Erasmus MC
University Medical Center Rotterdam

EUFEPS
European Federation for Pharmaceutical Sciences

EUFEPS Annual Meeting 2018
Crossing Barriers for Future Medicines

Athens, May 25, 2018

Clinical Evaluation and Interchangeability of Biotech Products and Biosimilars

(a Clinical Pharmacists View)

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Vs18e28

Conflict of Interest Statement

Generics and Biosimilars Initiative
Building trust in cost-effective treatments
www.gabionline.net

- I declare no personal financial interest in any pharmaceutical business.

- I entertain friendly relationschips with all innovative and generic / biosimilar companies and I help them all where I can.
- Companies / Organisations involved are: AbbVie, Amgen, Biogen, EGA (Medicines for Europe), Mundipharma, Pfizer/Hospira, Roche, Novartis/Sandoz

- I am the co-founder of the Generics & Biosimilars Initiative (GaBi), The Dutch Initiative Group on Biosimilars (IBN) and the KULeuven – ErasmusMC MABEL Research Fund

My personal motto as a hospital pharmacist

My drive is optimal treatment for all patients

at an affordable cost

Science gives us the best possible description of the world.

It is emotion that is distorting view.

Agenda

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1. Introduction
2. **The biosimilar landscape**
3. Biosimilars: Three Classes
4. Concerns: interchangeability and immunogenicity
5. Implementation, lessons learned: Communicate
6. Take Home Message

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2017 Top-10 worldwide sales biologicals (billion US$, ex fabrica)

Product	Sales 2017 (vs 2016)	Company	Patent expiration	
			EU	US
1. Adalimumab	13.9 (+15 %)	AbbVie / Eisai	2018	**2016 (!)**
2. Etanercept	8.3 (-10%)	Amgen / Pfizer	***2015***	2028
3. Rituximab	7.8 (+5 %)	Roche	***2013***	2016
4. Infliximab	7.8 (-12 %)	J&J / MSD	***2015***	2018
5. Trastuzumab	7.4 (+9 %)	Roche	***2014***	2019
6. Bevacizumab	7.0 (+4 %)	Roche	2022	2019
7. Insulin glargine	6.7 (-7 %)	Sanofi	***2014***	***2014***
8. Aflibercept	5.9 (+14 %)	Regeneron / Bayer	2022	2023
9. Nivolumab	5.8 (+25 %))	BMS	2026	2027
10. Pegfilgrastim	5.9 (+5 %)	Amgen	**2017**	***2015***

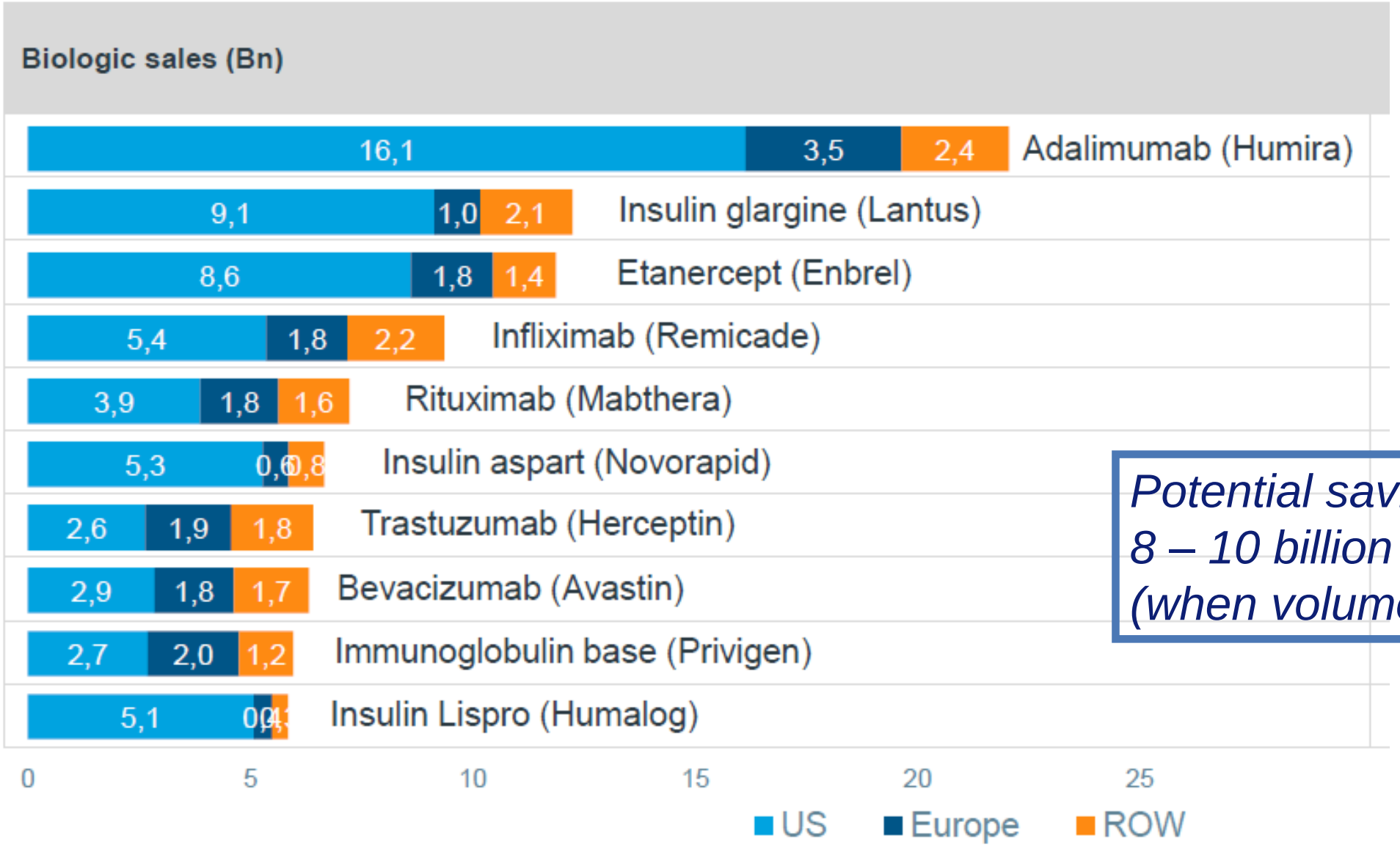
LaMerie Publishing,2018

Global Top 10 Biologics Sales

US$ MAT Q3 2017

European total 16.5 billion US$,

at hospital cost, list prices



Potential savings in EU:
8 – 10 billion US$ per year
(when volume constant)

