Overcoming the gap between clinical use of biosimilars and education of pharmacists and other healthcare providers

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Conflict of Interest Statement

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

- I entertain friendly relationships 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
For background

- www.gabionline.net
- www.gabi-journal.net
- www.biosimilars-nederland.nl
- www.pharm.kuleuven.be/clinpharmacotherapy/mabel
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 the view.
Agenda

- Introduction
- The Need for Education
- Educational support examples
- Resources for Pharmacists
- Resources for Patients
- Educating Future Healthcare Professionals
- Conclusion
Due to the complete *new development paradigm of biosimilars*, clinicians have difficulty accepting biosimilars as equal alternative to innovator products.

These doubts have also infected patient-organisations and patients.

More than 40 biosimilars licensed by EMA

Pharmacists should be able to educate physicians and other stakeholders, but also patients, on the value of biosimilars; but are these products sufficiently known to them?

The question is: have pharmacists been trained for this?

Who is familiar with the concept of EPAR and has read them?
<table>
<thead>
<tr>
<th>Molecule</th>
<th>Reference</th>
<th>Biosimilar(s)</th>
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<tbody>
<tr>
<td>Adalimumab</td>
<td>Humira</td>
<td>Amgevita, Cyltezo, Halimatoz, Hefiya, Imraldi, Solimbic</td>
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<tr>
<td>bevacizumab</td>
<td>Avastin</td>
<td>MVasi</td>
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<td>Enoxaparine</td>
<td>Clexane</td>
<td>Inhixa, Thorinane</td>
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<td>Eprex</td>
<td>Absaemed, Binocrit, Epoetin alfa Hexal, Retacrit, Silapo</td>
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<td>Etanercept</td>
<td>Enbrel</td>
<td>Benepali, Erelzi,</td>
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<tr>
<td>Filgrastim</td>
<td>Neupogen</td>
<td>Accofil, Filgrastim Hexal, Grastofil, Nivestim, Tevagratim, Zarzio</td>
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<td>Follitropin alfa</td>
<td>Gonal-f</td>
<td>Bemfola, Ovaleap</td>
</tr>
<tr>
<td>Infliximab</td>
<td>Remicade</td>
<td>Flixabi, Inflectra, Remsima, Zessly</td>
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<tr>
<td>Insulin glargine</td>
<td>Lantus</td>
<td>Abasaglar, Lusduna, Semglee</td>
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<tr>
<td>Insulin Lispro</td>
<td>Humalog</td>
<td>Insulin Lispro Sanofi</td>
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<tr>
<td>Rituximab</td>
<td>Mabthera IV</td>
<td>Blitzima, Ritemvia, Rituzena, Rixathon, Riximyo, Truxima</td>
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<tr>
<td>Somatropine</td>
<td>Genotropin</td>
<td>Omnitrope</td>
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<tr>
<td>Teriparatide</td>
<td>Forsteo</td>
<td>Movymia, Terrosa</td>
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<tr>
<td>Trastuzumab</td>
<td>Herceptin IV</td>
<td>Herzuma, Kanjinti, Ontruzant</td>
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</tbody>
</table>
Agenda

- Introduction
- **The Need for Education**
  - Educational support examples
  - Resources for Pharmacists
  - Resources for Patients
  - Educating Future Healthcare Professionals
- Conclusion
More tailormade-treatment ("precision medicine")

As pharmacist you need to understand both the diagnosis and know in detail the medicines involved.

There is more needed than a quick fix: it needs a complete overhaul of the curriculum
We need a lot of education to familiarise healthcare professionals with the new biologics and make them confident

- Biosimilars are suffering from

  **The Illusion of Explanatory Depth**
  
  (check WikiPedia)

  - Many healthcare workers think they know about biosimilars, but underestimate the complexity.
  - However, in most surveys it is clear that many HCP’s lack knowledge and hence confidence
    
    A. to apply biosimilars (e.g. transition from originator to biosimilar)
    
    B. to explain the need for change convincingly to patients
    
    C. to understand the psychology of drug-efficacy and dynamics of biologics-action
      (declining efficacy, nocebo effects)
Short Report

Changes in Biosimilar Knowledge among European Crohn's Members: An Update

Silvio Danese a,b, Gionata Fiocchi a,*

*BD Center, Humanitas Research Hospital, University, Rozzano, Milan, Italy aGastro-enterology, Department of Medicine, University of Massachusetts, Lowell, MA, USA

