Biosimilars, what is the best way to guide patients? Role of hospital and community pharmacists.

Kleio Bourika, MPharm, MSc, Community Pharmacist – Athens, Greece
Assist. Mina Kovačevič, MPharm, spec. clin. pharm., Institute of Oncology Ljubljana, Slovenia

02.07.2022

CONFLICT OF INTEREST

WE CERTIFY THAT THE SUBMISSION IS ORIGINAL WORK AND DECLARE THAT WE HAVE NO CONFLICTS OF INTEREST.

CONTENT

- BIOSIMILARS: CHALLANGE, CHANGE AND ACOMPLISHMENTS
- BIOSIMILARS IN ONCOLOGY/ HEMATOLOGY
- BIOSIMILARS IN SUPPROT THERAPY
- HOSPITAL USED BIOSIMILARS
- BIOSIMILARS AVAILABLE IN COMMUNITY PHARMACY AROUND EUROPE
- REGULATION OF BIOSIMILARS IN EU – WHAT, WHO, WHERE?
- LIST OF AVAILABLE BIOSIMILARS IN EUROPE – HELP IN HAND FOR PHARMACISTS
- IMPORTANT INFORMATION FOR HEALTHCARE PROFESSIONALS
- WHAT SHOULD PATIENTS KNOW ABOUT BIOSIMILARS
- IMPACT OF COVID-19 PANDEMIC ON BIOLOGIC MARKET

OBJECTIVES OF THIS SESSION

- Introduction of basic terms
- List of available biosimilars in EU
- Regulations of biosimilars
- Patient counselling on biosimilars

GENERAL TERMS

❖ Biologics

- A biologic is a medicine made from a variety of natural sources that may be human, animal or microorganism in origin.
- The first or original biologic on the market is termed “the originator” or “reference product”

❖ Biosimilars

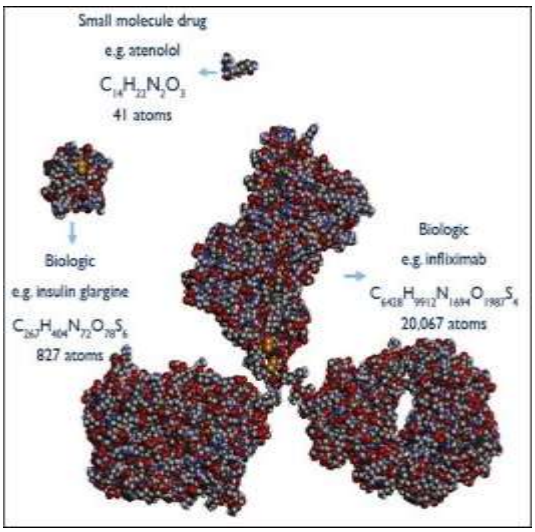
- A biosimilar is a biologic medicine that is similar to an already licensed biologic medicine in terms of quality, safety and efficacy.
- It is licensed to treat the same disease as the original innovator product.
- It can only be marketed after the patent protecting the originator product and any period of marketing exclusivity **have expired**.

Royal Pharmaceutical Society, Explaining Biosimilar Medicines – A quick reference guide, 2017

GENERAL TERMS

❖ Biosimilar Vs Generic medicine

- Generic medicine is an identical copy of a small molecule drug
- Biosimilars are very similar to the reference product **but not identical** due to:
  - Complexity of structure
  - Greater size
  - Inherent heterogeneity



Introduction to biosimilars and regulatory requirements, IAPO

Royal Pharmaceutical Society, Explaining Biosimilar Medicines – A quick reference guide, 2017

GENERAL TERMS

Comparison of development and characteristics between generics and biosimilars

Generic medicine	Biosimilar medicine
Usually produced by chemical synthesis	Obtained from a biological source
Generally possible to obtain exactly the same molecule	Possible to produce the molecule to a high degree of similarity due to unique biomanufacturing methods and a natural biological variability
Mostly smaller molecules, easier to characterize	Generally, larger structurally more complex molecules, which require multiple technologies for their characterization
Full data requirements on pharmaceutical quality	Full data requirements on pharmaceutical quality, plus additional quality studies comparing the structure and biological activity of the biosimilar with the reference medicine

EMA, Biosimilars in the EU, Information guide for healthcare professionals

GENERAL TERMS

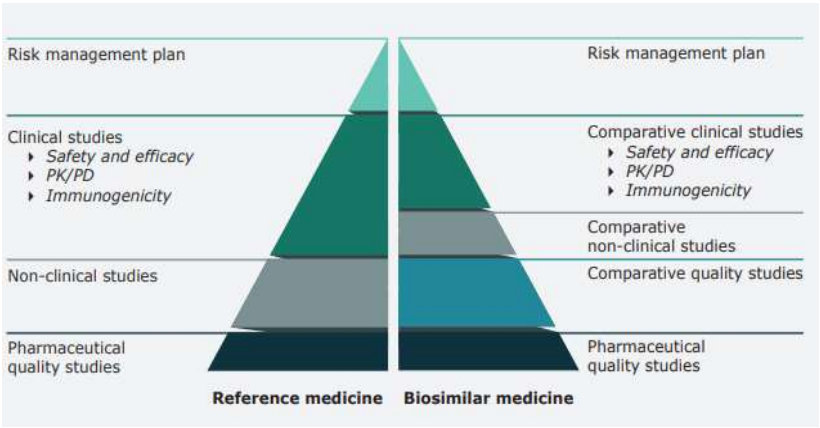
Comparison of development and characteristics between generics and biosimilars (cont.)