Biosimilars are a regulatory invention

- How I see biosimilars as of May 2018
  - A biosimilar medicinal product is a licensed medicinal product which is similar to a biological medicinal product that has already been authorised (the 'biological reference medicinal product')
- What does that mean?
  - It is a ***version*** of an already licensed rec-DNA drug product, for which similarity has been proven in an extensive ***comparability exercise***, encompassing physical, chemical, biological and pharmacological properties, including efficacy and safety.
  - This excludes all kinds of *bio-questionables* in existence in other regions of the world that have not been endorsed via the WHO pathway as a biosimilar. *Reference to such products as if biosimilars may be inferior is thus WRONG*.

EU Licensed biosimilars: 13 molecules, 39 brands (May 2018) *(not available in all EU-countries)*

Molecule	Reference	Biosimilar(s)
Adalimumab	Humira	Amgevita, Cyltezo, Imraldi, Solimbic
Enoxaparine	Clexane	Inhixa, Thorinane
Epoetine alfa	Eprex	Absaemed, Binocrit, Epoetin alfa Hexal, Retacrit, Silapo
Etanercept	Enbrel	Benepali, Erelzi
Filgrastim	Neupogen	Accofil, Filhgrastim Hexal, Grastofil, Nivestim, Ratiograstim, Tevagrastim, Zarzio
Follitropin alfa	Gonal-f	Bemfola, Ovaleap
Infliximab	Remicade	Flixabi, Inflectra, Remsima
Insulin glargine	Lantus	Abasaglar, Lusduna
Insulin Lispro	Humalog	Insulin Lispro Sanofi
Rituximab	Mabthera IV	Blitzia, Ritemvia, Rituzena, Rixathon, Riximyo, Truxima
Somatropine	Genotropin	Omnitrope
Teriparatide	Forsteo	Movymia, Terrosa
Trastuzumab	Herceptin IV	Herzuma, Ontruzant

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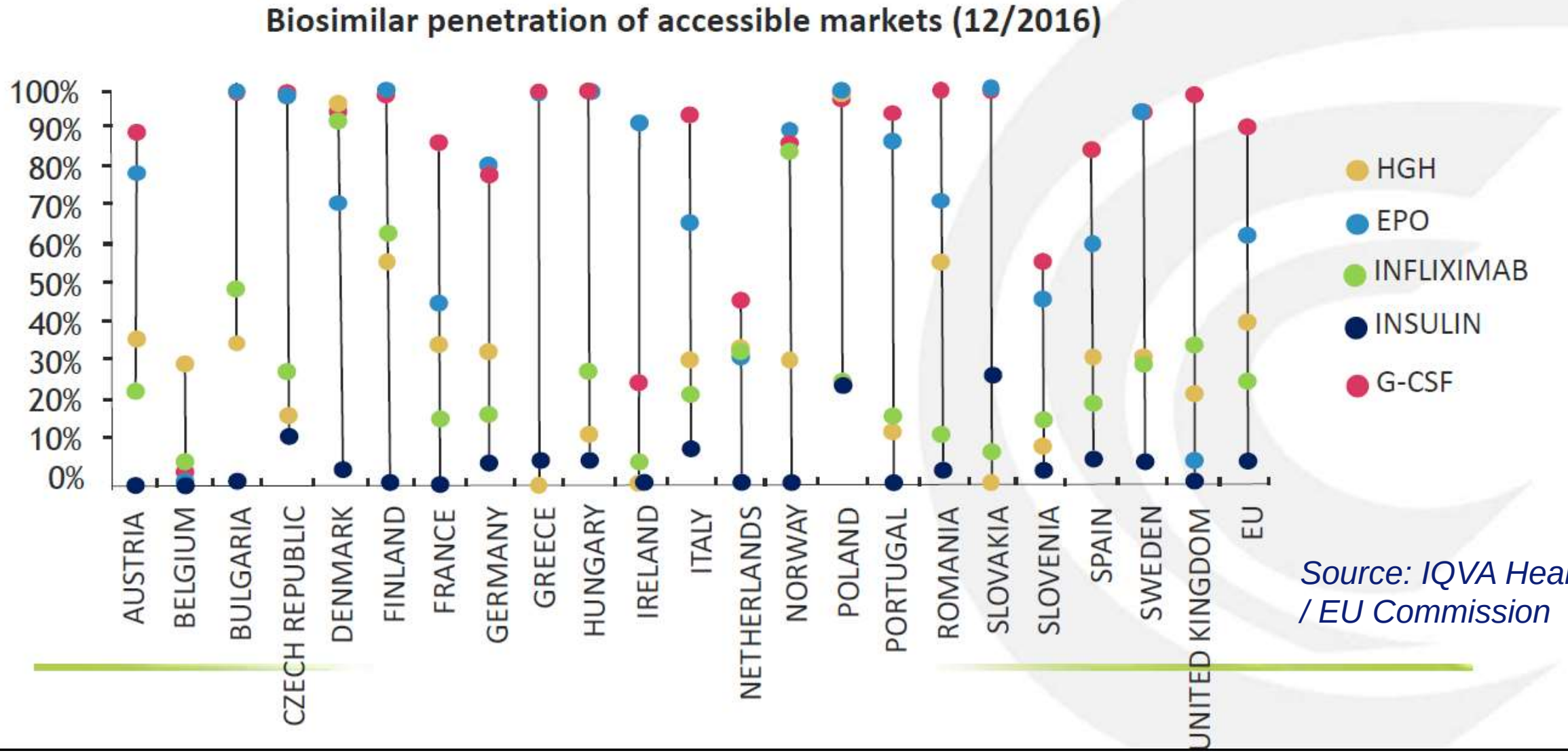
Three classes of therapeutic proteins (biologics)