Corresponding author: Prof. Silvio Danese, E-mail: silvio.danese@humanitas.it

Conference Presentation: ECCO Congress, Lugano, 2016

Awareness, Knowledge, and Behaviors of Specialty Physicians

Hillel Cohen · Donna Beydoun · David Chien · Tracy Dickey · Dorothy McCabe · Michael Muenzberg · Robert Pope · Jonathan Uy

Knowledge, behaviors and practices of community and hospital pharmacists towards biosimilar medicines: Results of a French web-based survey

Morgane Beck, Bruno Michel, Marie-Christine Rybarczyk-Vigouret, Dominique Levèque, Christelle Sordet, Jean Sibilia & Michel Velten

To cite this article: Morgane Beck, Bruno Michel, Marie-Christine Rybarczyk-Vigouret, Dominique Levèque, Christelle Sordet, Jean Sibilia & Michel Velten (2017) Knowledge, behaviors and practices of community and hospital pharmacists towards biosimilar medicines. Results of a French web-based survey, mAbs, 9, 2, 384-391, DOI: 10.1080/19440862.2016.1267087
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<th>Pharmacists</th>
<th>Number of participants</th>
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<th>Country</th>
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<td>UK</td>
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<td>Survey</td>
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<td>Hospital pharmacists + community pharmacists</td>
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Total number of participants: 1619

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<td>Australia</td>
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</table>

Total number of participants: 3088
Agenda

- Introduction
- The Need for Education
- **Educational support examples**
  - Resources for Pharmacists
  - Resources for Patients
  - Educating Future Healthcare Professionals
- Conclusion
Initiatives in Dutch Healthcare System

- Biosimilars Toolbox
  - Joint initiative from Dutch Association of Hospital Pharmacists and Federation of Medical Specialists

- BOM project
  - Educational Initiative from Biosimilars Nederland and Institute of Responsible Medicines Use
  - 3-year project, subsidised by Ministry of Health (800 k€E grant)
Dutch Hospital Pharmacists Association and Dutch Federation of Medical Specialists

- **Toolbox biosimilars** (April 2017)
- 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
(sorry, only available in Dutch)
Successful biosimilar-policies follow the *Rule of Four*

1. **Multi stake-holder approach**
   Include all that are involved: doctors, pharmacists, nurses, pharmacy-technicians, patient(organisations), hospital management

2. **Once voice principle**
   synchronise message from the healthcare-team; avoid nocebo-effects
   (present policy at patient council and medical staff of the hospital)

3. **Shared decision making**
   involve patient in decision-making process with positive attitude

4. **Gain sharing**
   Create win-win for those who do the work (e.g. the medical department)
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 (FDA, 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)

*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?
BOM: Tailormade Education on Biosimilars in Hospitals

National Educational Program for all Hospitals

Sponsored by Ministry of Health (3 year, 800 k€)
BOM-project: on a voluntary basis (at no cost)

Objectives

- Increase knowledge about biosimilars among prescribers, hospital staff and patients
- Stimulate the prescribing of most cost-effective alternative when prescribing a biological medicine
- Achieve maximal awareness of the potential offered by biosimilars to reduce healthcare costs and increase access to medicines.
How the program is executed?

- Zero-measurement: inventory of today's situation in the hospital
  - Acceptance of biosimilars; are there barriers?
  - Local initiatives already started
  - Efficiency of the drug-procurement process
- Initiation visit
- Tailormade educational program for all target-groups (incl. patients)
  - Lectures, classes, workshops, e-learning
- Monitoring developments (2 x per year)
  - What works, what failed
Agenda

- Introduction
- The Need for Education
- Educational support examples
- Resources for Pharmacists
- Resources for Patients
- Educating Future Healthcare Professionals
- Conclusion
Resources for pharmacists (and other HCP’s)

- Brochures and books
- Websites, e-learning
- Journal-articles
  - Google: biosimilars 1,870,000 (Google Scholar: 20,900)
  - Pubmed: biosimilars 2009
Step 1 Comparative quality studies

In vitro studies compare the protein structure and biological function using sensitive techniques capable of detecting minor differences with clinical relevance between the biosimilar and its reference medicine. These studies are much more sensitive than clinical trials for detecting such differences, as there is often variability among human subjects participating in trials. Differences that may affect clinical safety, efficacy or immunogenicity need to be further studied (e.g. in comparative non-clinical or clinical studies, step 2 and 3).

