is increasing - will continue with growing pressures

- Pharmaceutical expenditure grew by more than 50% in real terms during the past decade among OECD countries – typically the largest cost component in ambulatory care
- Scrutiny is increasing with ageing populations, increasing prevalence NCDs, stricter clinical targets, rising expectations and the continued launch of new premium priced biological medicines – now at over US$40,000/ patient/ month
- As a result, initiatives among health authorities across countries to optimise the use of medicines to address areas of unmet need whilst still aiming for comprehensive and equitable healthcare
- Countries are necessarily learning from each other – this will grow to maintain ideals and increasingly include biosimilars

Ref: Godman et al 2010 to 2015; WHO 2015; Kaplan et al 2013

Concerns with the increasing costs of biological medicines is a concern

- Biological pharmaceuticals are almost always priced at levels that lead to high treatment costs (acquisition drug costs)
- If a very small number of patients consume a large proportion of resources allocated to pharmaceuticals, this may be perceived as unfair - which in turn is politically sensitive
- If the high cost of treatment with biological pharmaceuticals for small groups of patients overwhelms the ability to pay for other treatments for larger patient groups - public opinion could become quite negative as well
- Biosimilars are a way to start addressing these issues as well as enhancing patient access to effective treatments where access is currently a concern

Ref: Befrits 2013

Biosimilars require clinical trials in patients unlike generics

The EMA has defined biosimilars as:

'A similar biological medicinal product, also known as Biosimilar, is a product which is similar to a biological medicine that has already been authorised, the so-called reference medicinal product.

The active substance of a biosimilar medicine is a known biological active substance and similar to the one of the reference medicinal product.

A similar biological medicinal product and its reference medicinal product are expected to have the same safety and efficacy profile and are generally used to treat the same conditions'

Ref: EU commission 2013

The high cost and budget impact of anti-TNFs impacts on their availability in Europe

- Global annual sales of the various anti-TNFs/anti-TNFR medicines now exceed $US25 billion - making anti-TNFs the most profitable medicine class in the world

- This is helped by their recognised place in the management of patients with rheumatoid arthritis (RA) and other immunological conditions, e.g. psoriasis and Chron's disease, with RA affecting approximately 1% of the population

- However, 10 out of 46 European countries recently surveyed do not reimburse biological medicines for RA - severely impacting on their subsequent utilisation and patient care

- Their high annual price (€9431 – 21349) and prevalence of RA versus disease modifiers such as methotrexate (€100 – 498) impacts on their reimbursement/ funding – with biosimilars a potential option

Ref: Monaco et al 2014; Putrik et al 2014

1. Introduction

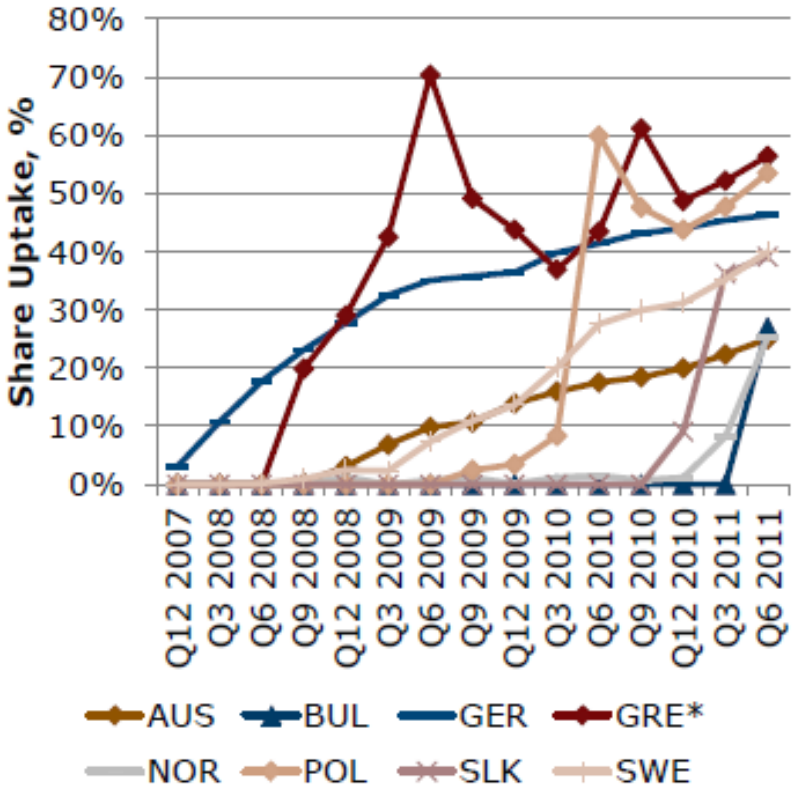
2. Activities with biosimilars in Europe