Generic medicine	Biosimilar medicine
Development based on demonstration of bioequivalence (i.e. that the generic and the reference medicine release the active substance into the body at the same rate and to the same extent under similar conditions)	Development based on demostration of biosimilarity using comparability studies (comprehensive head-to head comparison of the biosimilar with the reference medicine to show high similarity in chemical structure, biological function, efficacy, safety and immunogenicity)
Clinical data requirements are mainly pharmacokinetic bioequivalence studies	In addition to comparative PK and PD studies, safety and efficacy data maybe required, particularly for more complex biological medicines
All indications approved for the reference medicine can be granted based on demonstrated bioequivalence, without the need for further clinical data	Efficacy and safety have to be justified in each indication. However, confirmatory clinical trials with the biosimilar are usually not needed in every indication that has been approved for the reference medicine. After, demonstration of biosimilarity, extrapolation of data to other indications is possible if the scientific evidence available addresses all specific aspects of these indications.

EMA, Biosimilars in the EU, Information guide for healthcare professionals

ORIGINATOR vs. BIOSIMILAR

Comparison of data requirements for approval of a biosimilar Vs reference medicine



Positive benefit-risk balance

ORIGINATOR

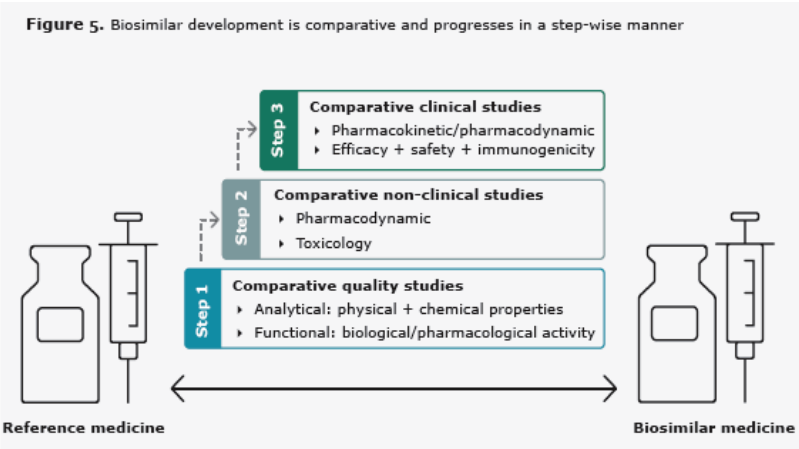
Evidence of safety and efficacy in pivotal trials in humans

BIOSIMILAR

- Biosimilarity
- Comparability studies with the reference medicine

EMA, Biosimilars in the EU, Information guide for healthcare professionals

ORIGINATOR vs. BIOSMILAR: Comparability studies



Comprehensive comparative quality studies prove that physicochemical properties and biological activity are **highly similar**

The comparative clinical and non-clinical studies, that support the approval of a biosimilar **rule out** differences which may affect the medicine's safety

EMA, Biosimilars in the EU, Information guide for healthcare professionals

The story so far…

❖ Biosimilars have been authorized for marketing:

- in the European Union (EU) since 2006,
- in Australia since 2010,
- in the US since 2015 and
- in Thailand since 2017.

❖ Biosimilars → cost effective choice for health care systems

- US market: estimation of ↓ $54 billion from 2017 to 2026.
- Europe: by 2020 the expected savings in health care costs through the use of biosimilars have been estimated to reach up to €33 billion

(Arnet I. et al, 2021, Community pharmacists' preparedness for substituting biologics and dispensing biosimilars – Lessons learned from a multinational survey, Exploratory research in Clinical and Society pharmacy 4:2021)

PROS AND CHALLANGES

PROS

- Cost reduction by competition
- Increased accessibility
- Foster of innovation

CHALLANGES

- Batch to batch variations
- Time and cost to develop
- Manufacturing process
- Intellectual property rights
- Education of: healthcare professionals, patients, pharmacists
- Uptake → challenging due to limited healthcare providers/patient's acceptance of biosimilars

Mewies, M. 2019. Biosimilars: Change, challenge, and accomplishments, Medical Writing, 28(2), p.60-65.

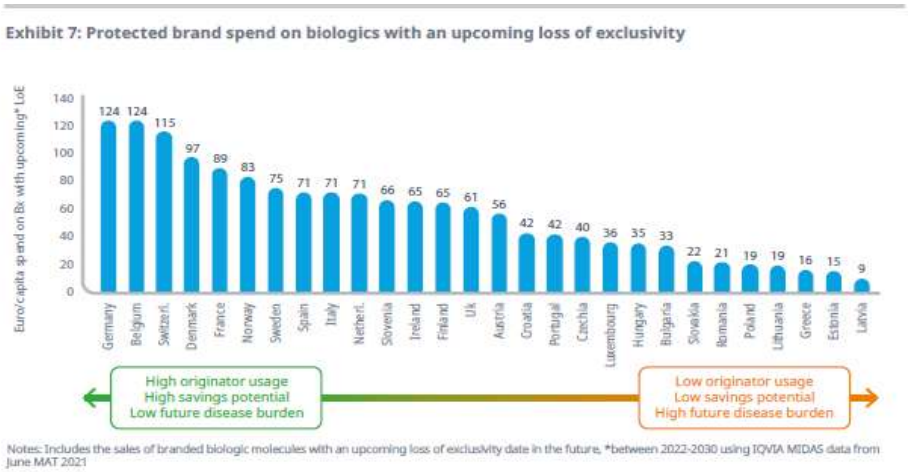
Vanderplas, J et al. 2021. Informing patients about biosimilar medicines: The Role of European Patient Associations, Pharmaceuticals, 14, 117.