- **Class 1**: substitution products
  - Hormones like growth factors or insulin
  - Effect visible / measurable in hours or days
- **Class 2**: proteins with a specific pharmacological effect
  - Like TNF-alfa inhibitors
  - Effect only visible after some time, but not in all patients
- **Class 3**: proteins with a less concrete clinical effect
  - “Targeted therapies” in oncology
  - The effect is a statistical chance some time in the future (survival)

biosimilar medicines
better access. better health.

Use of biosimilar medicines varies by country and therapeutic area



Source: IQVA Health / EU Commission

There is mixed uptake by molecule and country

No country has high penetration in all biosimilars

Europe, Japan, US & Canada- Biosimilar share of molecule treatment days

	Country	Biosimilar treatment day share (Oct 2017) infliximab	insulin glargine	etanercept	rituximab
EU5	UK	84.1%	5.0%	69.5%	36.5%
EU5	France	39.8%	5.4%	6.8%	-
EU5	Germany	48.7%	7.3%	41.8%	-
EU5	Italy	58.3%	15.6%	17.7%	2.9%*
EU5	Spain	44.9%	8.2%	5.3%	4.0%*
High penetration EU	Finland	92.0%	4.3%	-	-
High penetration EU	Norway	97.7%	3.4%	84.9%	-
High penetration EU	Poland	100.0%	24.6%	23.8%	-
High penetration EU	Denmark	98.1%	5.6%	86.0%	-
	Japan	5.8%	35.6%	-	-
	Canada	3.6%	0.5%	1.6%	-
	US	2.6%	14.6%	-	-

Note: *Uptake represented within 6 months of launch; Source: IQVIA MIDAS Restricted MTH Oct 2017

IQVIA™

Courtesy Per Troein / IQVIA, EAHP-congress 2018

16 Biosimilars under evaluation (EMA, May 2018)

- Adalimumab (5x)
- Bevacizumab (1x)
- Peg-filgrastim (8x)
- Trastuzumab (2x)

And more to come….

Table 2: Upcoming Trastuzumab Biosimilars Launches in Europe

BIOSIMILAR PRODUCT	MARKETER	LAUNCH YEAR
ONTRUZANT	MSD	2018
HERZUMA	Mundipharma	2018
KANJINTI	Amgen	2018
OGIVRI	Mylan	2019
PF-05280014	Pfizer	2019

Source: Decision Resources Group[1]

And more to come….

Table 2: Upcoming Trastuzumab Biosimilars Launches in Europe

Table 3: Upcoming Adalimumab Biosimilars Launches in Europe

BIOSIMILAR PRODUCT	MARKETER	LAUNCH YEAR
AMGEVITA / SOLYMBIC	Amgen	2018
CYLTEZO	Boehringer Ingelheim	2018
GP2017	Sandoz	2018
FKB327	Fujifilm Kyowa Kirin Biologics	2018
M923	Momenta	2019
MSB11022	Fresenius Kabi	2019
PF-06410293	Pfizer	2019
MYL-1401O	Mylan	2019
CHS-1420	Coherus BioSciences	2019
ONS-3010	Oncobiologics	2019

Source: Decision Resources Group[1]

And more to come….

Table 2: Upcoming Trastuzumab Biosimilars Launches in Europe

Table 3: Upcoming Adalimumab Biosimilars Launches in Europe

Table 4: Upcoming Pegfilgrastim Biosimilars Launches in Europe

BIOSIMILAR PRODUCT	MARKETER	LAUNCH YEAR
CHS-1701	Coherus BioSciences	2018
B12019	Cinfa Biotech	2018
MYL-1401H	Mylan	2019
ZIOXTENZO	Sandoz	2019
RGB-02	STADA	2019

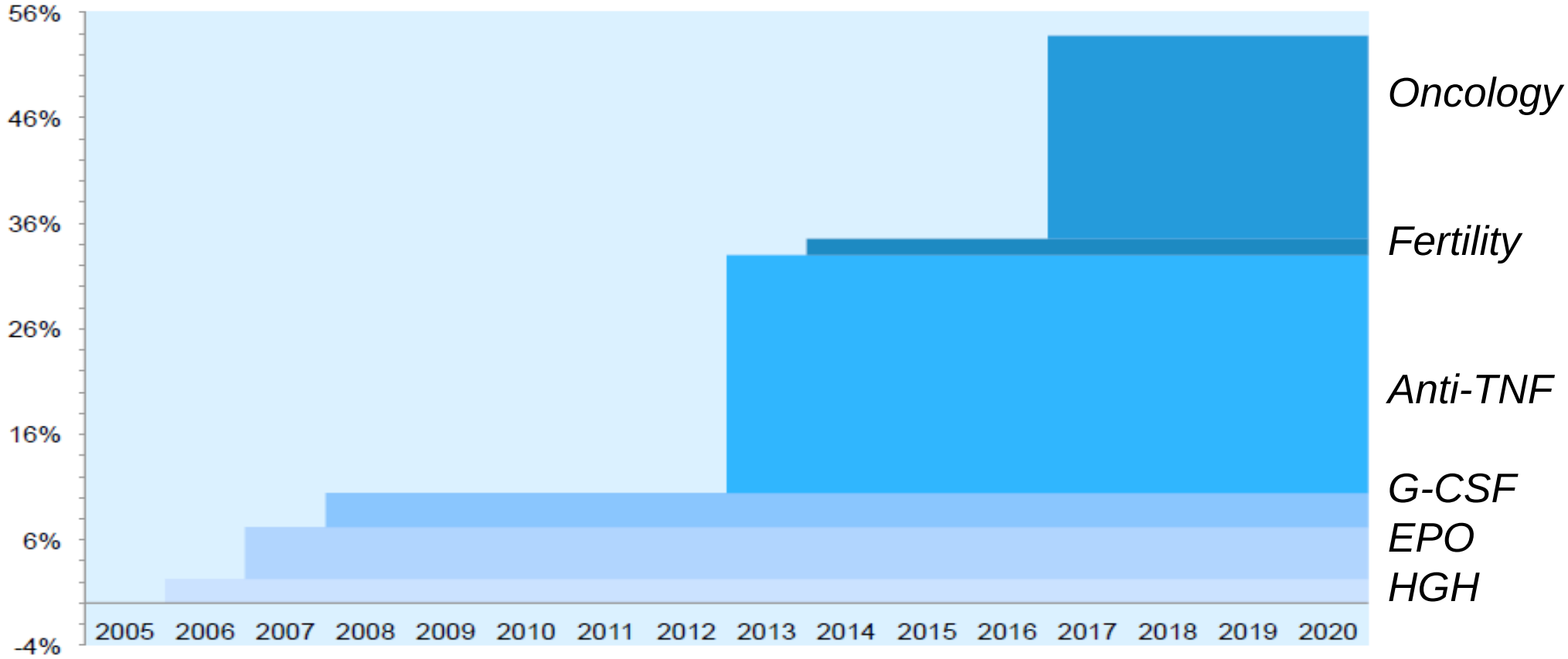
Source: Decision Resources Group[1]

