CURRENT POLICY ON ACCESS TO MEDICINES AND HEALTH IN EUROPE

The role of Biosimilar Medicines

Marc – A. Mahl, MD MBA(INSEAD)
President, Medicines for Europe

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The positive experience in Europe

Earlier, broader and expanded access to biologic medicines and healthcare products and services
Europe, the most important biosimilar medicines market in the world

EU cumulated nearly 100% of the use and experience with biosimilar medicines\(^1\) over last 10 years,

Since 2006, EU-approved biosimilar medicines have already generated worldwide more than 700 million days of patient experience\(^2\)

There are >40 biosimilar medicines authorised for 14 biologic reference products

Biosimilar medicines are available for nearly 70% of all therapy areas covered by biologic medicines

References: 1. IMS Health MIDAS MAT Q4 2016; Europe does not include Russia and Turkey
THE BENEFITS OF BIOSIMILAR MEDICINES

- Launch of biosimilar medicines
- Reduction of treatment cost
  - More patients treated
  - More treatment options
  - More autonomy to prescribe
  - More investment for:
    - Hospital infrastructure
    - Capacity building
    - Healthcare services

Eventually:
- Improved care and health outcomes for patients
- Ensured supply chain security
Biosimilars effectively deliver:
Reduced spending and increased use

NHS England:

3 drugs (Infliximab, Etanercept and Rituximab) show a reduced monthly spend but increased usage (16%)

Reduction from circa £41m/month to £24m

Source: Keith Ridge-NHS England: 16th Biosimilar Medicines Group Conference 2018
Large Body of Confirmatory Evidence - 12 Years of Biosimilar medicines Clinical Use

Real-world experience

700 million patient days\(^1\)

“Over the last 10 years, the EU monitoring system for safety concerns has not identified any difference in the nature, severity or frequency of adverse effects between biosimilars and their reference medicine”\(^2\)

Controlled experience

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\(^1\) Medicines for Europe information based on EMA Post-authorisation Safety Update Reports (PSURs)

\(^2\) EMA – European Commission: Biosimilars in the EU – Information guide for healthcare professionals, 2017 (link)
Widespread support for switching biosimilar medicines under supervision of a HCP

Source: Medicines for Europe Internal Biosimilar Mapping
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Biosimilars adoption differs significantly by country and by molecule.

NEW IQVIA report to be launched on 14 Sept 2018

Biosimilar medicines penetration (Dec 2016)


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Main drivers in Europe

- **Unbiased Information** about the science & regulation of biosimilar medicines
- **Payor Strategies** to encourage use of biosimilar medicines
- **Benefit Sharing** with stakeholders
Step 1: Addressing Concerns

1. Quality covered in Marketing Authorisation and by GMP rules
2. Safety profile of reference product well known/applies to biosimilars
3. Clinical and PhV data confirms no difference in immunogenicity
4. Over 700 million patient days confirm equivalent safety/efficacy
5. 90 switching studies confirm that concerns have no scientific basis
Step 1: Information and education

Government

Physicians, HCPs & Patients

Industry

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Step 2: Uptake encouraged by payors

Position papers, accumulated experience & tenders to drive uptake

UK: Introduction of therapeutic tendering for G-CSF (when evidence based-outcomes were the same, decisions about purchasing would be based on cost)
- Hospital protocols were changed to reflect preferred tender win

BS Filgrastim 80+(MS %)

Germany: EPO Biosimilar quotas implemented by majority of KVs have been key driver for uptake

BS EPOs 55+(MS %)

Denmark: RADS included biosimilars in the tender process. Multiple factors considered (Price, Quality of Device, Stability)

BS Filgrastim 65+(MS %)

Hungary: Prior biosimilars WP (Q3-2011), Hungary had very low BS uptake. Leading KOL endorsed the WP, it was then submitted to MoH which instituted favourable reimbursement for BS.

BS Filgrastim 95+(MS %)

Italy: Cost pressures have boosted biosimilars volume substantially. May 2013, AIFA published positive position paper. Uptake does vary by region

BS Filgrastim 65+(MS %); Somatropin 7(MS%)
Italy: Procurement law update

- New tender within 60 days after first biosimilar market entry
- No more “naïve patients only” rule
- AIFA recognizing interchangeability between reference product and correspondent biosimilars medicines

In Italy, AIFA position clarifies that biological and biosimilar medicines cannot be considered sic et simpliciter as generic products.

