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CURRENT POLICY ON ACCESS TO MEDICINES AND HEALTH IN EUROPE

The role of Biosimilar Medicines

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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

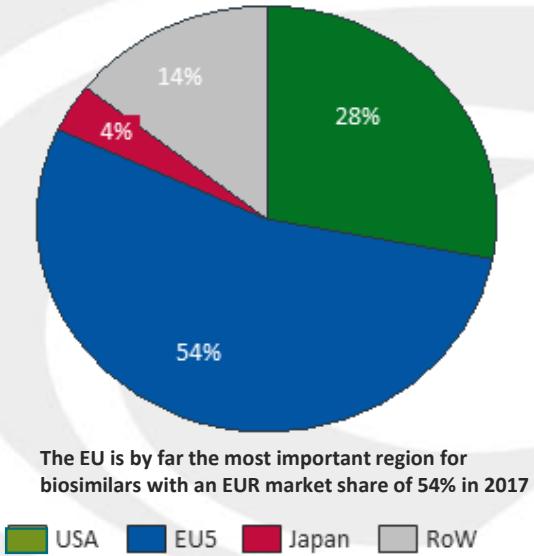
EU cumulated nearly 100% of the use and experience with biosimilar medicines[1] over last 10 years,

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**

Global Biosimilar Sales Split by Countries
(2017, EUR in %)

