Biosimilars in Clinical Practice: Formulary, interchange and substitution considerations (a European perspective)

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Honorary Professor KU Leuven, Belgium
Conflict of Interest Statement

- I declare no personal financial interest in any pharmaceutical business.
- My hospital receives financial compensation for the time I consult / lecture for 3rd parties, like speaking bureaus and pharmaceutical companies.
- I entertain friendly relationships with all innovative and generic / biosimilar companies and I help them all where I can. I don’t receive personally any payment for that.
- 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

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
<table>
<thead>
<tr>
<th>Biopharmaceuticals</th>
<th>2015 Sales (US$ billion)</th>
<th>Growth Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anti-tumor necrosis factor (TNF):</strong></td>
<td>$35.7</td>
<td>(+4%)</td>
</tr>
<tr>
<td>- (Enbrel, Remicade, Humira, Cimzia, Simponi)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Anti-cancer monoclonals:</strong></td>
<td>$29.2</td>
<td>(+15%)</td>
</tr>
<tr>
<td>- (e.g. MabThera, Herceptin, Avastin, Erbitux, Vectibix, Yervoy, XGeva)</td>
<td></td>
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</tr>
<tr>
<td><strong>Insulin and insulin analogues:</strong></td>
<td>$21.2</td>
<td>(+12%)</td>
</tr>
<tr>
<td>- (e.g. Humalog, Humulin, Lantus, Levemir, NovoRapid, Actrapid, Novomix-50)</td>
<td></td>
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</tr>
<tr>
<td><strong>Anti-inflammatory antibodies</strong></td>
<td>$15.5</td>
<td>(+21%)</td>
</tr>
<tr>
<td>- (e.g. Tysabri, Xolair, Orencia, Soliris, RoActemra, Stelara)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ophthalmic antibodies</strong></td>
<td>$7.7</td>
<td>(+11%)</td>
</tr>
<tr>
<td>- (Eylea, Lucentis)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Recombinant coagulation factors</strong></td>
<td>$7.7</td>
<td>(+6%)</td>
</tr>
<tr>
<td>- (e.g. Advate, NovoSeven RT, Kogenate FS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Erythropoetins (alfa- and beta-):</strong></td>
<td>$6.3</td>
<td>(-5%)</td>
</tr>
<tr>
<td>- (Aranesp, Procrit, Eprex, Epogen)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## 2015 Top-10 worldwide sales biologicals (billion US$)

<table>
<thead>
<tr>
<th>Product</th>
<th>Sales 2015 (vs 2014)</th>
<th>Company</th>
<th>Patent expiration</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Etanercept</td>
<td>9.0 (+2 %)</td>
<td>Amgen / Pfizer</td>
<td>EU 2015, US 2028</td>
</tr>
<tr>
<td>3. Infliximab</td>
<td>8.9 (-9 %)</td>
<td>J&amp;J / MSD</td>
<td>EU 2015, US 2018</td>
</tr>
<tr>
<td>4. Insulin glargine</td>
<td>7.2 (+6 %)</td>
<td>Sanofi</td>
<td>EU 2014, US 2014</td>
</tr>
<tr>
<td>5. Rituximab</td>
<td>7.1 (+4 %)</td>
<td>Roche</td>
<td>EU 2013, US 2016</td>
</tr>
<tr>
<td>6. Bevacizumab</td>
<td>6.8 (+6 %)</td>
<td>Roche</td>
<td>EU 2022, US 2019</td>
</tr>
<tr>
<td>7. Trastuzumab</td>
<td>6.6 (+6 %)</td>
<td>Roche</td>
<td>EU 2014, US 2019</td>
</tr>
<tr>
<td>9. Aflibercept</td>
<td>4.1 (+47 %)</td>
<td>Regeneron / Bayer</td>
<td>EU 2022, US 2023</td>
</tr>
<tr>
<td>10. Ranibizumab</td>
<td>3.6 (-13 %)</td>
<td>Roche / Novartis</td>
<td>EU ? 2022, US ? 2020</td>
</tr>
</tbody>
</table>
What are biosimilars?