Source: Decision Resources Group[1]

https://www.biosimilardevelopment.com/doc/the-european-biosimilars-landscape-what-to-expect-in-the-year-ahead-0001, April 10, 2018

Therapy classes exposed to biosimilar competition

Market share based on MAT 09 2015 sales values



EPO, erythropoietin; G-CSF, granulocyte colony-stimulating factor; HGH, human growth hormone

Troien P. Biosimilars – more for less. Available at: http://www.egaevents.org/presentations/2016bios/Per_Troein.pdf. Accessed March 2017

Biosimilars create uncertainty with prescribers

- **Innovative medicines**
  - Offer a clear advantage – whether real or not
  - Marketeers promise a solution for a therapeutic problem
  - And hence, the physician is prepared to take a certain risk
- **Biosimilars**
  - Don’t offer prescriber and patient a clear therapeutic advantage
  - May offer a modest price advantage for the patient / 3rd party payer
  - They may carry – as with any other new drug – some risk

Doctors and patients don’t like trouble with their medicines

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We will have 3-5 biosimilars per molecule

- How will we use these multiple biosimilars?
  - How to select a biosimilar (e.g. for the hospital formulary)?
  - What about interchangeability and switching / transitioning?
  - Wat about immunogenicity?
  - And what about substitution?
- Critical information
  - European Assessment Reports (EPARs)
  - Scientific literature (lags 1-3 years behind; MfE reading list)
  - Professional standards and other guidance

biosimilar medicines
better access. better health.

http://www.medicinesforeurope.com/wp-content/uploads/2016/03/Biosimilars-Reading-list-update-20160831.pdf

Reading List | Biosimilar Medicines

Contents

What are concerns of prescribers and patients?

- Risk of immunogenicity in transitioning from innovator to biosimilar
- Lack of experience in transitioning (erroneously called “switching”)
  - Switching has a different connotation for physicians!
- Insufficient knowledge about new drug development paradigm
  - More education needed

Immunogenicity of (humanised) therapeutic proteins

- What is the risk of immunogenicity / anti-drug-antibodies (ADA's)
  - Neutralising and non-neutralising
  - Altered PK (reduced half-life)
  - Reduction in clinical efficacy (reduced plasma concentration)
  - Allergic drug reactions
- Immunogenicity risk is over-estimated
  - Most humanised medicinal proteins have low or no immunogenicity risks
  - Many ADA's have no clinical significance
- Low risk e.g. filgrastim, insulins, etanercept
- Higher risk: infliximab, adalimumab

10 years of EMA-experience (2014): Enhanced immunogenicity has not yet been seen

Open Access Full Text Article

REVIEW

Multidisciplinary approach to evaluating immunogenicity of biosimilars: lessons learnt and open questions based on 10 years' experience of the European Union regulatory pathway

This article was published in the following Dove Press journal:
Biosimilars
25 June 2014
Number of times this article has been viewed

Paul D Chamberlain

NDA Advisory Board, NDA Advisory Services Ltd, Surrey, UK

Abstract: Clinical evaluation of comparative immunogenicity represents an important component of the European Union regulatory review process for candidate biosimilar products. The clinical evaluation is part of a multidisciplinary review that cross-refers to product quality attributes as well as preclinical and ongoing risk management considerations. Results from the

Infliximab biologics have the same immunogenic epitopes

ORIGINAL ARTICLE

Cross-immunogenicity: antibodies to infliximab in Remicade-treated patients with IBD similarly recognise the biosimilar Remsima

Shomron Ben-Horin,[1] Miri Yavzori,[1] Itai Benhar,[2] Ella Fudim,[1] Orit Picard,[1] Bella Ungar,[1] SooYoung Lee,[3] SungHwan Kim,[3] Rami Eliakim,[1] Yehuda Chowers[4]

ABSTRACT

Objective The cross-immunogenicity of the recently approved infliximab-biosimilar Remsima (CT-P13) with the originator drug Remicade is still unknown.

Significance of this study

Gut 2015; doi:10.1136/gutjnl-2015-309290

Infliximab biologics have same immunogenic epitopes

ORIGINAL ARTICLE

Cross-immunogenicity: antibodies to infliximab in Re recog

Shomron
Bella Un

ABSTRACT
Objective
approved in
the originat

Conclusions Anti-Remicade antibodies in patients with IBD recognise and functionally inhibit Remsima to a similar degree, suggesting similar immunogenicity and shared immunodominant epitopes on these two infliximab agents. In contrast, anti-adalimumab antibodies do not cross-react with Remsima or Remicade.