Step 2 Comparative non-clinical studies

These studies include pharmacodynamic studies in vitro, which look at binding and activation (or inhibition) of physiological targets and immediate physiological effects in cells. Pharmacodynamic studies in vivo (animal models) are only done if no suitable in vitro model exists. In vivo toxicological studies are only required in certain cases, for example when the biosimilar is produced in a new type of cell or organism, or when the formulation includes new excipients not used previously.

Step 3 Comparative clinical studies

The aim of studies in humans is not to demonstrate safety and efficacy in patients, as these have already been established for the reference medicine. Clinical trials are tailored to confirm biosimilarity and to address any questions that may remain from previous analytical or functional studies.

Figure 5. Biosimilar development is comparative and progresses in a step-wise manner
Understanding Biologics: From Protein to Clinical Practice

Authors: Wojciech Jurczak, MD, PhD; Brian Kirby, MD, FRCPath; Eduardo Mysler, MD; Steffen Thirstrup, MD, PhD; Arnold G. Vuito, PhD, FCP

Educational Impact Challenge

The goal of this activity is to educate healthcare professionals about the inherent complexity of biological medicines (biologics and biosimilars) and highlight the analytical assessment of quality that applies to both biologics and biosimilars.

Before you begin this activity, please assess your clinical knowledge by completing this brief survey. Answering these questions again after the activity will allow you to see what you learned and to compare your answers with those of your peers.
Biosimilars in Haematology: Plotting the Course to Long-Term Sustainability

Welcome and Introduction

A Patient’s Journey: Initiating Biosimilars

Why We Need Biosimilars: Mapping Out a Path to Sustainable Care

Q&A

A Patient’s Journey: A Life With Biosimilars

Panel Speaks: Navigating the Totality of Evidence for Rituximab Biosimilars: How Much and Which Data Necessary?

Q&A

A Patient’s Journey: Does Extrapolation and Switching Matter?

Panel Speaks: Data Extrapolation With Biosimilars: Improving Accessibility in Practice

Concluding Remarks and Ask the Faculty

Learning Objectives
Developing the nation's biosimilars program
9 Kozlowski, J Woodcock, K Midtun - England Journal of Medicine, 2011 - Mass Medical Society
To improve access to biologic drugs, Congress authorized the FDA to create an abbreviated pathway for approving drugs that are "biosimilar" to approved products. Reconciling the science of biosimilar development with a new regulatory framework is challenging.

A European perspective on the market accessibility of biosimilars
PJ Decleir, S Simoons - Biosimilars, 2012 - ingentaconnect.com
Paul J Decleir, Steven Simoons. Laboratory for Pharmaceutical Biology, Research Centre for Pharmaceutical Care and Pharmacoekonomics, Department of Pharmaceutical Sciences, KU Leuven, Belgium. Abstract: Biosimilars.

The challenge of biosimilars
Background. The purpose of this report was to review issues associated with the introduction of alternative versions of biosimilars in the oncology setting. Design. Data were obtained by searches of MEDLINE. Published references from relevant English-language journals.

Analytical tools for characterizing biopharmaceuticals and the implications for biosimilars
Biologics such as monoclonal antibodies are much more complex than small-molecule drugs, which raises challenging questions for the development and regulatory evaluation of follow-on versions of such biopharmaceutical products (also known as biosimilars) and their use.

Biosimilars: what clinicians should know
Biosimilar medicinal products (biosimilars) have become a reality in the EU and will soon be available in the US. Despite an established legal pathway for biosimilars in the EU since 2004, increasing and detailed regulatory guidance on data requirements for their approval.

Biosimilars—why terminology matters
Open up the possibility of developing biologics similar to those original products and to rely on licensing, in part, on the extensive knowledge gained with the original products. Although some versions of original biopharmaceuticals are already available.

Biosimilars: the science of extrapolation
Despite the establishment of a specific approval pathway, the issuance of detailed scientific guidelines for the development of similar biological medicinal products (so-called biosimilars) and the approval of several biosimilars in the European Union, acceptance of biosimilars has been slow.
Reading List | Biosimilar Medicines

Status: April 2018

Contents by topic

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

Contents by therapeutic area

A. Rheumatology
B. Dermatology
C. Gastro-intestinal
D. Oncology
E. Endocrinology

The Top 5 Biosimilars Articles for the Week of August 20

The Center for Biosimilars® recaps the top news for the week of August 20, 2018.