- How I see biosimilars as of September 2017
  - 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.
August 2017
More then 30 biosimilars licensed by EMA
(not available in all EU-countries)

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Company</th>
<th>Approval date</th>
<th>Brandname</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatropin</td>
<td>Sandoz</td>
<td>Apr 2006</td>
<td>Omnitrope</td>
</tr>
<tr>
<td>Epoetin alfa</td>
<td>Medice</td>
<td>Aug 2007</td>
<td>Abseamed</td>
</tr>
<tr>
<td>Epoetin alfa</td>
<td>Sandoz</td>
<td>Aug 2007</td>
<td>Binocrit</td>
</tr>
<tr>
<td>Epoetin alfa</td>
<td>Hexal</td>
<td>Aug 2007</td>
<td>Epoetin Alfa Hexal</td>
</tr>
<tr>
<td>Epoetin zeta</td>
<td>Hospira</td>
<td>Dec 2007</td>
<td>Retacrit</td>
</tr>
<tr>
<td>Epoetin zeta</td>
<td>Stada</td>
<td>Dec 2007</td>
<td>Silapo</td>
</tr>
<tr>
<td>Filgrastim</td>
<td>AbZ-Pharma</td>
<td>Sep 2008</td>
<td>Biogastim</td>
</tr>
<tr>
<td>Filgrastim</td>
<td>Ratiopharm</td>
<td>Sep 2008</td>
<td>Ratiogastim</td>
</tr>
<tr>
<td>Filgrastim</td>
<td>Teva</td>
<td>Sep 2008</td>
<td>Tevagastim</td>
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<tr>
<td>Filgrastim</td>
<td>Hexal</td>
<td>Feb 2009</td>
<td>Filgrastim Hexal</td>
</tr>
<tr>
<td>Filgrastim</td>
<td>Sandoz</td>
<td>Feb 2009</td>
<td>Zarzio</td>
</tr>
<tr>
<td>Filgrastim</td>
<td>Hospira/Pfizer</td>
<td>Jun 2010</td>
<td>Nivestim</td>
</tr>
<tr>
<td>Infliximab</td>
<td>Hospira/Pfizer</td>
<td>Sep 2013</td>
<td>Inflectra</td>
</tr>
<tr>
<td>Infliximab</td>
<td>Celltrion</td>
<td>Sep 2013</td>
<td>Remsima</td>
</tr>
<tr>
<td>Follitropin alfa</td>
<td>Teva</td>
<td>Sep 2013</td>
<td>Ovamelag</td>
</tr>
<tr>
<td>Filgrastim</td>
<td>Apotex</td>
<td>Oct 2013</td>
<td>Grastofil</td>
</tr>
<tr>
<td>Follitropin alfa</td>
<td>Finox</td>
<td>Mar 2014</td>
<td>Bemfola</td>
</tr>
<tr>
<td>Filgrastim</td>
<td>Accord Healthcare</td>
<td>Sep 2014</td>
<td>Accofil</td>
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<tr>
<td>Insulin glargine</td>
<td>Eli Lilly</td>
<td>Sep 2014</td>
<td>Abasaglar</td>
</tr>
<tr>
<td>Etanercept</td>
<td>Samsung Bioepis</td>
<td>Jan 2016</td>
<td>Benepali</td>
</tr>
<tr>
<td>Infliximab</td>
<td>Samsung Bioepis</td>
<td>May 2016</td>
<td>Flixabi</td>
</tr>
<tr>
<td>Enoxaparin-Na</td>
<td>Techdow</td>
<td>Sep 2016</td>
<td>Inhixa</td>
</tr>
<tr>
<td>Enoxaparin-Na</td>
<td>Pharmathen</td>
<td>Sep 2016</td>
<td>Thorinane</td>
</tr>
<tr>
<td>Insulin glargine</td>
<td>MSD</td>
<td>Nov 2016</td>
<td>Lusduna</td>
</tr>
<tr>
<td>Teriparatide</td>
<td>Stada</td>
<td>Nov 2016</td>
<td>Movymia</td>
</tr>
<tr>
<td>Teriparatide</td>
<td>Gedeon Richter</td>
<td>Nov 2016</td>
<td>Terrosa</td>
</tr>
<tr>
<td>Rituximab</td>
<td>Celltrion</td>
<td>Feb 2017</td>
<td>Truxima</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>Amgen</td>
<td>March 2017</td>
<td>Amgevita, Solymbic</td>
</tr>
<tr>
<td>Rituximab</td>
<td>Sandoz</td>
<td>June 2017</td>
<td>Riximyo,Rixathon</td>
</tr>
<tr>
<td>Rituximab</td>
<td>Celltrion</td>
<td>June 2017</td>
<td>Blitzima, Ritemvia, Rituzema</td>
</tr>
<tr>
<td>Etanercept</td>
<td>Sandoz</td>
<td>June 2017</td>
<td>Erelzi</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>Samsung</td>
<td>August 2017</td>
<td>Imraldi</td>
</tr>
</tbody>
</table>
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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)
2014: First-class EU biosimilar uptake as % of accessible market

Source: IMS Health / EU Commission
Or even a more clear example: GCSF (2013)

Volume uptake of GCSF biosimilars in standard units vs. daily GCSF available market products

Source: IMS Health, MIDAS, July 2013 MAT
Second Class: Therapeutic proteins with a pharmacological action

- These proteins do not mimic a biological function, but act mostly as a pharmacological antagonist e.g. binding a circulating protein or blocking a receptor