ACCESIBILITY OF BIOSIMILARS

- Growth in access is limited due to historic usage of protected brands
  - Behavioural economics
    - Default status
    - Familiarity
    - Outcome bias

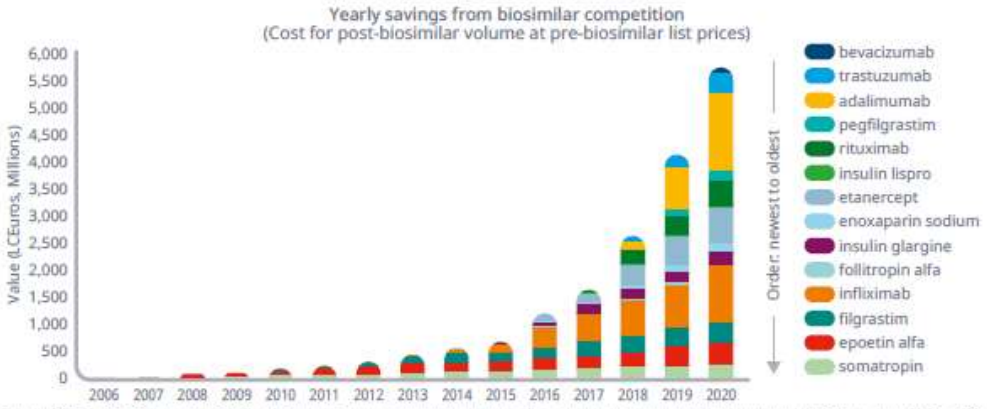
Nabhan C, Fillman J, Ernst FR, Feinberg BA. Community oncologists' perception and understanding of biosimilars' role in oncology.

Savings depending on the usage of originator



Cost reduction by competition

Exhibit 4: Long-term view on list price savings from biosimilar competition

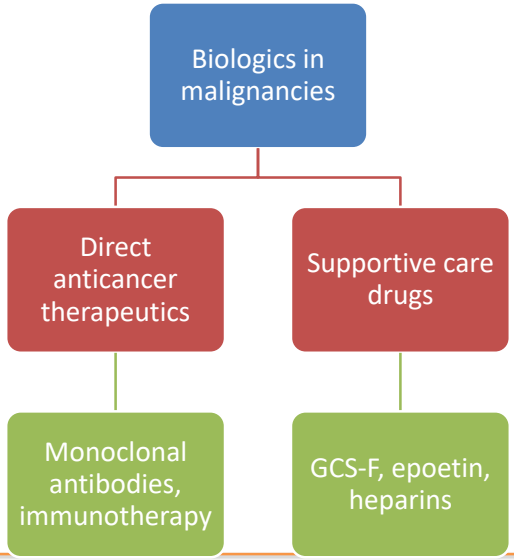


Source: IQVIA MIDAS™ data from 2006 – 2020, using Euros at constant exchange rates; 14 originator products with approved biosimilars from 2006 – 2020 (includes biosimilar and originator), covering the full European Economic Area (33 CTYs), calculated volume is in treatment days determined by WHO-DDD, and where values are unavailable via Oncology Dynamics Physician Survey (2017) DDD estimates

CONCERNS?

- Immunogenicity (cross immunogenicity)
- Efficacy/effectiveness
- Safety/quality
- Switching/extrapolation/interchangeability
- Nocebo effect
- Payment?

BIOLOGICS IN CANCER TREATMENT

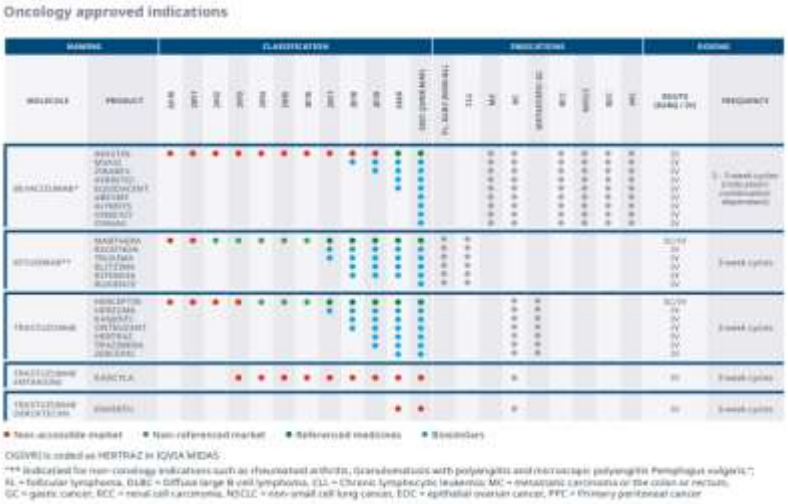


BIOSIMILARS IN ONCOLOGY/HEMATOLOGY

- Monoclonal antibodies are able to bind monospecifically to certain cells or proteins to treat cancer with the stimulation of patient's immune system to attack cancer cells
- Approaching biosimilar competition: not many molecules are available, since the total oncology market includes new innovative medicines that would be classified as non-accessible
- Rituximab: iv and sc form → Mabthera iv is classified as reference product, sc form of Mabthera is classified as non-referenced product

