

CURRENT POLICY ON ACCESS TO MEDICINES AND HEALTH IN EUROPE

The role of Biosimilar Medicines

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President, Medicines for Europe

Baltimore, 05th September 2018

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

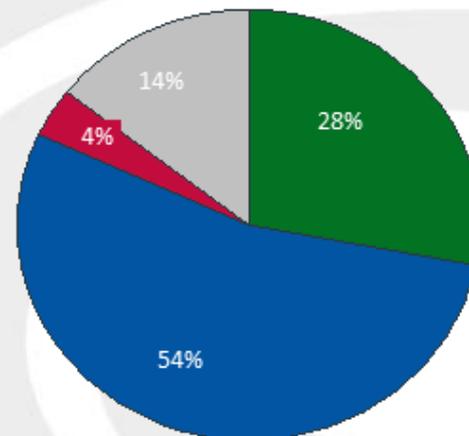
EU cumulated nearly 100% of the use and experience with biosimilar medicines¹ over last 10 years,

Since 2006, EU-approved biosimilar medicines have already generated worldwide more than **700 million days of patient experience²**

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

USA EU5 Japan RoW

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

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

IMPROVED CARE AND HEALTH OUTCOMES FOR PATIENTS



ENSURED SUPPLY CHAIN SECURITY

Biosimilars effectively deliver: Reduced spending and increased use

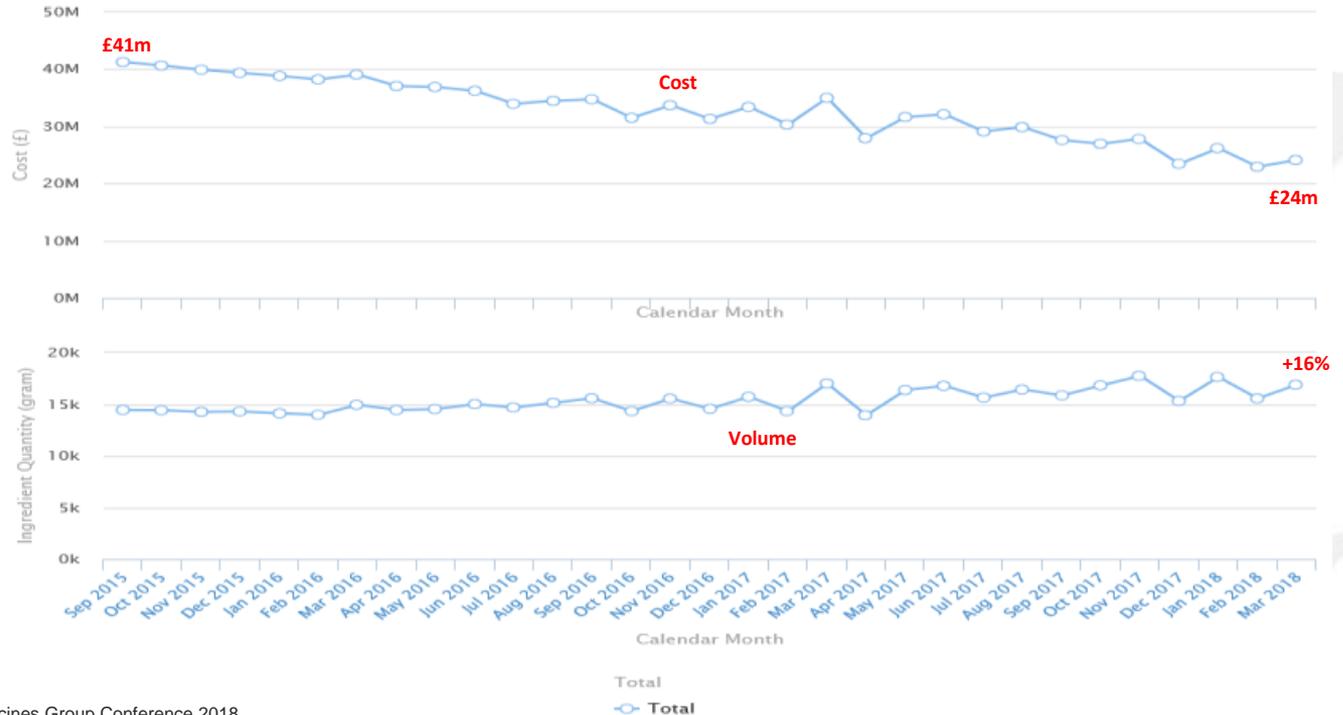


NHS England:

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

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

Drugs: ATC: L01XC02 - Rituximab, L04AB01 - Etanercept, L04AB02 - Infliximab. **Specialties:** Internal (exc. Stock, Sales) (225 of 230). **Prescription Types:** All



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 days¹

*“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

Articles

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

Reith G, Gajjar M, Inge T, Olsen T, Grevi G, Gell P, Møller-Jensen M, Mikkelsen L, Esm A, Karavandary E, Kisti A, Lander C, Mørk J, Jensen J, Jensen T, Jørgensen L, Jørgensen S, Jørgensen T, Jørgensen U, Jørgensen V, Jørgensen W, Jørgensen X, Jørgensen Y, Jørgensen Z, Jørgensen AA, Jørgensen AB, Jørgensen AC, Jørgensen AD, Jørgensen AE, Jørgensen AF, Jørgensen AG, Jørgensen AH, Jørgensen AI, Jørgensen AJ, Jørgensen AK, Jørgensen AL, Jørgensen AM, Jørgensen AN, Jørgensen AO, Jørgensen AP, Jørgensen AQ, Jørgensen AR, Jørgensen AS, Jørgensen AT, Jørgensen AU, Jørgensen AV, Jørgensen AW, Jørgensen AX, Jørgensen AY, Jørgensen AZ, Jørgensen BA, Jørgensen BB, Jørgensen BC, Jørgensen BD, Jørgensen BE, Jørgensen BF, Jørgensen BG, Jørgensen BH, Jørgensen BI, Jørgensen BJ, Jørgensen BK, Jørgensen BL, Jørgensen BM, Jørgensen BN, Jørgensen BO, Jørgensen BP, Jørgensen BQ, Jørgensen BR, Jørgensen BS, Jørgensen BT, Jørgensen BU, Jørgensen BV, Jørgensen BW, Jørgensen BX, Jørgensen BY, Jørgensen BZ, 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Clinical and epidemiological research
Concise report

A nationwide non-medical switch from originator infliximab to biosimilar CT-P13 in 802 patients with inflammatory arthritis: 1-year clinical outcomes from the DANBIO registry

Bente Glomborg^{1,2}, Inge Juul Sørensen^{2,3}, Anne Gitte Lohr², Hanne Lindgaard², Anja Linusson², Oliver Hendricks², Inge Marie Jensen Hansen², Dorthe Vendelbo Jensen^{2,4}, Natalia Manlio^{2,5}, Jakob Espesen^{2,6}, Mette Klarlund^{2,6}, Jolanta Grydehøj^{2,6}, Sabine Sparre Diepenink², Salome Kristensen^{2,7}, Jimmi Sloth Olsen^{2,8}, Henrik Nordin², Stavros Chrysidis^{2,9}, Dorthe Dalsgaard Pedersen^{2,10}, Michael Veedhald Sørensen^{2,11}, Lis Smedegaard Andersen^{2,12}, Kathrine Lederballe Gren², Niels Steen Krogh^{2,13}, Lars Pedersen^{2,14}, Merete Lund Helstrand^{2,14} ¹ On behalf of all departments of rheumatology in Denmark

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

Regulatory guidance

Healthys
DOI: 10.1007/s40259-017-0210-0

CURRENT OPINION

Interchangeability of Biosimilars: A European Perspective

Pekka Kurki¹ · Leon van Aerts² · Elena Wolff-Holz³ · Thijs Venke Shäbel⁴ · Martina Weise⁵

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

Clinical guidance

ESMO Open
Current Evidence

CrossMark

Biosimilars: a position paper of the European Society for Medical Oncology, with particular reference to oncology prescribers

Josep Tabernero,¹ Malvika Vijay,² Pi Paolo G. Casali,³ Andros Cervantes,⁴ Jacek Jassem,⁵ George Pantherou,⁶ Christoph C Zielinski,⁷ Rolf A. Stroh,⁸ Keith McGregor,⁹ Fortunato Ciardiello,¹⁰ Silvin Danova,¹¹ Giuseppina Fiorino,¹² Tim Dainoff,¹³ Marc Ferrante,¹⁴ Julian Panes,¹⁵