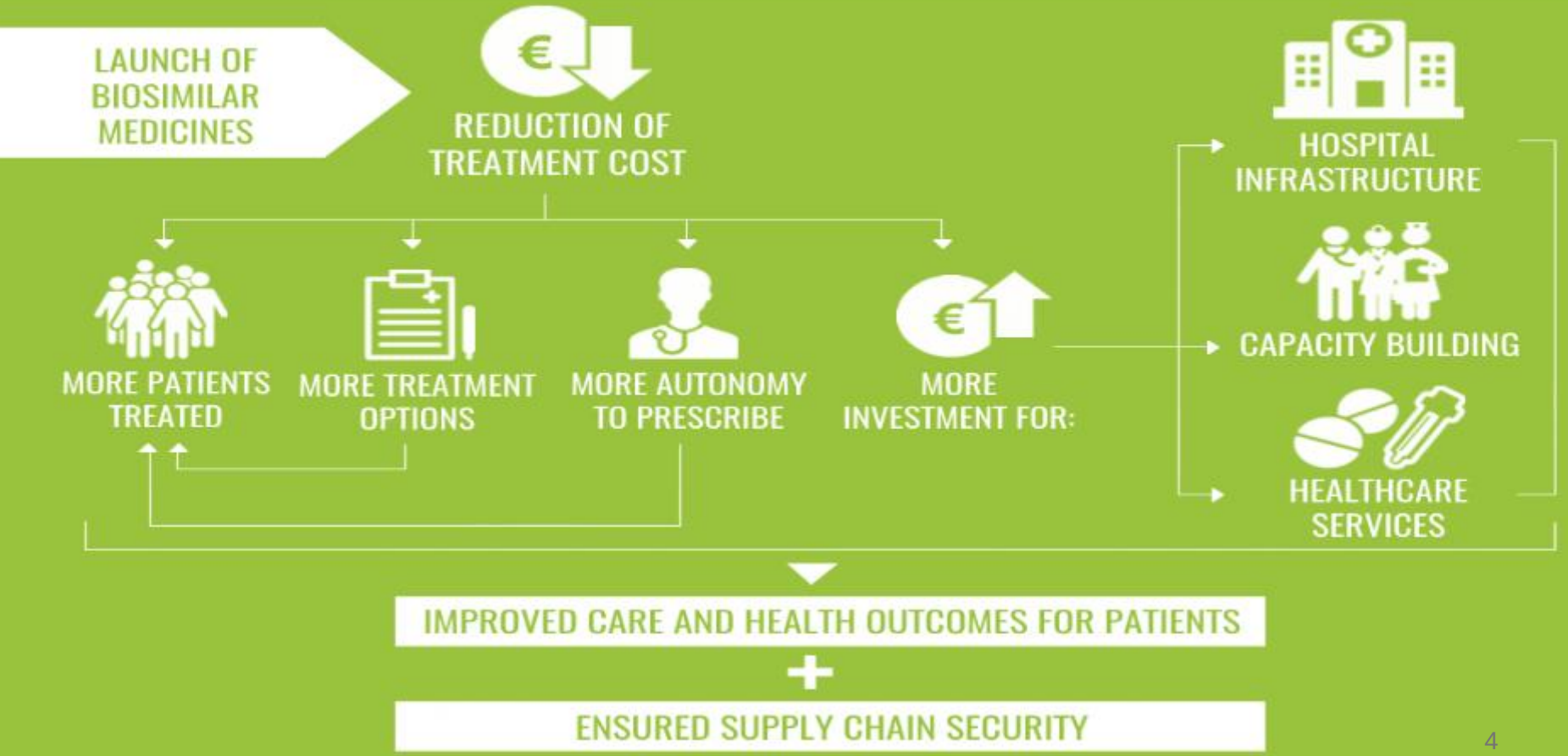


The EU is by far the most important region for biosimilars with an EUR market share of 54% in 2017

References: 1. IMS Health MIDAS MAT Q4 2016; Europe does not include Russia and Turkey
2. Medicines for Europe. Factsheet on Biosimilar Medicines 2016. Available at: http://bit.ly/2bFnrt0. Accessed April 2017

Source: IQVIA MIDAS.

THE BENEFITS OF BIOSIMILAR MEDICINES



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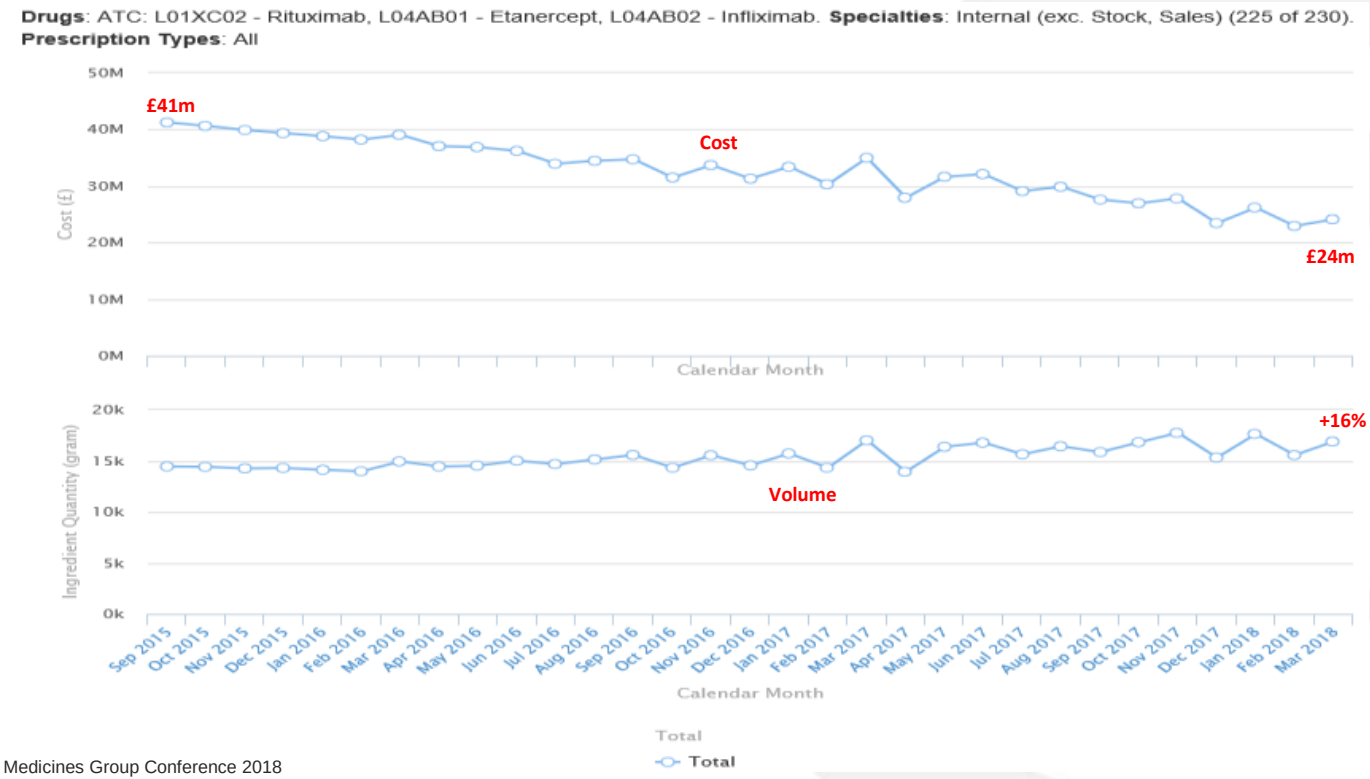
Biosimilars effectively deliver:
Reduced spending and increased use