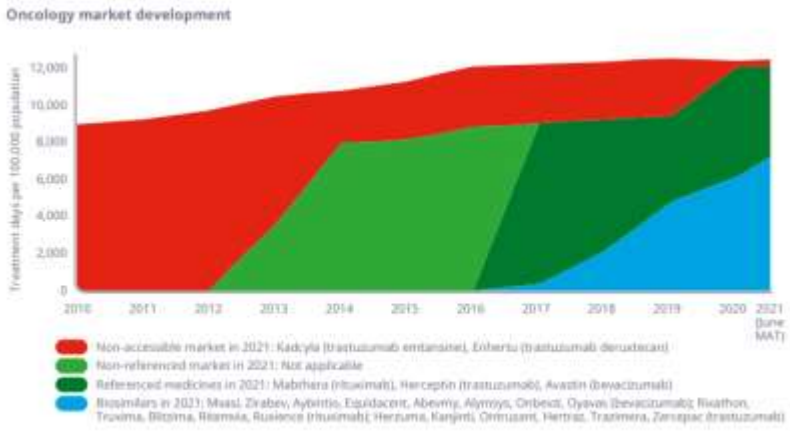
IQVIA. 2021. The Impact of Biosimilar Competition in Europe.

BIOSIMILARS IN ONCOLOGY/HEMATOLOGY



IQVIA. 2021. The Impact of Biosimilar Competition in Europe.

ONCOLOGY MARKET IN DEVELOPMENT



IQVIA. 2021. The Impact of Biosimilar Competition in Europe.

BIOSIMILARS IN ONCOLOGY/HEMATOLOGY/AUTOIMMUNE DISEASES

- Monoclonal antibodies:
  - Rituximab: CLL, CD20+ lymphomas, follicular lymphomas
  - Trastuzumab: HER-2+ breast and gastric cancer
  - Bevacizumab: breast cancer, renal cell carcinoma, ovarian cancer, cervical cancer, NSC lung cancer
- Proteins that mimic receptors:
  - Adalimumab: rheumatoid arthritis, psoriasis, Crohn´s disease, ulcerative colitis, ankylosing spondylitis
  - Infliximab
  - Etanercept

SWITCHING STRATEGIES IN ONCOLOGY/HEMATOLOGY

- Multidisciplinary steering group to support biosimilar adoption to be formed → 90 % of new patients should start a best value biological drug, 80 % off all existing patients should be switched to biosimilar within 12 months (NHS)

This should be supported with patient communication materials

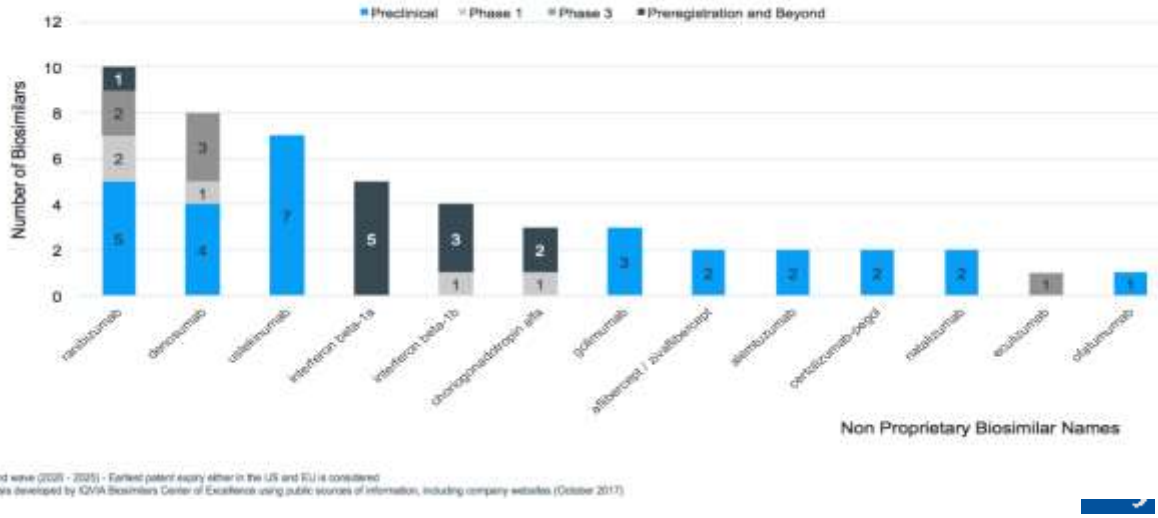
- Economic considerations

Cornes, P. and McBride, A. 2020. Biosimilars in Hematology and Oncology.