ECCO Position Statement

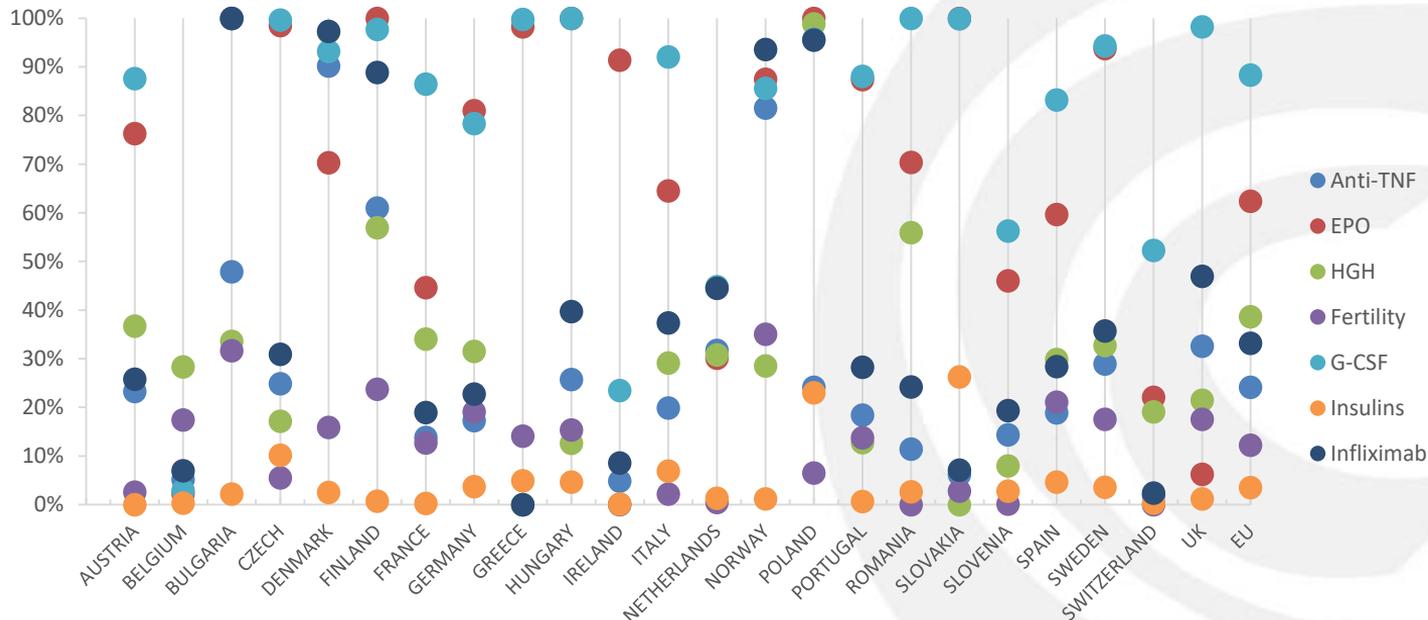
ECCO Position Statement on the Use of Biosimilars for Inflammatory Bowel Disease—An Update

Consensus-based recommendations for the use of biosimilars to treat rheumatological diseases

Jonathan Kay,¹ Monika M Schoels,² Thomas Dörner,³ Paul Emery,⁴ Tore K Kvien,⁵ Josef S Smolen,^{2,6} Ferdinand C Breedveld,⁷ on behalf of the Task Force on the Use of Biosimilars to Treat Rheumatological Diseases

Biosimilars adoption differs significantly by country and by molecule

Biosimilar medicines penetration (Dec 2016)