August 24, 2018

1. Pemetrexed Not Cost-Effective, Even When Used With Biosimilar Trastuzumab
2. Phase 3 Trials May Be Unnecessary for Biosimilars, Paper Argues
3. With Eradicating Biosimilars Coming In, Alesion Granted Priority Review for ALN18010
4. Biosimilars Trastuzumab CHPT Launches in Japan, But Not for Breast Cancer

Transcript:
Hi, I’m Samantha DiGrande for The Center for Biosimilars®, your resource for clinical, regulatory, business, and policy news in the rapidly changing world of biosimilars.

Here are the top 5 biosimilars articles for the week of August 20.

Number 5: A Japanese company has launched Celtrion’s trastuzumab biosimilar in Japan, but the product will only be sold to treat HER2-positive gastric cancers.

Number 4: The FDA has granted priority review for Alexion’s proposed long-acting C5 complement inhibitor that could help stave off biosimilar competition for the Soliris market.

Number 3: A new paper in BioDrugs argues that phase 3 studies may no longer be necessary for biosimilars.

Number 2: The United Kingdom’s National Institute for Health and Care Excellence says it does not recommend Perjeta for routine use after surgery in patients with breast cancer, even though using the drug in combination with biosimilar trastuzumab could reduce the total cost of treatment.

Number 1: Pfizer’s proposed adalimumab biosimilar demonstrated similar efficacy, safety, and immunogenicity profiles to the reference Humira at 26 weeks of treatment in patients with rheumatoid arthritis.

A little help….

Pfizer Calls for FDA Guidance on False or Misleading Information About Biosimilars

Misleading statements, says Pfizer in a citizen petition to the FDA, cast doubt on the safety and efficacy of biosimilars.

READ MORE >>

Contributor Content

Biosimilar Nonmedical Switching Must Never Undermine Patient Safety

Assessing the Next Wave of Biosimilars

Letter to the Editor: European Pharmacovigilance for Biosimilars is Robust and Provides Meaningful Information

HH3 Seeks Input on “American Patients First” Proposals

CMS Finalizes Policy to Lower the Cost of Biosimilars

READ MORE >>

Trending

Are Phase 3 Studies for Biosimilars Unethical? Avalere’s Gillian Woollett Weighs In

Pfizer Calls for FDA Guidance on False or Misleading Information About Biosimilars

Blocking PDGF Could Make Bevacizumab More Effective in Treating Glioblastoma

British Columbia Will Reimburse for Renflexis, Merck Announces

READ MORE >>
### Multimedia

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<td>Keeping up with fast-paced clinical, regulatory, and policy innovation in healthcare is difficult. Our video interviews provide insight from key experts in the field of biosimilars, and help keep you informed.</td>
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<tr>
<td>Our Peer Exchange™ program provides a multi-stakeholder perspective on important issues that providers, pharmacists, payers, and patients grapple with as they step into the world of biosimilars.</td>
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<td>Our podcast, &quot;Not So Different,&quot; provides insights from and discussions with stakeholders from across the biosimilars landscape.</td>
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WHO calls for more education

The WHO says that educational policies—including local initiatives among physicians in hospitals or in the outpatient setting—will be of key importance to greater biosimilar uptake in these nations, because acceptance and trust in biosimilars among healthcare providers is a driver of uptake.
Policies for biosimilar uptake in Europe: An overview

Evelien Mookens1*, Arnold G. Vulto2, Isabelle Huys3, Pieter Dyf4, Brian Godman5, Simona Kavalek6, Barbara Claus7, Maria Dimitrova8, Giuneca Petkova8, Ljiljana Soćev-Briško6, Juraj Slaby9, Robin Sebesta9, ONI Lauri1,13, Allan Karr1,4, Margarete Beck13, Joanna E. Martikainen10, Gisbert W. Selko10, Susen Spillane18,19, Laura McCullough18,19, Gianluca Trifiro20, Patricia Vela Bonanno21, Asbjørn Mack22, Antra Fogle23, Anita Viksna23, Magdalena Władysziuk24, Helder Mota-Filipe25, Dmitry Moshkov26, Marija Kalaba27, Simona Mencec Bedraš28, Jurij Fürst29, Corrine Zara30, Peter Skjold31, Einar Magnusson32, Steven Simoons1