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

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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

[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

National guidance

Authorities supporting physician-led switching

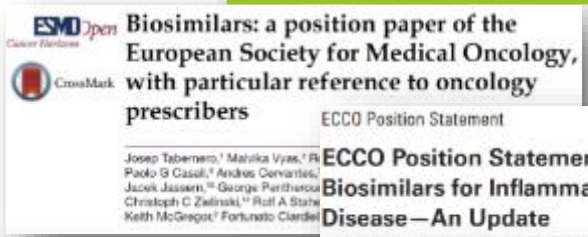
No public position available

Source: Medicines for Europe Internal Biosimilar Mapping

Regulatory guidance

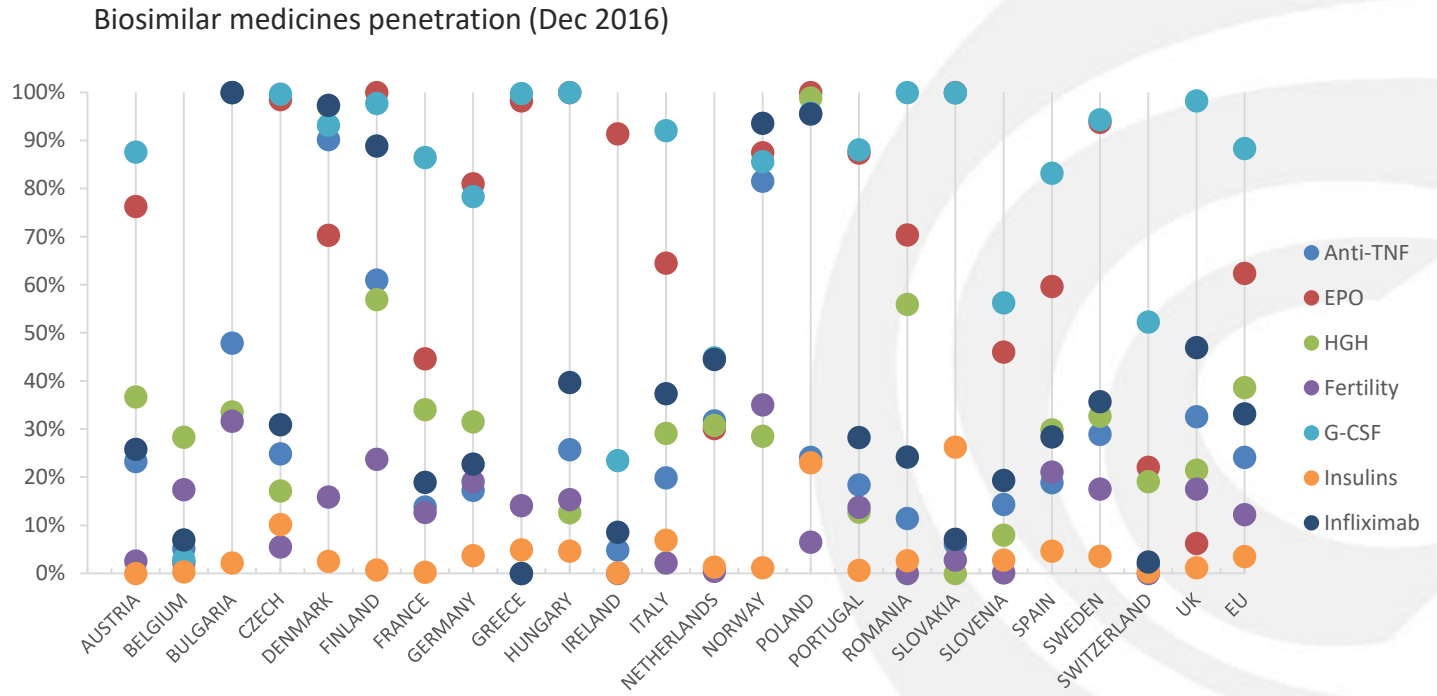
"In our opinion, switching patients from the original to a biosimilar medicine or vice versa can be considered safe."