- The clinical effect may be visible and measurable within days or weeks
  - In a proportion of patients

- Currently licensed biosimilars infliximab and etanercept (adalimumab recently licensed, but as yet not on the market).
Third Class: therapeutic proteins with a remote clinical effect

- These protein drugs provide a statistical chance on benefit some time in the future (e.g. trastuzumab, rituximab).
- For these we need deep trust in the principles of similarity.
- On what is the purported clinical effect based?
- Can we expand the use in other types of cancer?
- Doctors may be very reluctant to accept clinical similarity of these molecules (“You can’t gamble with patients’ lives”)

- Only recently been licensed; no experience yet
Biosimilars in Registration (EMA, August 2017)

- Adalimumab (2x, Boehringer-Ingelheim)
- Bevacizumab (2x)
- Infliximab (1x)
- Insulin glargine (1x)
- Peg-filgrastim (3x)
- Trastuzumab (5x; Amgen, Celltrion, Mylan, Samsung)
Therapy classes exposed to biosimilar competition

Market share based on MAT 09 2015 sales values

- Oncology
- Fertility
- Anti-TNF
- G-CSF
- EPO
- HGH

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

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
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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 fomulary)?
  - What about interchangeability?
  - And what about substitution?

- Critical information
  - European Assessment Reports (EPARs)
  - Scientific literature (lags 1-3 years behind; reading list)
  - Professional standards and other guidance
Reading List | Biosimilar Medicines

Contents

1. General information
2. Biological variability
3. Regulatory & scientific framework
4. Information for prescribers
5. Terminology
6. Extrapolation of indications
7. Immunogenicity
8. Traceability of biopharmaceuticals
9. Physician-led switching
10. The economic case

How to select a biosimilar

Niels Boone,¹ Hugo van der Kuy,¹ Mike Scott,² Jill Mairs,² Irene Krämer,³ Arnold Vulto,⁴ Rob Janknegt¹

ABSTRACT
In the past few years biosimilars have penetrated the market following the expiry of patents of originator variants. This offers the opportunity to apply high-tech protein products at a lower cost. In contrast to small-molecule generics, clinicians and pharmacists have found it difficult to judge the efficacy and safety profiles of complex protein products. In recent years, the European Medicines Agency (EMA) has gained knowledge on assessing comparability between biosimilars and originator products in scientific and legal areas. This article provides an overview of an extensive set of 31 previously drawn biosimilar selection criteria and describes how several of these criteria are covered by EMA regulations and guidelines. A panel of experts (authors) reviewed the criteria and produced a shortlist of 10 criteria relevant for clinicians and pharmacists.

A different generic approach
Non-protein drugs are typically organic molecules of low molecular mass and well-defined molecular structure. Because the molecular structure of such a small-molecule drug can be fully analytically characterised, it is fairly easy for a generic drug manufacturer to produce a bio-equivalent medicinal product with the same drug usage form containing the same active ingredient as the innovator's drug product.

A protein product is a heterogeneous mixture of large molecules based on a sequence of amino acids folded in secondary and tertiary three-dimensional structures, which undergo post-translational folding processes to ultimately fold into a complex spatial structure. Post-translational modification is a function of host cells, which are not identical for the biosimilar and the originator medicinal product. This complex process is difficult to reproduce even in the production process of the originator drug. A full chemical characterisation of the product resulting from this process is a challenge using multiple analytical tools. However, it is not easy to decide which battery of chemical tests should be per-
Biosimilar selection criteria

- European biosimilar expert panel established 31 general selection criteria
- 10 were judged as relevant for clinical practice
- Decision matrix: biosimilar versus originator product
- European collaboration collecting and interchanging data for specific therapeutic groups
- Content is filled by experts
- MD and pharmacist can give their own weight to criteria

Krämer I, et al. EJHP Practice 2008;14:73–6;
Selection criteria

Production process/manufacturer

1. Is the manufacturer of the API and the medicinal product experienced in the production of biopharmaceuticals?

2. How long has the biopharmaceutical been on the market?

3. How extensive is the clinical experience with each individual biosimilar? Expressed as the number of patient days worldwide

Product specifications

4. Are there any differences in drug formulation and administration in comparison to the reference product of other biosimilars?