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* evelien.mookens@kuleuven.be


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Generics & Biosimilars Initiative (founded in 2008)

www.gabi-online.net

Under Development: GaBi Latin America
Generics and Biosimilars Initiative – Building trust in cost-effective treatments

GaBi Online
Building trust in cost-effective treatments

GaBi Journal, Volume 7, 2018, Issue 2, now available online!
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31 August 2018

This week’s line-up

>> EMA approves adalimumab and pegfilgrastim biosimilars
The European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) announced on 27 July 2018 that it had recommended granting marketing authorization for the adalimumab biosimilar Hanlo and also for the pegfilgrastim biosimilars Palazye ... Continue reading...

>> Alternative mAb purification strategies: a tool to increase global access to biotherapeutics?
The monoclonal antibodies’ (mAbs) market is dominant among therapeutic biologics. Between 2013 and 2017, it has witnessed the approval of 11 biosimilars and 33 new molecules by the regulatory authorities in the EU and the US. A foreseen increase in demand arising from ... Continue reading...

>> AbbVie signs another licensing deal for adalimumab biosimilar
US-based pharma giant AbbVie has signed yet another licensing deal for a biosimilar version of its blockbuster arthritis drug Humira (adalimumab) ... Continue reading...
Agenda

- Introduction
- The Need for Education
- Educational support examples
- Resources for Pharmacists
- **Resources for Patients**
- Educating Future Healthcare Professionals
- Conclusion
European Commission Q&A on biosimilars for patients (available in almost all EU-languages)

- It contains questions and answers on biosimilar medicines and is now available in 23 languages, serving as a reliable source of information for patients.

- This consensus information on biosimilar medicinal products was drafted by and for patients together with representatives of the European Medicines Agency, the European Commission and concerned stakeholders [the European Patients Forum (EPF), the European Federation of Crohn’s & Ulcerative Colitis Associations (EFCCA), the Standing Committee of European Doctors, European Federation of Pharmaceutical Industries and Associations (EFPIA), European Association for BioIndustries (EuropaBio) and Medicines for Europe]. The Q&A was first launched in English in January 2017.

http://ec.europa.eu/DoksRoom/documents/26643
Dutch Pilot: Monitor biological medicines

Pilot project towards a patient-reported outcome measure (PROMs) based national drug safety monitoring system for biological medicines

Identification of bottlenecks and success factors

Method:
- Bimonthly questionnaires – adverse drug reactions (ADRs) biological medicines
- Possibility to enrichment data by requesting follow up (patient and practitioners including pharmacists)
Monitor biological medicines

**Initiator:** Ministry of Health (2016)

**Goal:** Establishment of a national safety monitoring system for biological medicines

- Monitoring the safety of biological drugs by PROMs
- Contribute to public acceptance of biosimilars

**Inclusion criteria patients:**

- Chronic inflammatory disease patients that use a biological
  - Inflammatory bowel disease
  - Inflammatory rheumatic disease
  - Inflammatory skin disease

**Multicentre:** 8 hospitals and 3 registry’s (at least)
Aims:

- Early recognition of unexpected and/or serious ADRs whether or not they are batch-related.
- Insight into spectrum of ADRs per disorders and/or biological agents in practice, including the impact, treatment and course of the ADRs.
<table>
<thead>
<tr>
<th>Biological medicines</th>
<th>Brand name (innovator en biosimilar)</th>
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<tbody>
<tr>
<td>Abatacept</td>
<td>Orencia®</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>Amgevita®, Cyltezo®, Humira®, Imraldi</td>
</tr>
<tr>
<td>Anakinra</td>
<td>Kineret®</td>
</tr>
<tr>
<td>Brodalumab</td>
<td>Kytnheum®</td>
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<tr>
<td>Canakinumab</td>
<td>Ilaris®</td>
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<tr>
<td>Certolizumab pegol</td>
<td>Cimzia®</td>
</tr>
<tr>
<td>Dupilumab</td>
<td>Dupixent®</td>
</tr>
<tr>
<td>Etanercept</td>
<td>Benepali®, Enbrel®, Erelzi®</td>
</tr>
<tr>
<td>Golimumab</td>
<td>Simponi®</td>
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<tr>
<td>Guselkumab</td>
<td>Tremfya®</td>
</tr>
<tr>
<td>Infliximab</td>
<td>Flixabi®, Inflectra®, Remicade®, Remsima®</td>
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<tr>
<td>Ixekizumab</td>
<td>Taltz®</td>
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<tr>
<td>Natalizumab</td>
<td>Tysabri®</td>
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<tr>
<td>Rituximab</td>
<td>Mabthera®, Rixathon®, Truxima®</td>
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<td>Sarilumab</td>
<td>Kevzara®</td>
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<tr>
<td>Secukinumab</td>
<td>Cosentyx®</td>
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<tr>
<td>Tocilizumab</td>
<td>Roactemra®</td>
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Future