The assay was tested against a panel of 55 antibodies; no difference in immunogenicity

Harmonization of Infliximab and Anti-Infliximab Assays Facilitates the Comparison Between Originators and Biosimilars in Clinical Samples

Ann Gils, PharmD, PhD, Thomas Van Stappen, PharmD,* Erwin Dreesen, PharmD,* Ruth Storme, PharmD,* Séverine Vermeire, MD, PhD,† and Paul J. Declerck, PharmD, PhD**

(Inflamm Bowel Dis 2016;22:969–975)

The assay was tested against a panel of 55 antibodies; no difference in immunogenicity

Harmonization of the Comparison B Clinical Samples

Ann Gils, PharmD, PhD, Thom*
Séverine Vermeire, MD, PhD,†

Results: MA-IFX6B7 and MA-IFX10F9 exhibit equal reactivity toward Remicade, Remsima, and Inflectra. The infliximab ELISA quantifies the biosimilars equally well as Remicade. Quantification of anti-infliximab antibodies in the serum of patients treated with Remicade revealed highly correlated titers between biosimilars and Remicade.

And there is full cross-immunogenicity between CT-P13 and Remicade antibodies

BioDrugs (2017) 31:223–237
DOI 10.1007/s40259-017-0219-4

ORIGINAL RESEARCH ARTICLE

Evaluation of the Cross-reactivity of Antidrug Antibodies to CT-P13 and Infliximab Reference Product (Remicade): An Analysis Using Immunoassays Tagged with Both Agents

Walter Reinisch[1,2] · Jørgen Jahnsen[3,4] · Stefan Schreiber[5] · Silvio Danese[6] · Julián Panés[7] · Alejandro Balsa[8] · Won Park[9] · JiSoo Kim[10] · Jee Un Lee[11] · Dae Hyun Yoo[12]

And there is full cross-immunogenicity between CT-P13 and Remicade antibodies

BioDrugs (2017) 31:223–237
DOI 10.1007/s40259-017-0219-4

ORIGINAL RESEARCH

**Evaluation of the
P13 and Infliximab
Using Immunoass**

Walter Reinisch[1,2] · Jørgen
Julián Panés[7] · Alejandro B
Dae Hyun Yoo[12]

Key Points

This study demonstrated that antibodies against the infliximab biosimilar CT-P13 and the infliximab reference product (RP; Remicade) recognise and bind RP and CT-P13, respectively.

The cross-reactivity of CT-P13 and its RP indicate that the two products share immunodominant epitopes.

Are there signals from transition trials?

Drugs (2018) 78:463–478
https://doi.org/10.1007/s40265-018-0881-y

SYSTEMATIC REVIEW

Switching Reference Medicines to Biosimilars: A Systematic Literature Review of Clinical Outcomes

Hillel P. Cohen[1] · Andrew Blauvelt[2] · Robert M. Rifkin[3] · Silvio Danese[4] · Sameer B. Gokhale[5] · Gillian Woollett[6]

- 7 molecules, 14 diseases, 90 studies, 14.225 patients
- Great majority no difference in immunogenicity, efficacy and safety

Conclusion

- Even with a high immunogenic molecule like infliximab, the immunogenicity between innovator Remicade and its biosimilars CT-P13 and SB2 (data not shown) is indistinguishable
- There is also no signal in any of the transition trials
- EMA regulators did a very good job
    - Why is there an ongoing request for more data?
    - Do prescribers have no access to literature?

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Lessons learned:

Communication, communication and communication

- **Multistakeholder approach**
  - Involve all those relevant: prescribers, pharmacists, patients, nurses, procurement dept. and hospital managers
- **Speak with one voice**
  - Avoid distorting information
  - Beware of attribution and nocebo-effects
- **Shared decision making: involve patients**
  - advantages and disadvantages
- **Gain sharing**
  - Who will benefit?

The confusing definition issue / words to avoid

- **Switching** is both:
  - Change from one treatment / molecule to another
  - Change from reference product to biosimilar

    (also confusingly coined *non-medical switching*).
  - Better word **transitioning**: only for biosimilars (Dörner, 2016)
- **Interchangeability**: EMA differs fundamentally from FDA
  - Very confusing: population versus individual level
- **Substitution**:
  - Why discuss? We don't do it (with few exceptions).
- Using these words is framing the discussion (see: Lakoff/YouTube)

Weise et al. Nature Biotechnology 29, 690–693 (2011)
Dörner et al Ann Rheum Dis doi:10.1136/annrheumdis-2016-209166

George Lakoff: In Politics, Progressives Need to Frame Their Values

Interview online here.

The following is a Truthout interview with Professor George Lakoff about his latest effort, THE ALL NEW Don't Think of an Elephant!, to convince progressives to "frame" their political language and appeals based on deep-seated and active values. These are positions and actions that most of the public supports, but absent appropriate "framing" often vote their fears instead of progressive beliefs. It is necessary to ground a nurturing politics for the common good and core values in language and a moral foundation that appeals – rhetorically and emotionally – to the better selves of voters.

Mark Karlin: Before we get into the new edition of Don't Think of an Elephant!, THE ALL NEW Don't Think of an Elephant!, I wanted to ask you a bit more about something you said to me in a conversation at your home awhile back. You noted that it's not surprising that Republicans are more persuasive than Democrats because they are more skilled at selling and marketing. Does this also relate to the prevalence of consumer advertising in the US that convinces people to buy things that they don't need or want?