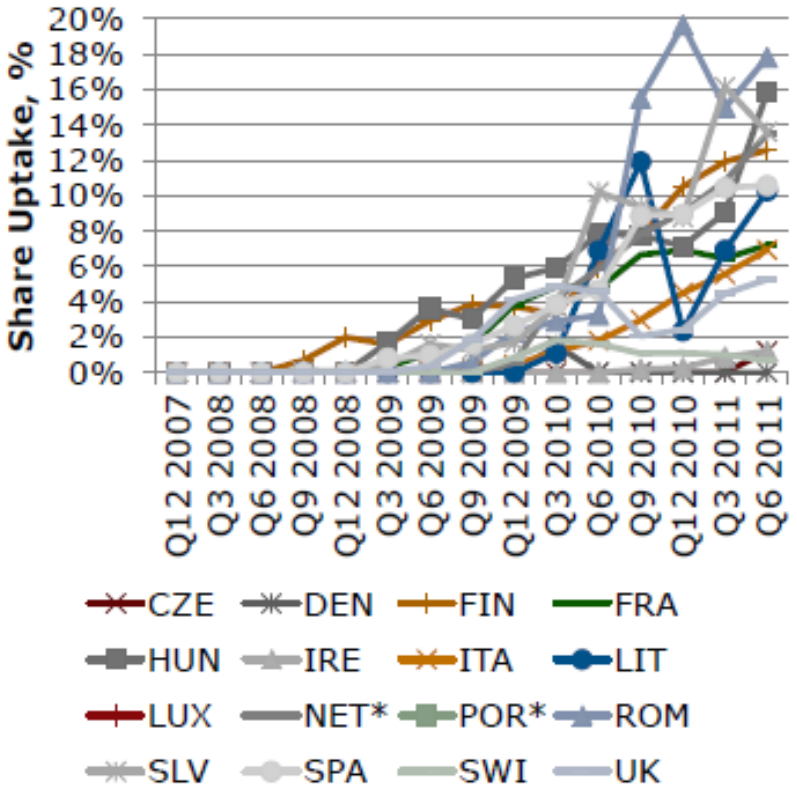
3. Conclusions

There has been varying use of biosimilars across Europe. This is beginning to change

- To date their has been varying use of biosimilars
- This has not been helped by misinformation regarding their safety and efficacy versus the originators as well as limited price reductions
- This is changing with more evidence about issues such as immunogenicity as well as recent activities in countries such as Norway
- The role out of these developments will enhance the use of biosimilars across Europe
- The increasing the availability of new biosimilars including those for trastuzumab will further help health authorities and patients

To date there has been varying use of biosimilars across Europe, e.g. EPO, - not helped by disinformation and other activities





Ref: IMS 2012

There has been considerable disinformation regarding biosimilars necessitating activities

- NEFARMA - *A biosimilar is, therefore, in fact a new product that on the basis of limited studies is given authorisation for a very specific indication'* and *'In the future patients will be using more and more biosimilars. This can lead to situations whereby physicians prescribe another medicine than what the patient is used to. In this case, patients need to be alert to more and different side effects and should contact their physician immediately in such events'*