BIOSIMILARS IN DEVELOPMENT → "SECOND WAVE OF BIOSIMILARS"

Huml, R.A. et al. 2018. Trends in Biosimilars: Innovative Approaches to Expediting Development

Figure 6. Biosimilars in Development for the 'Second Wave' of Biosimilars[31]



Second wave (2020 - 2025) - Earliest patent expiry either in the US and EU is considered
Analysis developed by IQVIA Biosimilars Center of Excellence using public sources of information, including company websites (October 2017)

BIOSIMILARS IN SUPPORTIVE CANCER CARE

- Supportive cancer therapy:
  - is the use of medicines to counteract unwanted effects of cancer treatment
  - Therapies for supportive care were the first approved biosimilars in EU
    - ❖Filgrastim and epoetin alfa (2007)
  - Many biosimilars have been approved for all indications of the reference product
  - Approval achieved by:
    - ○ direct comparisons to the reference product using analytic methods to indicate similarities in molecular structure, in vitro properties, PK and PD properties and MoA
    - ○ Efficacy and safety studies

Cornes P. and Aapro M., 2018, The impact of biosimilars in supportive care in cancer. Supportive Oncology

BIOSIMILARS IN SUPPORTIVE CANCER CARE – EPOETIN – α

- Erythropoiesis-stimulating agents (ESAs)
  - red blood cell factors – stimulate bone marrow
  - Used to treat CIA (Chemotherapy-induced Anemia)
  - Original ESAs : epoetin alfa, epoetin beta, epoetin zeta, epoetin theta and darbepoetin alfa
    - Identical amino acid sequences
    - Major difference - glycosylation patterns
  - 2007: the patent of epoetin alfa (EPREX) expired
    - Biosimilars approved by EMA: Binocrit ®, Abseamed®, Hexal ®, Retacrit®

Foreman E., 2020, Biosimilars in supportive care. Co-oncology. 32: 4
Yang J. et al., 2019, Efficacy and safety of supportive care biosimilars among cancer patients: a systematic review and meta-analysis,Spinger Nature Switzerland

BIOSIMILARS IN SUPPORTIVE CANCER CARE – EPOETIN – α

- Studies on Epoetin – alfa
  - Yang et al.
    - metaanalysis of one RCT and five cohort studies
    - Comparison of epoetin –α biosimilars vs reference product
    - Results showed similar efficacy in terms of mean increase
      - in haemoglobin,
      - haemoglobin response rate,
      - similar incidence of adverse events
  - ASCO in association with American Society of Haematology
    - One RCT and three cohort studies in cancer associated anaemia
    - Results => equivalence in effectiveness and safety

Foreman E. ,2020/ Yang J. et al., 2019

BIOSIMILARS IN SUPPORTIVE CANCER CARE – EPOETIN – α

- Example of the impact of biosimilar ESAs in cost effectiveness
  - NICE heath technology appraisals
    - 2008 ESAs were considered as not cost effective at list price
      - As a result blood transfusion was the only treatment for CIA
    - 2014 introduction of biosimilars had reduced the prices
      - As a result NICE reviewed their guidance and ESAs were approved for reimbursement within NHS

Foreman E., 2020, Biosimilars in supportive care. Co-oncology. 32: 4
Yang J. et al., 2019, Efficacy and safety of supportive care biosimilars among cancer patients: a systematic review and meta-analysis,Spinger Nature Switzerland

BIOSIMILARS IN SUPPORTIVE CANCER CARE – filgrastim

- Granulocyte colony-stimulating factors (G-CSFs)
  - White blood cell factors – stimulate the proliferation and differentiation of neutrophil precursors and the function of mature neutrophils
  - Used to treat chemotherapy-induced neutropenia (CIN)
  - Original G-CSFs: filgrastim, pegfilgrastim, lenograstim
  - 2006: the patent expired
    - Examples of biosimilars approved by EMA: Biograstim®, Zarzio®, Accofil®, Nivestim®
  - Metaanalysis of 13 RCTs and 9 cohort studies
    - Comparison of filgrastim biosimilar vs reference product
    - Results showed similar efficacy
    - Similar incidence of adverse events

Foreman E. ,2020/ Yang J. et al., 2019

BIOSIMILARS IN SUPPORTIVE CANCER CARE – filgrastim

- Example of the impact of biosimilar filgrastim in cost effectiveness
  - Before the launch of biosimilar filgrastim, the use was restricted to patients on the most severely myelosuppressive treatment regimes.
  - The introduction of biosimilars not only delivered cost savings but also increased usage => allowing more patients to benefit from treatment.
  - NHS made an estimated 1 million GBP per year cost saving despite an increase of 40% in usage.
  - In Europe, the savings were estimated at € 85 million per year

Foreman E., 2020, Biosimilars in supportive care. Co-oncology. 32: 4
Yang J. et al., 2019, Efficacy and safety of supportive care biosimilars among cancer patients: a systematic review and meta-analysis,Spinger Nature Switzerland

HOSPITAL USED BIOSIMILARS IN ONCOLOGY/HEMATOLOGY

- Rituximab
- Trastuzumab
- Bevacizumab

DIRECT ANTICANCER THERAPY

- Filgrastim
- Peg filgrastim

SUPPORT THERAPY/TREATMET OF DIFFERENT COMORBITITIES

- Epoetin alfa
- Enoxaparin Sodium
- Insulin aspart
- Insulin glargine
- Insulin lispro

BIOSIMILARS AVAILABLE IN COMMUNITY PHARMACY

- Filgrastim
- Peg filgrastim

- Epoetin alfa
- Enoxaparin Sodium
- Insulin aspart
- Insulin glargine
- Insulin lispro
- Teriparatide