While considering that the choice of treatment remains a clinical decision entrusted to the prescriber, the latter is also entrusted with the task of contributing to an appropriate use of resources for the sustainability of the healthcare system and the correct patient information on the use of biosimilars.

As demonstrated by the regulatory authorization process, the risk-benefit ratio of biosimilars is the same as that of the reference originators. For such reason, AIFA considers biosimilars as interchangeable products with the correspondent reference originators. This consideration holds true for naïve patients as for patients already under treatment.

Moreover, in view of the fact that the process of evaluation of biosimilarity it is conducted by the EMA and the national regulatory authorities at the highest level of knowledge scientific and based on all available evidence, are not necessary further comparative assessments carried out at regional or local level.
Step 3: Benefit sharing models

Successful introduction of biosimilar medicines use in clinical practice
University Hospital Southampton NHS Foundation Trust – Managed Switching

- Managed switching program – Biosimilar infliximab for IBD
- Team discussions with physicians – agreement with entire medical staff
- Additional staffing to implement and monitor a safe switch
- Additional clinical monitoring and surveillance included at the request of patient panel
- Some of cost-savings being reinvested in improvements of patients’ care
- Continuous communication with patients during switch

134 patients switched from originator to biosimilar infliximab. Only 2 patients have requested review of the switch on medical grounds

Estimated savings after 4 months: £293,000
Biosimilar medicines policies
Physician incentives essential biosimilar market: Norway hospital/retail market

**Anti-TNF**
- Hospital product
- Financial incentive to prescribe biosimilar medicine
  ➔ Massive use of biosimilar medicines

**Insulin**
- Retail product
- No financial incentive to prescribe biosimilar medicine
  ➔ Limited use of biosimilar medicines

Biosimilar market shares 2016

- **82%** Anti-TNF (infliximab + etanercept)
- **1%** Insulin
Patient supplies of retail biosimilars

Adalimumab implementation strategy in UK

Challenge:

• Treatment initiation often in hospital - treatment continuation for months / years in homecare and retail space
• Secure patient prescription and supply consistency, while keeping cost, patient compliance therapy outcome under control
• So far no experience in Europe with hospital – retail transition for Biosimilars

UK strategy:

• Branded and Biosimilar Subgroup is supported the National Homecare Medicines Committee (NHMC) to make recommendations
• This plan will involve engagement and sign up by both providers and commissioners across the NHS in England
• Trusts are requested to ensure the transition is appropriately managed in the context of prescription timelines and range of homecare providers
Concluding remarks

- Vast EU experience with biosimilars - relevant for global users
- Therapeutic equivalence of biosimilar medicines secured by thorough approval process.
- Biosimilar medicines deliver benefits across the healthcare community: better access, earlier access and more treatment options, while contributing to a greater balance in healthcare budgets.
- The body of evidence confirms physician-led switching is safe.
- More benefits could be delivered with supportive policy measures, e.g. improved payor strategies, benefit-sharing schemes, clinical guidance adaptations and a clear regulators' positions on misleading information.
- The biosimilar journey is reaching a new turn with the emergence of biosimilars in retail: preparedness and agility of the system will be needed for a sustainable biosimilars pipeline and inmarket product basket.
THANK YOU!

For more information: https://www.medicinesforeurope.com/biosimilar-medicines/
Contact: jmarechal@medicinesforeurope.com
Biosimilar Medicines Group Membership
Information and education from officials and regulators

- **What you need to know about biosimilar medicinal products**
  European Commission, 2013
  [link](#)

- **What I need to know about biosimilar medicines – Information for patients**
  European Commission, 2016
  [link](#)

- **Biosimilars in the EU – Information guide for healthcare professionals**
  EMA, 2017
  [link](#)

- **The impact of biosimilar competition in Europe**
  QuintilesIMS, 2017
  [link](#)

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Health Care Professionals initiatives to accompany patient-physician dialogue

- Hospital Pharmacists guideline on introducing biosimilar medicines in the hospital
  

- European Specialised Nurses guideline on introducing biosimilar medicines in the hospital
  
  • Available on 26 June: [http://www.esno.org/](http://www.esno.org/)
In addition, industry supports the dissemination of information resources.