- Lee and colleagues (Amgen) - '*the potential for differences between an innovator biologic and a biosimilar is greater than that between a biologic before and after a manufacturing change. Due to the potential for differences, a biosimilar manufacturer should provide data to ensure that differences between the biosimilar and the innovator biologic will not impact the efficacy or safety of its product. Considering the current limitations of analytics, these data should include comparative clinical testing to confirm biosimilarity'*

Ref: NEFARMA 2013; Lee et al 2012

This level of disinformation promoted activities from the EU Commission

- The EU Commission in 2013 issued '**What you need to know about Biosimilar Medicinal Products. A consensus information document**' to address key issues regarding biosimilars including concerns with their effectiveness and safety

- ***Qu: 11***. *Is there any difference in safety between the biosimilar and the reference product?*

- *Answer - No, an approved biosimilar medicine and its reference medicine are expected to have the same safety and efficacy profile. EU legislation defines the studies that need to be performed for the biosimilar medicine to demonstrate similarity in quality, safety and efficacy (therapeutic effect) in relation to its reference medicine, and that there is no significant clinical difference to the reference medicine. Based on the information published on the EMA website, no specific safety issue has been identified for approved and marketed biosimilar medicines at the time of publication of this consensus information document'*

Ref: EU Commission 2013

To date there have only been limited price reductions for biosimilars. This is changing

- To date there have only been limited price reductions for biosimilars versus the considerable price reductions for oral generics (up to 98%)
- Price reductions for biosimilars have typically averaged between 15% to 30% of the originator price in both Europe and US
- This has been higher in Austria - price reductions are 48% for the first multiple sourced biosimilar; mirroring the situation for small molecule oral generics
- However, the situation in Norway regarding biosimilars especially for Infiximab will change this landscape