NEW IQVIA report to be launched on 14 Sept 2018

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

Drivers of biosimilar access in Europe



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

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



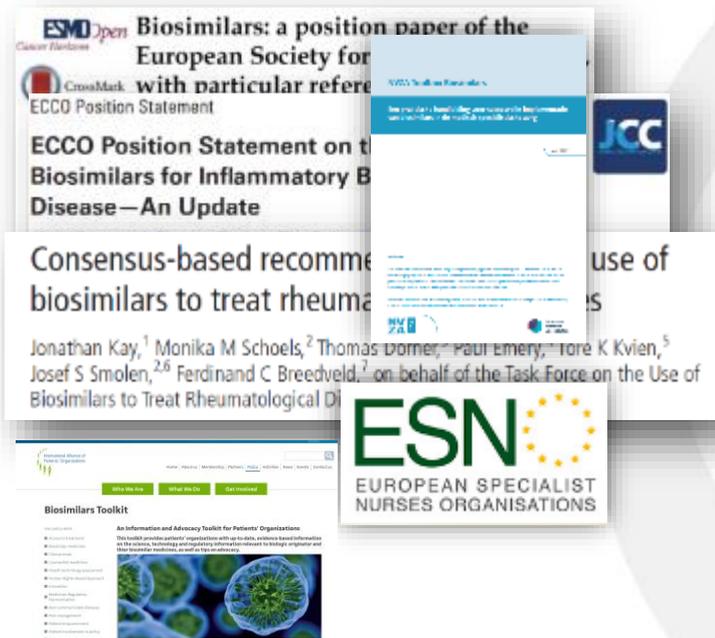
1. Quality covered in Marketing Authorisation and by GMP rules
2. Safety profile of reference product well known/applies to biosimilars
3. Clinical and PhV data confirms no difference in immunogenicity
4. Over 700 million patient days confirm equivalent safety/efficacy
5. 90 switching studies confirm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