5. What is the current number of registered indications for the biopharmaceutical/biosimilar?
Summary  The stability of the rituximab biosimilar CT-P10, in 50 mL vials at a concentration of 10 mg/mL, and after dilution to final concentrations of 1 and 4 mg/mL and storage in polyolefin bags at 4°C and 25°C was studied by several orthogonal and complementary methods. No significant change (as defined by a magnitude greater than the inter-batch variability) was observed, for each of the parameters characterizing physical and chemical stability studied, for the two concentrations and temperatures tested, or for any of the three batches tested. This implies that cold-chain rupture and exposure to room temperature up to 15 days both for vials and diluted bags have no deleterious consequence on the quality of the product. Moreover, this extended stability permits safe in-advance preparation, dose-banding or flat-dose, that to avoid unnecessary delays in the management of the patient, improvement of the pharmacy and nurse workload and money saving by avoiding non justified losses of this expensive drug.
Evaluation of the physicochemical and biological stability of reconstituted and diluted SB2 (infliximab)

Jihyun Kim, Jihyun Chung, Sujin Park, Saem Jung, Dukwon Kang

ABSTRACT
Objectives To evaluate the critical quality attributes that might affect the stability of an infliximab biosimilar. According to its Summary of Product Indications for this biosimilar are the same as those for the reference product.

particle sizes and biological activity. The stability of reconstituted SB2 was assessed for 60 days at 5°C and for 7 days at 25°C. Stability of diluted SB2 at concentrations that ranged from 240 mg/250 mL (3 mg/kg; 80 kg patient) to 400 mg/250 mL (5 mg/kg; 80 kg patient) was assessed for 7 days at both temperatures.
Selection criteria (continued)

Clinical efficacy

6. Are there different results in comparison to the reference product?

Clinical safety and tolerability

7. Which (serious and mild) AEs and in which frequency were they reported in clinical trials with the biopharmaceutical?

8. Are there any contraindications, precautions, or warnings which are different compared to the reference product?

9. Is immunogenicity, as far as known, caused by a homogenous type of antibody or is there a high intra-individual and inter-individual variability? Is there a difference between biosimilar products regarding drug antibody homogenicity?

10. Are there differences in the incidence and severity of drug interactions?
Biosimilar selection criteria

- Pre-qualification criteria (can be knock-out criterion)
  - Reliability of supply
  - 24/7 medical support
  - Financial and reimbursement criteria
  - Medication safety aspects: labelling
  - Reference product registered in EU
    - E.g. Gastrofil; nonclinical part development was performed using Neukine, a non-EU-product

- Final criterion: price

Challenges

- Data can be coloured / biased
- Scoring and weighting is subjective
- System requires constant updating and review
- The originator may continue to have the best data
- In new biosimilars, patient-specific immunogenicity data will only emerge after some time; when is long enough?

- That a drug has been licensed does not imply that we will use it
Challenges

- Comparison of different products is not easy
  - Requires detailed study of e.g. EPAR
  - Requires constant update of information (cf. Flixabi®)
- Frequent transition of immunogenic biosimilars not advisable
  - Is a change once a year acceptable?
- Presence of several biosimilars in a hospital is a logistic nightmare
- EU directive on tendering (2004, update 2014)
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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
- Make selection process transparent for all
  - Advantages and disadvantages
  - Who will gain (preferably: gain sharing)
- Beware of attribution and nocebo-effects
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 discussing (see: Lakoff/YouTube)

*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
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’)

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)

Subject: Positioning Statements on Physician-led Switching\(^1\) for Biosimilar Medicines
Date: Update March 2017

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EU Regulators NEW!!!.................................................................................................................................................. 3
EU – Consortium of individual Regulators (2017) NEW!!!.......................................................................................... 3
Dutch Hospital Pharmacists Association and Dutch Federation of Medical Specialists

- **Toolbox biosimilars**
- A practical guide for successful 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
- Will become (freely) available in English
How to build trust in biosimilars?

- **Reduce the information gap**
  - Regulators can communicate their knowledge professionals:
    - “The past 10 year there has not been a single 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.
May 2017:
New guidance from EU-commission on biosimilars
European Commission Q&A on biosimilars for patients

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.
Biosimilars Toolkit

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
Biosimilars

News

FDA approves biosimilar infliximab

Renflexis
posted 03/03/2017

Samsung Biologics announced on 29 April 2017 that the US Food and Drug Administration (FDA) had approved its biosimilar version...

EMA approval for etanercept and rituximab biosimilars
posted 03/04/2017

The European Medicines Agency’s

Research

Computer modelling for glycoengineering of biosimilars
posted 06/03/2017

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

Prospective study finds switching to biosimilar infliximab safe
posted 05/03/2017

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 Brown Knoll Biologics’ Humira biosimilar. The Fujifilm corporation...

Biosimilars of etanercept
posted 04/03/2017

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Agenda

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
Take-home message

- The first biosimilar in the market may not be the best
- Comparison of biosimilars is not easy and based on a mixture of arguments; These arguments can be weighed in a matrix
- First the quality and some practical modalities should be evaluated
- Price comes second
- Avoid frequent changes
- Organise selection and implementation in a multidisciplinary fashion and with one voice and COMMUNICATE

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Thank you very much for your attention.

Questions?

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