Clinical guidance



Biosimilars adoption differs significantly by country and by molecule

NEW IQVIA report to be launched on 14 Sept 2018



Source: IQVIA. Medicines for Europe - Generics and Biosimilars Report (2017).

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Drivers of biosimilar access in Europe

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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

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Step 1: Addressing Concerns

- Fear of “low quality” of Biosimilars medicines
- Safety database insufficient at time of licensing
- Increased immunogenicity
- Efficacy may be different from reference product
- Switching from reference to biosimilar medicines

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

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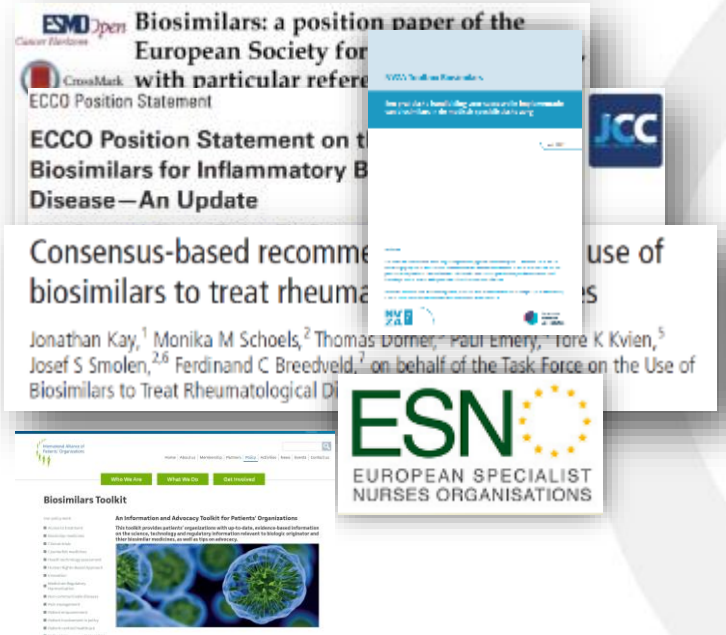
Step 1: Information and education