SUPPORT THERAPY/TREATMET OF DIFFERENT COMORBIDITIES

List of authorized biosimilars in EU

Non – Proprietary name	Originator Product	Therapeutic area	Biosimilar (Date of authorization)	
Adalimumab	Humira	Rheumatoid /psoriatic/juvenile arthritis; ankylosing spondylitis; psoriasis; ulcerative colitis; Chron disease; uveitis	Imraldi (08/2017) Yuflyma (02/2021) Hyrimoz (07/2018) Hefiya (07/2018) Idacio (04/2019) Kromeya (04/2019)	Hukyndra (11/2021) Libmyris (11/2021) Hulio (09/2018) Amgevita (03/2017) Amsparity (02/2020) Helimatoz (07/2018)
Bevacizumab	Avastin	Colorectal/ breast/ ovarian/peritoneal/ uterine cervical neoplasms, NSCL/ renal cell carcinoma	Abemvy (04/2021) Zirabev (02/2019) Oyavas (03/2021) Alymsys (03/2021)	Equidacent (09/2020) Onbevzi (01/2021) Aybintio (08/2020) Mvasi (01/2018)
Enoxaparin Sodium	Clexane	Venous thromboembolism	Inhixa (09/2016) Thorinane (09/2016)	
Epoetin alfa	Eprex	Anemia; autologous blood transfusion; chronic kidney failure	Binocrit (08/2007) Abseamed (08/2007) Retacrit (12/2007)	Epoetin Alfa Hexal (08/2007)

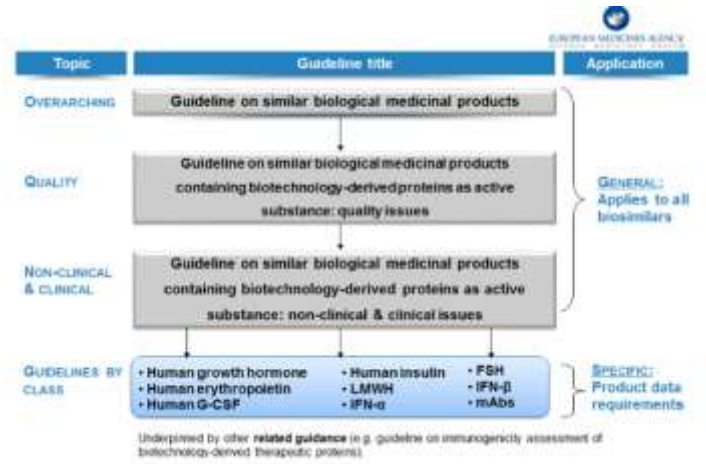
List of authorized biosimilars in EU

Non – Proprietary name	Originator Product	Therapeutic area	Biosimilar (Date of authorisation)	
Etanercept	Enbrel	Rheumatoid /psoriatic/juvenile arthritis; ankylosing spondylitis;	Erelzi (06/2017) Nepexto (05/2020)	Benepali (01/2016)
Filgrastim	Neupogen	Neutropenia; hematopoietic stem cell transplantation; cancer	Nivestim (06/2010) Tevagrastim (09/2008) Accofil (09/2014) Flixabi (05/2016)	Grastofil (10/2013) Ratiograstim (09/2008) Zarzio (02/2009) Filgrastim Hexal (02/2009)
Insulin aspart	NovoRapid	Diabetes Mellitus	Insulin aspart Sanofi (06/2020) Kirsty (02/2021)	
Insulin glargine	Lantus	Diabetes Mellitus	Abasaglar (09/2014) Semglee (03/2018)	
Insulin lispro	Humalog 100 U/ml	Diabetes Mellitus	Insulin lispro Sanofi (07/2017)	
Infliximab	Remicade	Psoriatic arthritis; psoriasis; Chron disease;ankylosing spondilitis	Inflectra (09/2013) Remsima (09/2013) Zessly (05/2018)	

List of authorized biosimilars in EU

Non – Proprietary name	Originator Product	Therapeutic area	Biosimilar (Date of authorisation)	
Pegfilgrastim	Neulasta	Neutropenia	Fulphila (11/2018) Ziextenzo (11/2018) Stimufend (03/2022) Pelgraz (09/2018) Udenyca (09/2018)	Pelmeg (11/2018) Cegfila (12/2019) Nyvepria (11/2020) Granustek (06/2019)
Ranibizumab	Lucentis		Byooviz (04/2022)	
Rituximab	Mabthera	Non-Hodgkin lymphoma; leukemia; rheumatoid arthritis;	Truxima (02/2017) Riximyo (06/2017) Rixathon (06/2017)	Ritemvia (07/2017) Blitzima (07/2017) Ruxience (04/2020)
Somatropin	Genotropin	Turner syndrome; prader- willi syndrome; pituitary dwarfism	Omnitrope (04/2006)	
Teriparatide	Forsteo	Osteoporosis	Movymia (01/2017) Terrosa (01/2017) Livogina (08/2020)	
Trastuzumab	Herceptin	Breast/ gastric neoplasms	Herzuma (02/2018) Trazimera (07/2018) Ogivri (12/2018)	Ontruzant (11/2017) Zercepac (07/2020) Kanjinti (05/2018)

REGULATION OF BIOSIMILARS



EMA scientific and clinical guidelines on biosimilarity

Virginia Acha & Jorge Mestre-Ferrandiz (2017) Translating European regulatory approval into healthcare uptake for biosimilars: the second translational gap, Technology Analysis & Strategic Management, 29:3, 263-275

CONSTITUTION OF MARKETING AUTHORISATION

https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines

The Centralized Procedure and the EMA

ONE:

- Marketing Authorization Application
- Evaluation
- Authorization in all EU member states
- Invented Name
- Product Information
- Summary of Product Characteristics (SmPC)
- Labelling
- Package Leaflet (PL)

ALL:
EU languages

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PHARMACOVIGILANCE OF BIOSIMILARS

- **Traceability is important!** → each individual institution should make sure that biosimilars are traceable

- **What to include in ADR report:**
  - Trade name
  - INN
  - Batch number and expiry date
  - The dosage form and route of administration

Biosimilars in the EU, Information guide for healthcare professionals.