In the EU we have unified licensing, but not unified access

Legislation is only part of the story

- There exists a formal legal framework (i.e. EMA)
- Versus a less formal local interpretation with many variations

- Acceptance of a biosimilar is dependent on how different stakeholders act.
  - Physicians, patients, pharmacists, 3rd party payers, policy makers
- Essential to buy in “ownership” from stakeholders like prescribers (e.g. via guidelines) and patients(-organisations)

“The” **biosimilar does not exist**

May 2017

EAHP Position Paper on Biosimilar Medicines

This paper sets out the position of the European Association of Hospital Pharmacists (EAHP) on biosimilar medicines.

The objective of the paper is to set out the position of EAHP on important issues concerning biosimilars including the role of hospital pharmacists regarding the uptake of biosimilars in healthcare in terms of selection, procurement, logistics, information, education and collecting real life experience (e.g. in monitoring and pharmacovigilance).

A biological medicine is a medicine that contains one or more active substances made by or derived from a biological source i.e. living cells or organisms. The European Medicines Agency (EMA) defines a biosimilar medicine as "a biological medicine that is developed to be similar to an existing biological medicine (the 'reference medicine/reference product')".[1]

Overall, EAHP has confidence in EMAs regulatory pathway for biological reference products and biosimilar medicines. EAHP, as for all other medicines, recommends informed patient involvement and shared decision making.

Overview of all European statements on transitioning biosimilars *(from Medicines for Europe)*

biosimilar medicines
better access. better health.

Memo

Subject: **Positioning Statements on Physician-led Switching[1] for Biosimilar Medicines**

Date: **Update March 2017**

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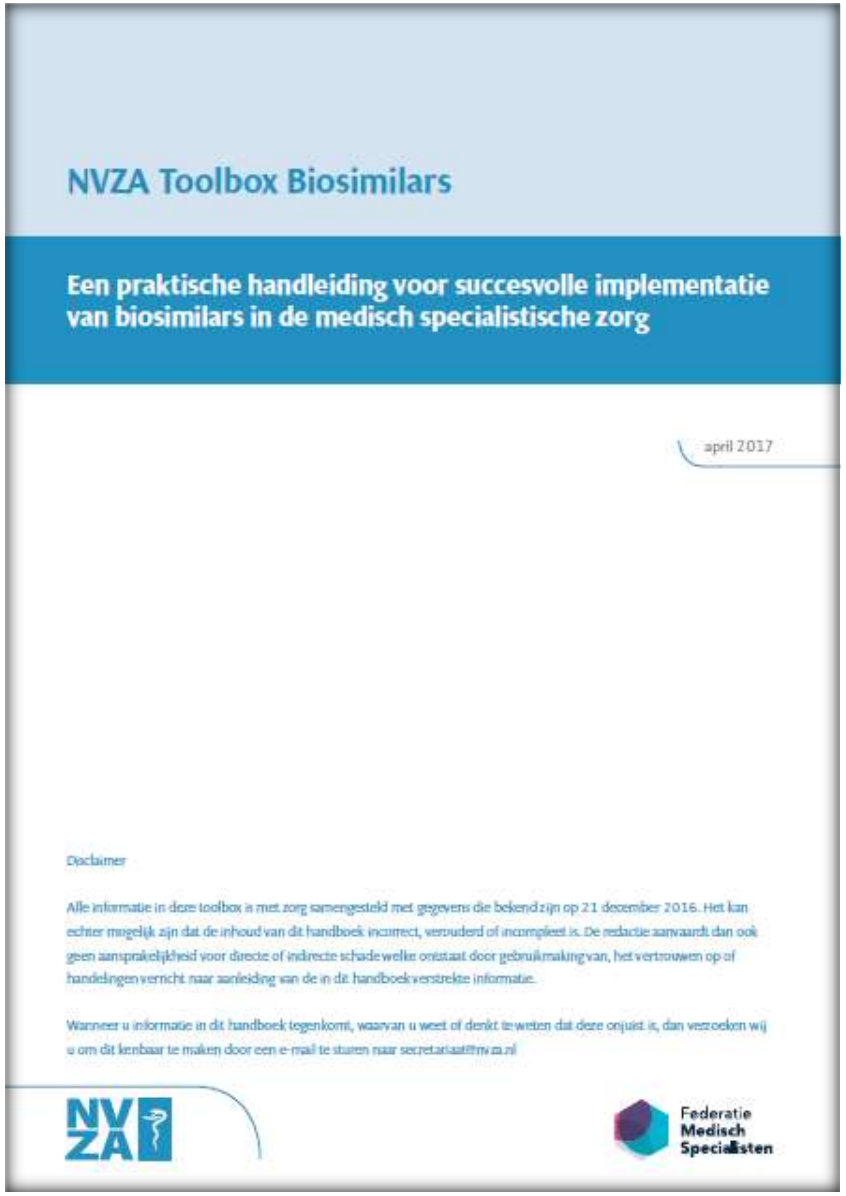
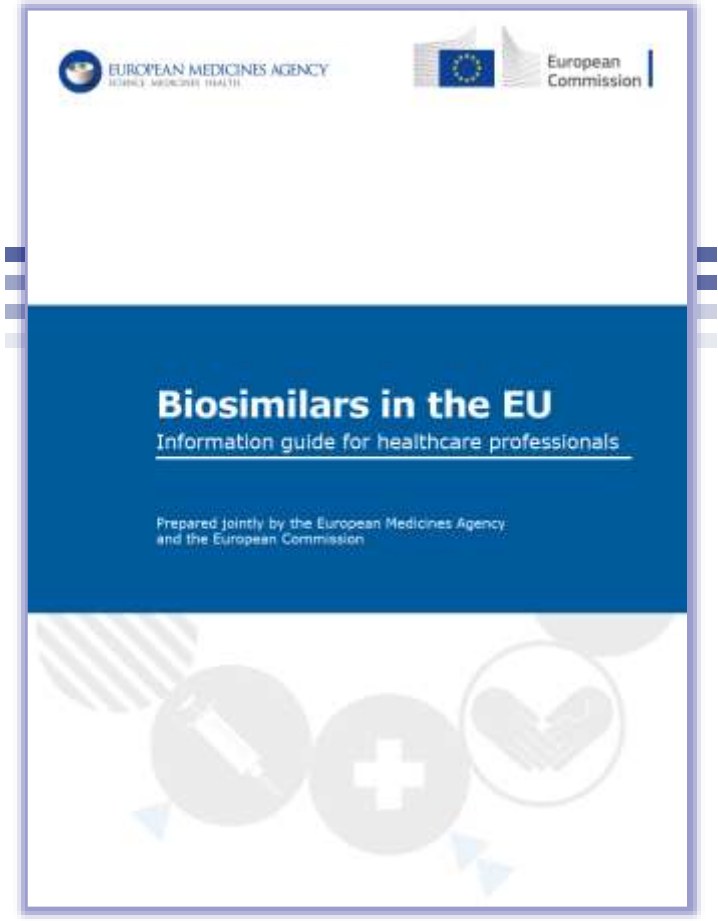
Dutch Hospital Pharmacists Association and Dutch Federation of Medical Specialists