Government

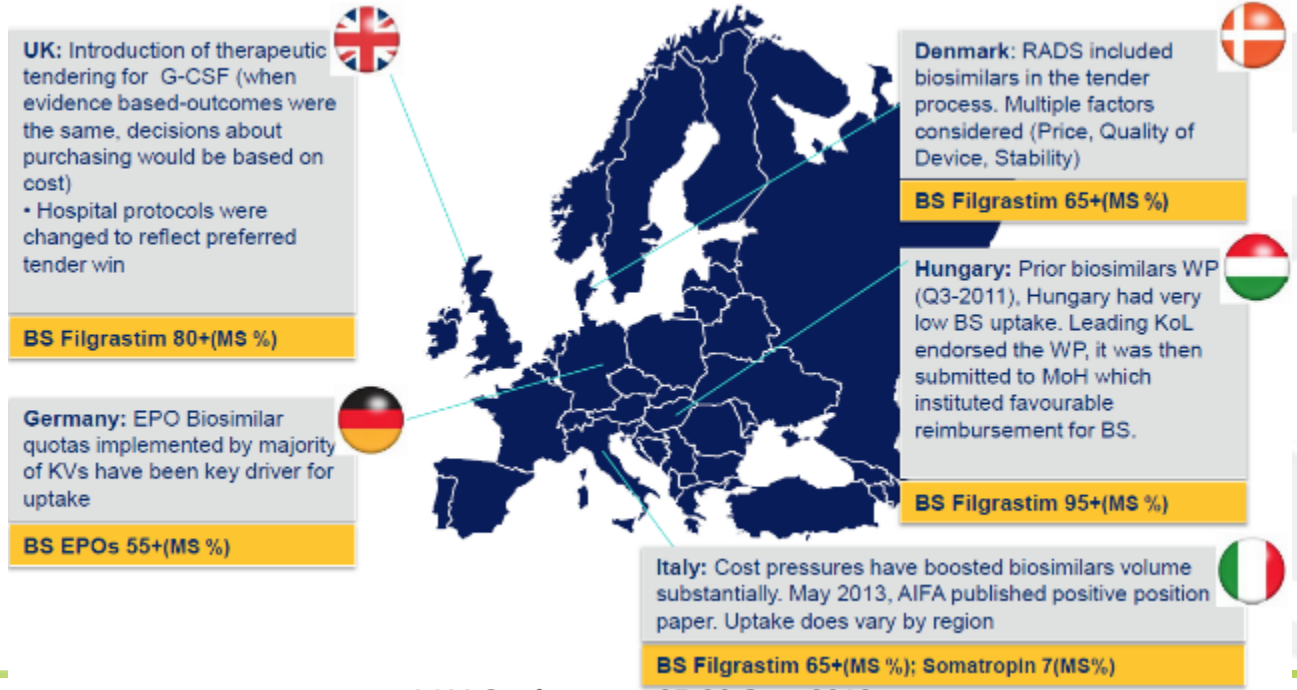
Physicians, HCPs & Patients



Industry

Step 2: Uptake encouraged by payors

Position papers, accumulated experience & tenders to drive uptake



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

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Biosimilar medicines policies

Physician incentives essential biosimilar market: Norway hospital/retail market

Anti-TNF

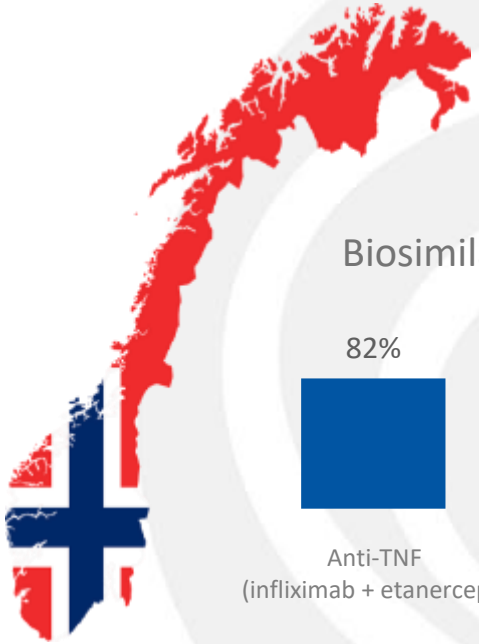
- Hospital product
- Financial incentive to prescribe biosimilar medicine

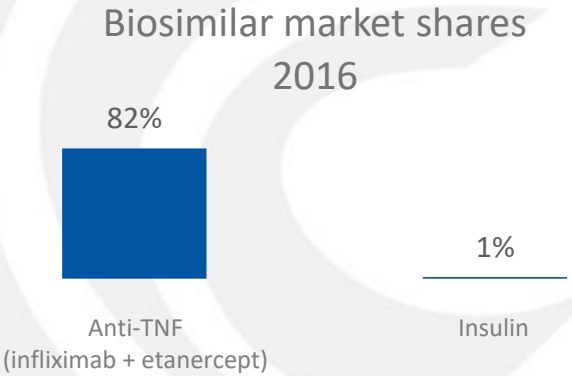
→ **Massive use of biosimilar medicines**

Insulin

- Retail product
- No financial incentive to prescribe biosimilar medicine

→ **Limited use of biosimilar medicines**





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**

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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 accross 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

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17th

Biosimilar Medicines CONFERENCE

28-29 MARCH 2019

AMSTERDAM

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THANK YOU!