Interchangeability: Switching - Substitution

- Interchangeability
  - refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect. This could mean replacing a reference product with a biosimilar (or vice versa) or replacing one biosimilar with another. Replacement can be done by:

✓ **Switching**, which is when the prescriber decides to exchange one medicine for another medicine with the same therapeutic intent.

✓ **Substitution** (automatic), which is the practice of dispensing one medicine instead of another equivalent and interchangeable medicine at pharmacy level without consulting the prescriber.

EMA does not regulate **interchangeability, switching and substitution** of a reference medicine by its biosimilar. These fall within the remit of EU Member States.

(EMA, Biosimilars in the EU, Information guide for healthcare professionals)

Interchangeability: Switching - Substitution

EMA: Biosimilars in the EU - Information guide for healthcare professionals

"There is no reason to believe that harmful immunogenicity should be expected after switching between highly similar biological medicines"

"Any decision on switching should involve the prescriber in consultation with the patient, and take into account any policies that the country might have regarding the prescribing and use of biological medicines."

"Switching is a growing practice in some Member States"

NATIONAL FRAMEWORK OF BIOSIMILARS (Slovenia)

- All biosimilars used in Slovenia are authorised through centralized procedure (CP) → they fully consent to European guidelines
- In Slovenia, biosimilars are not included on the list of Regulations on interchangeable medicines; regulation, guidelines and advices
- In Slovenia the biological medicines are not allowed to be substituted on the pharmacy level without consulting the physician
  - As all are available in Slovenia it is up to the hospital which one is going to be used
  - **Institute of oncology**: Committee for Medicines decides which biosimilar will be available (70 % of the cheapest on the market, 30 % second cheapest, tenders for originator); up to physician which drug the patient will receive

NATIONAL FRAMEWORK OF BIOSIMILARS (Greece)

- Greece:
  - ➢ Circ. 126908/12.12.2018 ΕΟΦ (National Organization for Medicines)
    - *EMA/CHMP/437/04 Rev 1 (23.10.2014): Guideline on similar biological medicinal products*
    - *EMEA/CHMP/BMWP/42832/2005 Rev 1 (18.12.2014): Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues*
    - *EMA/CHMP/BWP/247713/2012: Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance –quality issues*
    - *EMA/940451/2011: Questions and answers, 5 May 2011*

  - ➢ Definition of biosimilar
  - ➢ Differences between reference and biosimilar products
  - ➢ Comparability studies
  - ➢ Safety of biosimilars => first treatment to newly diagnosed patients
    => switching is allowed under specific conditions

Automatic Substitution for biological medicines in Europe

Allowed (under specific conditions)	(Planned) changes to legislation	Not allowed		No info
France[a]	Germany[d]	Austria	Italy	Bulgaria
Hungary[a]	Norway [e]	Belgium	Malta	Cyprus
Latvia		Croatia	Netherlands[b]	Estonia
Lithuania		Czech Republic	Portugal	Liechtenstein
Poland [b]		Denmark	Romania	Luxembourg
		Finland	Spain	Slovakia
		Greece	Sweden	Slovenia
		Iceland	UK	
		Ireland		

[a]Authorized by law under specific conditions (e.g., only for treatment naive patients), but not implemented in practice".
[b]Automatic substitution is not recommended, but due to a lack of regulation or specific guidance, automatic substitution may occur.
[c]For insulin biosimilars, insurance companies are increasingly forcing pharmacies to substitute to the biosimilar.
[d]New legislation planned (GSAV: Gesetz für mehr Sicherheit in der Arzneimittelversorgung), that will allow biologicals to be substituted at pharmacy level.
[e]Proposal to alter Pharmacy Act § 6-6 (basis for generic (automatic) substitution in pharmacies), eventually permitting automatic substitution of new classes of medicinal products, e.g., biological drugs.
Sources: consulted NCA websites and (40–43).

Barbier L. et al. Regulatory Information and Guidance on Biosimilars and Their Use Across Europe: A Call for Strengthened One Voice Messaging, 2022 Frontiers in Medicine

THE IMPACT OF COVID-19 PANDEMIC ON PRESCRIBING OF THE BIOLOGICS

- The impact on biologic prescribing is clearly visible across Europe at the peak of the COVID-19 pandemic.
- During the initial lockdown phase across Europe, prescribing dynamics were dramatically changed **due to the prioritization of COVID-19 patients, intensive care, and chronic conditions.** This resulted in a reduction in 7 of the 9 therapy areas studied in the IQVIA report, with the highest being in non-urgent segments such as fertility (-40 % at peak). It has taken 18 months for a rebound (+65 % for fertility treatments in Q2 2021) to counteract the drop.
- Most concerning is the impact on oncology. As the pandemic has developed, concerns have focused on oncology with delays in surgeries, chemotherapy and fewer diagnoses being conducted.