- **Toolbox biosimilars** (April 2017)
- A practical guide for succesful implementation
  - Scientific background, definitions and position papers (e.g. MEB)
  - New patients, existing patients
  - Implementation: task force and roadmap
  - Policies for transitioning
  - Information materials, letters

MEB, Medicines Evaluation Board

How to build trust in biosimilars?



- **Reduce the information gap**
  - Regulators can communicate their knowledge actively to medical professionals:
    - “The past 10 year there has not been a single serious incident with biosimilars”
    - The assessment system worked as expected
    - Raised mistrust was not justified and we learned better in the meantime
- **Avoid trouble around switching**
  - Convince prescribers on the (financial) advantages for the society, without compromising quality of treatment.

And so they did…..

BioDrugs (2017) 31:83–91
DOI 10.1007/s40259-017-0210-0

CURRENT OPINION

Interchangeability of Biosimilars: A European Perspective

Pekka Kurki[1] · Leon van Aerts[2] · Elena Wolff-Holz[3] · Thijs Giezen[4] · Venke Skibeli[5] · Martina Weise[6]

And so they did…..

BioDrugs (2017) 31:83–91
DOI 10.1007/s40259-017-0210-0

CURRENT OPINION

Interchangeability of Biosimilars: A European Perspective

Pekka Kur
Venke Skil

On the basis of current knowledge, it is unlikely and very difficult to substantiate that two products, comparable on a population level, would have different safety or efficacy in individual patients upon a switch.
Our conclusion is that biosimilars licensed in the EU are interchangeable

However….

- This does not mean that biologics should be changed at random in a high frequency

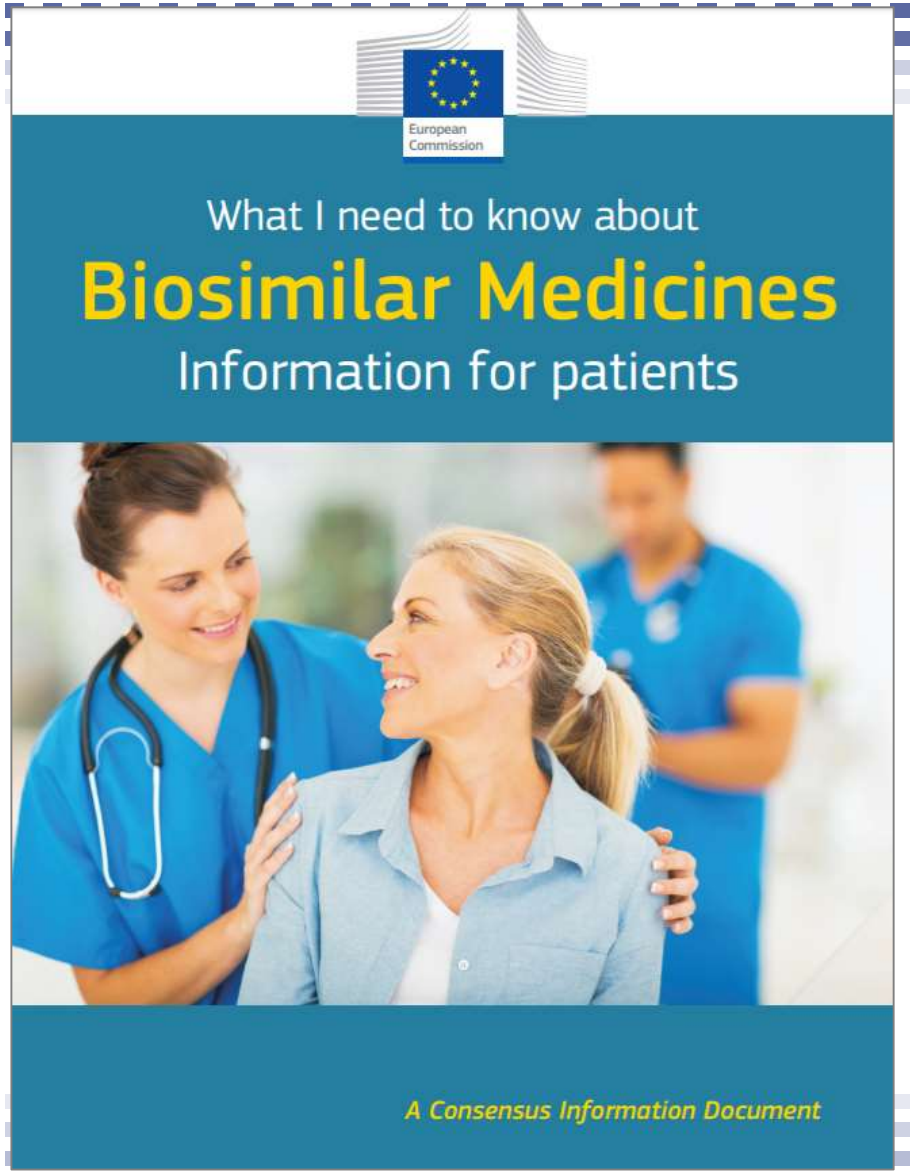
- Both for patient convenience and traceability product-stable treatment is desirable
  - But immunogenicity is for the currently licensed products no argument

- Arbitrarily, one could say: do not change more often than once every 1 or 2 years
  - But there is no scientific guidance for this

European Commision Q&A on biosimilars for patients
(available in almost all EU-languages)

Similar to the *Focus* explainer on biosimilars, the 9-page EC explainer, available in seven languages, offers a quick 10,000-foot view of the biosimilars landscape, answering questions that patients might have on what a biologic is, what a biosimilar is, how biosimilars compare to generics, what types of studies biosimilars must undergo prior to approval and how to define extrapolation.