Ref: Godman 2013; Matusewicz, Godman et al 2015

The hospitals in Norway combine to achieve good discounts through tendering

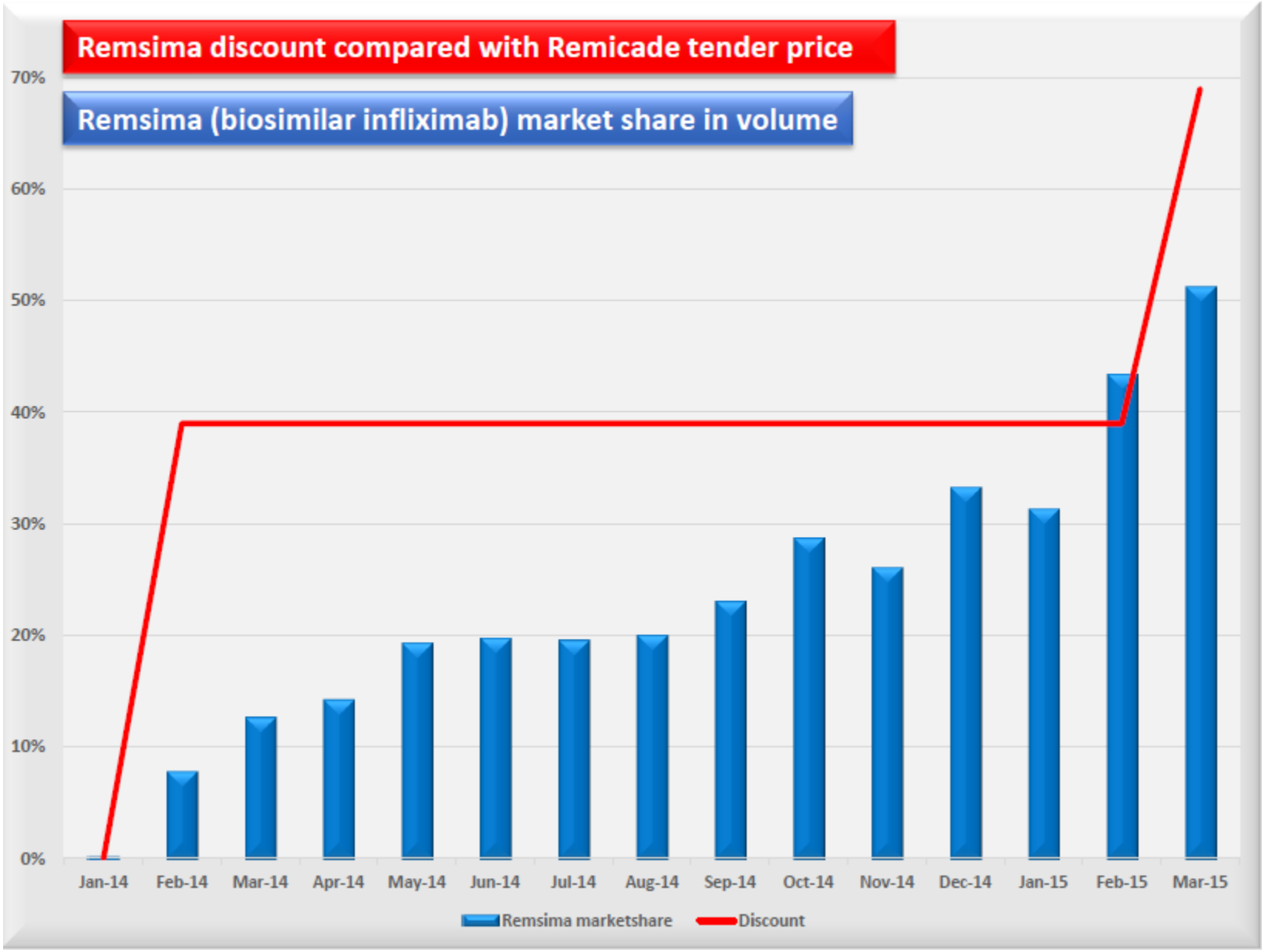
- Currently, tender prices for EPO and filgrastim in Norway are discounted up to 89% among hospitals. Discounts for use outside of hospitals are around 50% for filgrastim and around 25% for epoetin, with a total market share of over 80%

- The new tender for biosimilar Infliximab (Remsima – Orion) started on 1 March 2015 and lasts a year – with the tender price 69% below the REMICADE tender price and 72% below the REMICADE list price (considerable discount from before)

- Alongside this – the Ministry of Health in Norway has funded a study, NOR-SWITCH, to compare REMICADE with Remsima after switching from REMICADE to generate safety and efficacy data regarding Remsima (scheduled to report in 2016)