The impact of biosimilar competition in Europe, December 2021, IQVIA

THE IMPACT OF COVID-19 PANDEMIC ON PRESCRIBING OF THE BIOLOGICS

Order: lowest to highest peak

THERAPY AREA	Q2 2020 vs. Q2 2019	Q2 2021 vs. Q2 2020
GCSF	17%	8%
Anti-TNFs	5%	12%
EPO	-1%	5%
HGH	-3%	4%
PTH (teriparatide)	-5%	0%
Oncology	-7%	9%
Insulins	-8%	5%
LMWHs	-15%	21%
Fertility	-40%	65%

Source: IQVIA MIDAS (Q2 2021), Rx only; Biologic molecules exclude ATC V (vaccines, and various)

BIOSIMILARS – ENGAGING PATIENTS IN THE DECISION

- Evidence that patients have anxieties about biosimilars despite the significant public health benefit
- These concerns can be translated into lower compliance => leading to important consequences for patients with worse clinical outcomes
- Physicians and allied health professionals
  - must understand these concerns and
  - learn how to respond to them

⇨ In order to engage patients over biosimilars in advance of their use

Cornes P. and Aapro M., 2018, The impact of biosimilars in supportive care in cancer. Supportive Oncology

WHAT SHOULD PATIENTS KNOW ABOUT BIOSIMILARS?

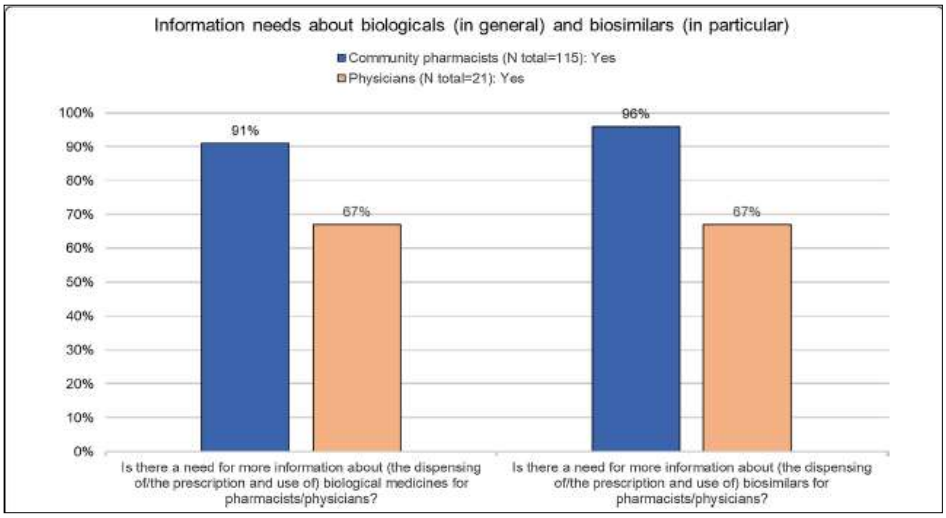
There are 5 main strategies to inform patients about biosimilars:

1. Provide understandable information
2. In positive and transparent way,
3. Tailored to the individual's needs,
4. Within one voice and
5. Supported by audio-visual material.

- As with all medicines, ***patients need to be able to make a fully informed decision*** about whether to take a biological or biosimilar medicine or not, and to be fully involved in deciding what treatment to pursue together with their healthcare team
- ***Therefore essential that patients have access to clear and impartial information*** about what biological and biosimilar medicines are, and what their growing availability will mean for them

Vanderpals, Y. et al. 2021. Informing Patients about Biosimilar Medicines: The Role of European Patient Associations

https://www.iapo.org.uk/sites/default/files/files/IAPO%20Briefing%20Paper.pdf



Barbier et al., 2021, Knowledge and perception of biosimilars in ambulatory care: a survey among Belgian community pharmacists and physicians, Journal of Pharmaceutical policy and practice.

IMPORTANT INFORMATION FOR HEALTHCARE PROFESSIONALS

- **A Checklist - Topics to be discussed with the patient & caregivers**
  - Use of biologic therapies in the specific disease
  - Definition of a biosimilar
  - Totality of evidence required of a biosimilar
  - Efficacy similar to innovator biologic
  - Safety similar to innovator biologic
  - Delivery/administration of the agent
  - Device use (if applicable)
  - Access to treatment
  - Insurance coverage and out-of-pocket cost
  - Services available to support the patient
  - Clinical trials including standard biosimilar trial design (active innovator comparator; no placebo arm)
  - Manufacturer identity

Patient Preference and Adherence 2016:10
https://ec.europa.eu/growth/content/commission-publishes-qa-biosimilar-medicines-patients-0_en

IMPORTANT INFORMATION FOR HEALTHCARE PROFESSIONALS

- A Question & Answer document from the European Commission
- A Briefing Paper for Patient Organizations

TALK POSITIVELY

https://www.ema.europa.eu/en/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf

https://www.iapo.org.uk/sites/default/files/files/IAPO%20Briefing%20Paper.pdf

CONCLUSION

- Biosimilars are increasing patient access to treatment, however there are still some countries where the accessibility is still challenging
- Significant
- A need for structured guidelines
- The need for up-to-date information is crucial in order to understand biosimilars

Mewies, M. Biosimilars: Change, challenge, and accomplishments, Medical Writing, 2019, 28(2), p.60-65.

THANK YOU FOR YOUR ATTENTION!