Step 1: Information and education

Government



Physicians, HCPs & Patients

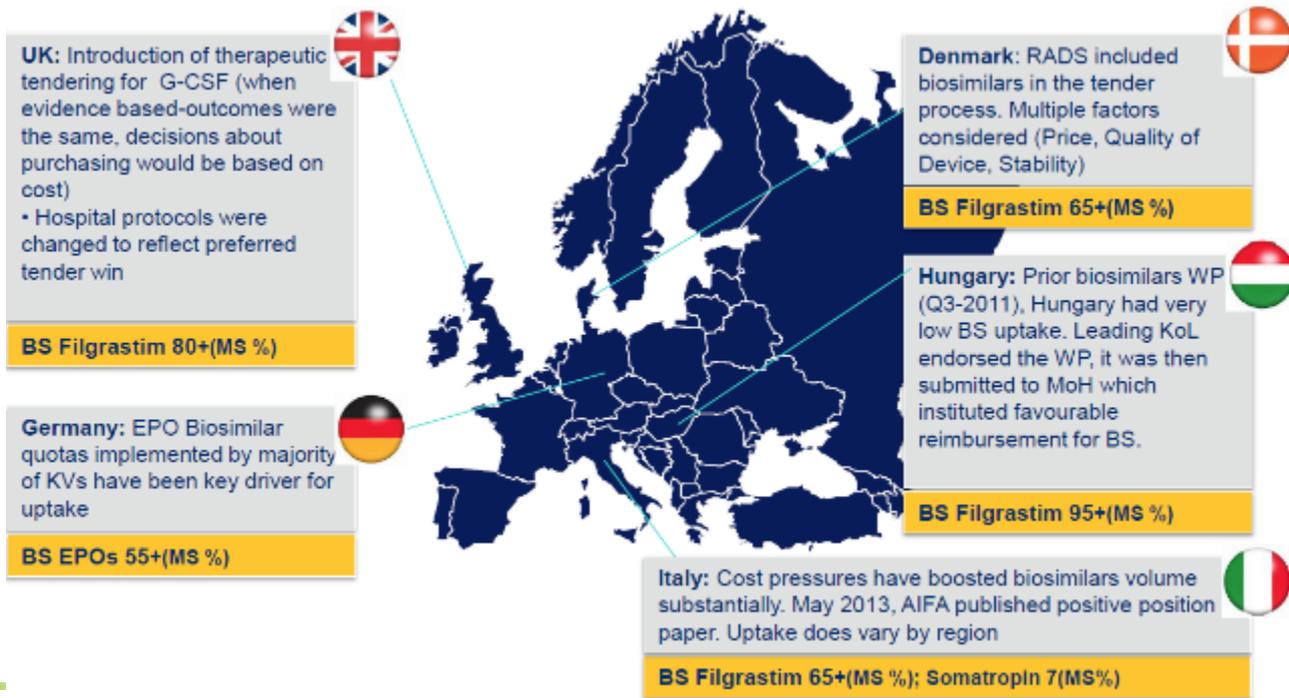


Industry



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

Biosimilar medicines policies



Physician incentives essential biosimilar market: Norway hospital/retail market

Anti-TNF

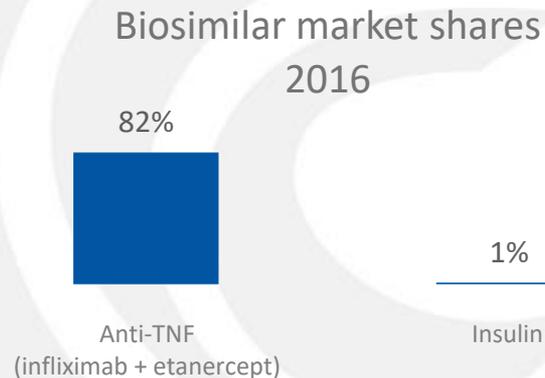
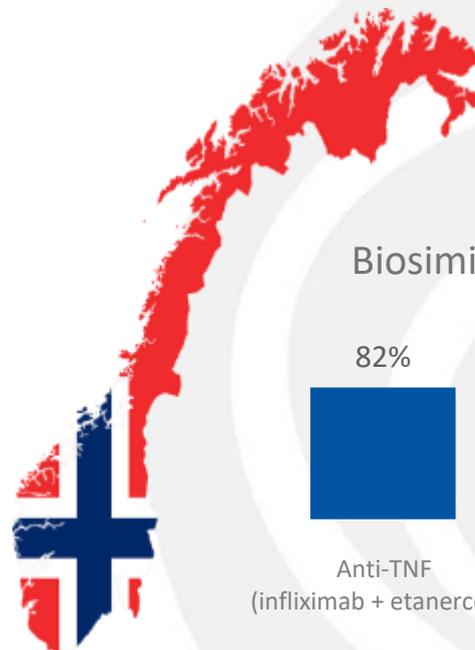
- Hospital product
- Financial incentive to prescribe biosimilar medicine

→ **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**

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



17th

Biosimilar Medicines

CONFERENCE

28-29 MARCH 2019

A M S T E R D A M



#BIOS19
#BiologicsforAll

THANK YOU!

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

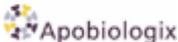
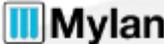
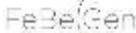
Contact: jmarechal@medicinesforeurope.com



Biosimilar Medicines Group Membership

COMPANIES

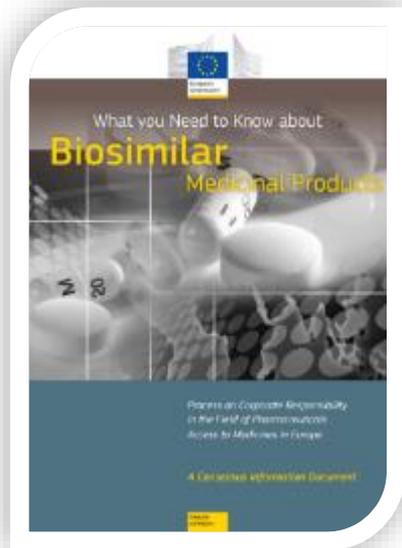
ASSOCIATIONS

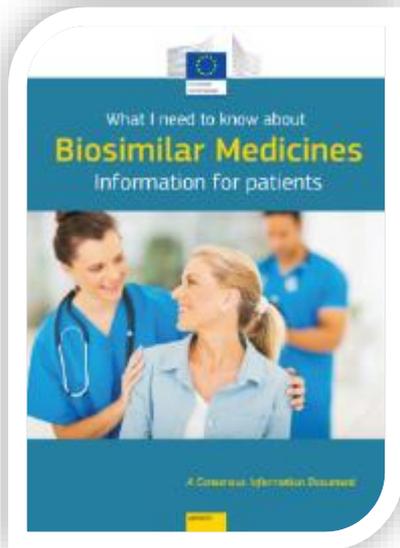
The background of the slide is a close-up photograph of a stack of colorful folders or binders. The folders are in various colors including red, yellow, green, blue, and purple. The edges of the pages are visible, creating a layered, textured effect. A semi-transparent grey circle is overlaid on the right side of the image.

RESOURCES

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/>