In addition to offering links to additional sources of information for patients, the explainer also provides a quick rundown on what to do if a biosimilar leads to an adverse event, as well as a list of currently available biosimilars in the EU.



http://ec.europa.eu/DocsRoom/documents/20961

IAPO biosimilar toolkit

https://www.iapo.org.uk/biosimilars-toolkit

International Alliance of Patients' Organizations

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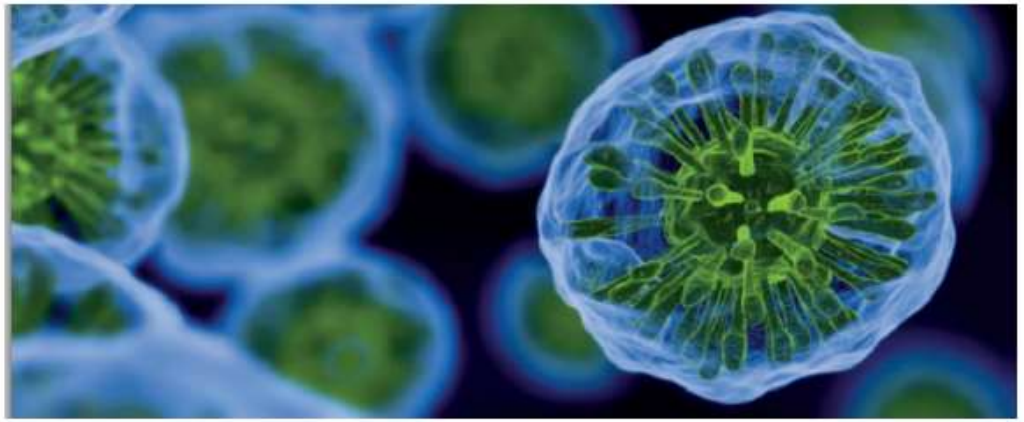
Biosimilars Toolkit

Policy positions

- Access to treatment
- Biosimilar medicines
- Clinical trials
- Counterfeit medicines
- Health technology assessment
- Human Rights-Based Approach
- Innovation
- Non-communicable diseases
- Patient involvement in policy
- Patient-centred healthcare
- Patient Engagement in Hospitals
- Patient Info & Health Literacy
- Patient safety
- Priority medicines
- Sustainable development goals
- Universal health coverage
- WHO reform
- Working with industry

An Information and Advocacy Toolkit for Patients' Organizations

This toolkit provides patients' organizations with up-to-date, evidence-based information on the science, technology and regulatory information relevant to biological and biosimilar medicines, as well as tips on advocacy. It is available in English, Spanish and Portuguese.



We believe that patients should be aware of what biological and biosimilar medicines are and what the implications of their increasing availability will mean to them. We hope that these resources will help patient advocates to make informed judgments on the value of biological and biosimilar medicines and actively engage in debate and discussion.

2008:
Closing the information gap (www.gabionline.net)

- Umbrella initiative to build trust in cost-effective treatments:
  - One-stop website with comprehensive information on generics and biosimilars
  - Peer reviewed open-access scientific journal
  - Scientific symposia
  - Educational meetings
  - Patient information

GaBi
Generics and Biosimilars Initiative
Building trust in cost-effective treatments
www.gabionline.net

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Biosimilars

News

FDA approves biosimilar infliximab Renflexis

posted 08/05/2017

Samsung Bioepis announced on 24 April 2017 that the US Food and Drug Administration (FDA) had approved its biosimilar version...

EMA approval for etanercept and rituximab biosimilars

posted 28/04/2017

The European Medicines Agency's

Research

Computer modelling for glycoengineering of biosimilars

posted 06/05/2017

In order to be approved by regulatory agencies, biosimilars are required to match all pharmacological properties of the origi...

Prospective study finds switching to biosimilar infliximab safe

posted 05/05/2017

A study of the infliximab biosimilar Remsima has, according to the authors, shown similar 'safety and survival' of biosimilar...

General

Fujifilm ramps up biosimilars production as UK court allows Humira biosimilar

posted 04/05/2017

A UK court has ruled in the favour of Japan-based Fujifilm Kyowa Kirin Biologics' Humira biosimilar. The Fujifilm corporation...

Biosimilars of etanercept

posted 04/05/2017

Last update: 28 April 2017Etanercept is a biological

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Agenda

EUFEPS Annual Meeting 2018
Crossing Barriers for Future Medicines

1. Introduction
2. The biosimilar landscape
3. Biosimilars: Three Classes
4. How to select a biosimilar
5. Implementation, lessons learned: Communicate
6. **Take Home Message**

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Take-home message

- Twelve years of biosimilars show an undamaged safety reputation
- The quest for more data originates from lack of knowledge / education
- Comparison of biosimilars is not easy and based on a mixture of arguments
- The choice between IV (biosimilar) / SC (originator) is a multi-factorial problem
- Currently licensed biosimilars are deemed fully interchangeable
    - Although stable treatment is desirable for traceability reasons
- Organise selection and implementation in a multidisciplinary fashion and with one voice and **COMMUNICATE**

- Thank you very much for your attention.

- Questions?

- Contact: a.vulto@gmail.com