For more information: https://www.medicinesforeurope.com/biosimilar-medicines/

Contact: jmarechal@medicinesforeurope.com

patients • quality • value • sustainability • partnership

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Biosimilar Medicines Group Membership

COMPANIES

ASSOCIATIONS

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RESOURCES

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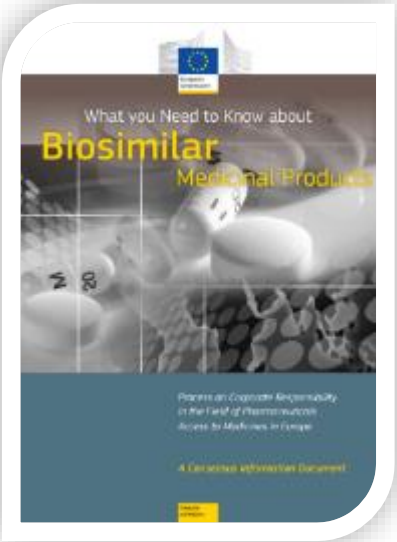
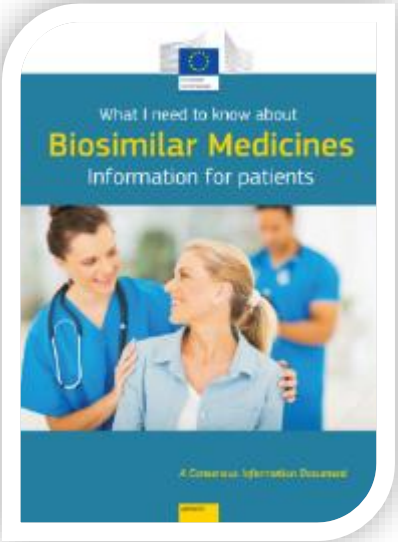
Information and education from officials and regulators



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)

Health Care Professionals initiatives to accompany patient-physician dialogue

Hospital Pharmacists guideline on introducing biosimilar medicines in the hospital

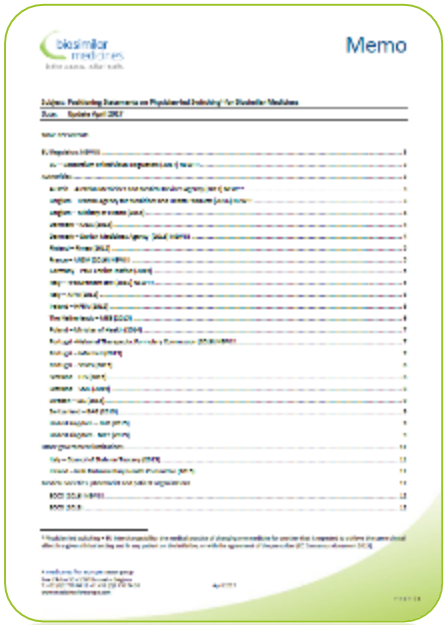
Link: http://nvza.nl/wp-content/uploads/2017/04/NVZA-Toolbox-biosimilars_7-april-2017.pdf

European Specialised Nurses guideline on introducing biosimilar medicines in the hospital

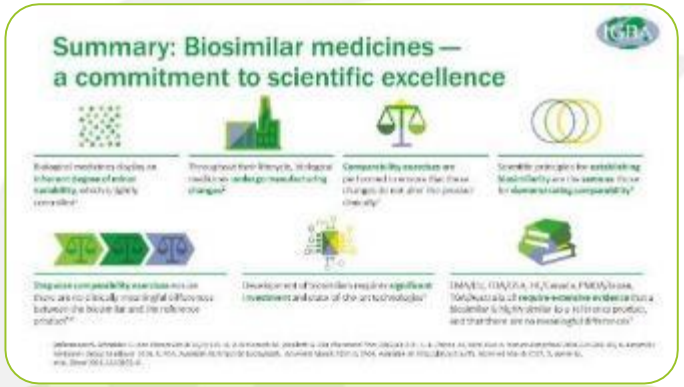
- Available on 26 June: http://www.esno.org/

In addition, industry supports the dissemination of information resources

[Reading List on Biosimilar Medicines]



[Overview of positions on EU physician-led switching for biosimilar medicines]



IGBA Biosimilars Communication tool kit