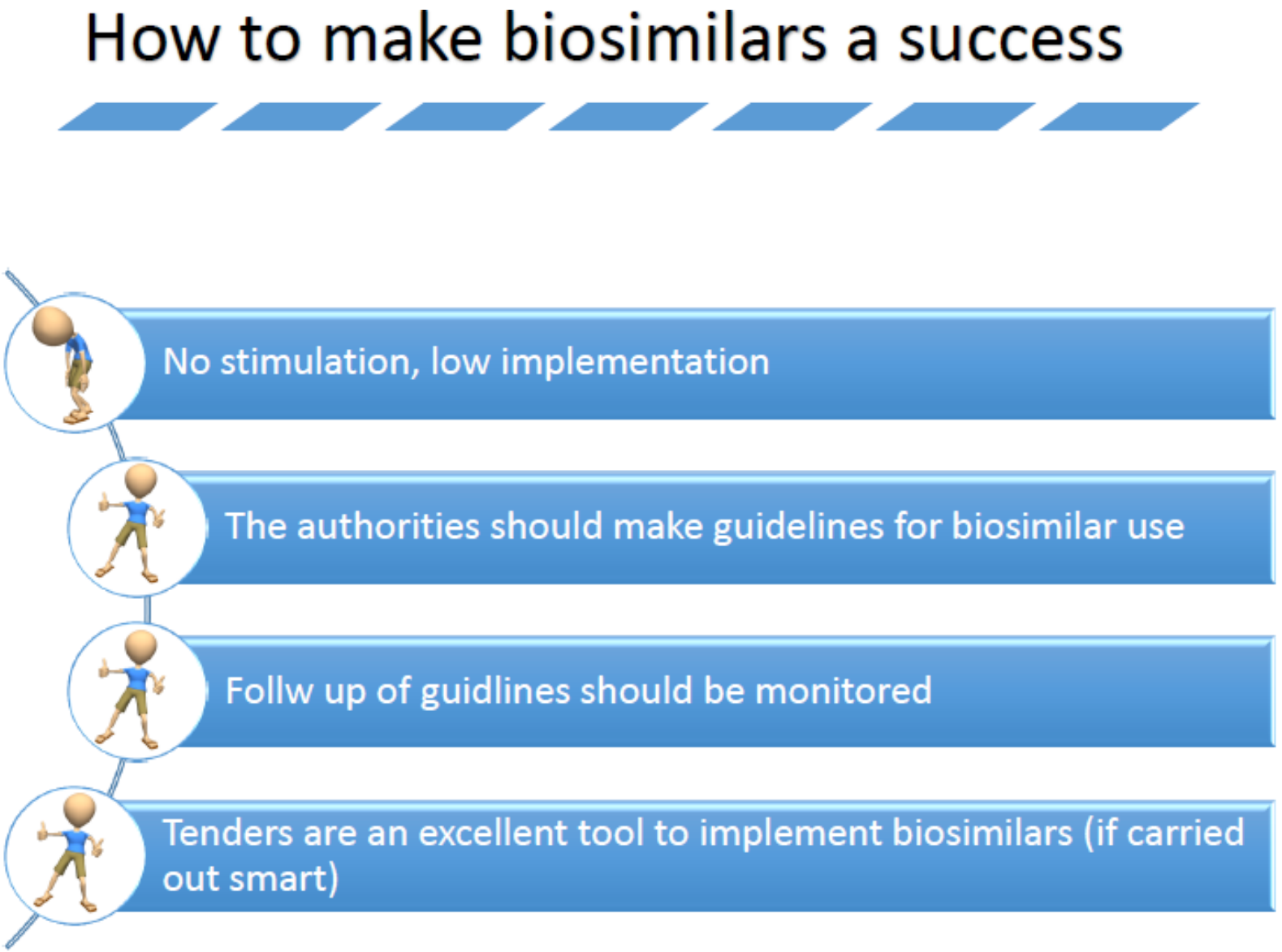
- Preliminary experience with Remsima has been positive – further increasing sales

Ref: Mack 2015; Matusewicz, Godman et al 2015



Ref: Mack – AOTM/ Piperska Conference 2015; Matusewicz, Godman et al 2015

The colleagues in Norway concluded:



Ref: Mack – AOTM/ Piperska Conference 2015

1. Introduction

2. Activities with biosimilars in Europe

3. Conclusions

Biosimilars are here to stay. Their use will increase as more safety data becomes available

- We will see growing use of biosimilars across Europe
- This will be helped by studies demonstrating issues regarding patient safety and efficacy are rhetoric rather than a reality
- As a result – help counteract myths still being promulgated by originator companies (this is still happening for oral generics e.g. clopidogrel)
- Growth in their utilisation will be further stimulated by increasing discounts, building on the experiences in Norway and other countries
- As a result, helping to increase patient access to effective therapies – benefiting all concerned

Thank You

Any Questions!

Brian.Godman@ki.se;
Brian.godman@strath.ac.uk;
mail@briangodman.co.uk