- Evaluation of the pilot project (mid 2019)
- National drug safety monitoring system for biological medicines based on PROMs
- Extension to medicines for which additional monitoring is required
- Connecting with other existing initiatives (e.g. registry’s), making PROMs available for patient centred health systems.
- Optimal use of collected data
Agenda

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- Resources for Pharmacists
- Resources for Patients
- **Educating Future Healthcare Professionals**
- Conclusion
Education about biological medicines for the future pharmacist

• **Aim:** mapping education about biological medicines, including biosimilars, in the current curricula of the future pharmacists across Faculties of Pharmacy

• **Method:**
  - Short electronic survey
  - Addressed to Deans/programme directors/faculty members
  - Disseminated with the help of FIP, British Pharmacological Society European Association of Faculties of Pharmacy
Education about biological medicines for the future pharmacist (launched in the holiday season…. Very preliminary results)

- **27 responses across 20 countries in the world**

<table>
<thead>
<tr>
<th>Country</th>
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<tbody>
<tr>
<td>Argentina</td>
<td>Kenya</td>
<td>Macedonia (FYROM)</td>
<td>Romania</td>
</tr>
<tr>
<td>Belgium</td>
<td>Colombia</td>
<td>Malta</td>
<td>Slovakia (2x)</td>
</tr>
<tr>
<td>Bosnia and Herzegovina</td>
<td>Finland</td>
<td>The Netherlands (2x)</td>
<td>Spain (3x)</td>
</tr>
<tr>
<td>Brazil (2x)</td>
<td>Hungary (2x)</td>
<td>Poland</td>
<td>Turkey</td>
</tr>
<tr>
<td>Canada</td>
<td>Indonesia</td>
<td>Portugal</td>
<td>UK (2x)</td>
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</table>
Education about biological medicines for the future pharmacist

Number of hours devoted to biological medicines in general/biosimilars during the curriculum
Education about biological medicines for the future pharmacist

• Overall, aspects about biological medicines (incl. biosimilars) are addressed over different courses and years in the curriculum (e.g. biotechnology, pharmacology, pharmacotherapy, hospital/public pharmacist specialization)

• Some universities have specific courses about biologicals and/or future/innovative medicines
  • Utrecht University, The Netherlands, has a the master-of-pharmacy curriculum a 6-weeks compulsory course in biologics (incl. ATMP’s) & biosimilars

• Commonly addressed topics about biosimilars are comparability, interchangeability with originator, production aspects, differences in structure, monitoring, cost aspects, regulatory pathway
Education about biological medicines for the future pharmacist

- **Cost effective use of medicines** is discussed in most curricula (during courses such as pharmacoeconomics, rational drug use, pharmaceutical care)

- Some respondents indicate that cost effective use of medicines is not discussed or very briefly

- The **choice between different (biological) medicines** is less generally addressed during the curriculum
Education about biological medicines for the future pharmacist

Help us to gain more insights via…:

https://docs.google.com/forms/d/e/1FAIpQLSeCZ3lCMGkSUP0lyA1QjO6uL2JCsdO3G0hF75gIZpBiCG8Wqw/viewform?usp=sf_link

Education about biological medicines for the future physician:

https://docs.google.com/forms/d/e/1FAIpQLSf3h4bdTbk8udtNMKkyzmwobCSanrM6ceSddgA-l5ixLBzdGw/viewform?usp=sf_link
Education about biological medicines, including biosimilars, for the future pharmacist - a global survey

The following survey aims to map the educational efforts about biological medicines, including biosimilars, incorporated in the current curricula for the future pharmacists. This survey aims to address the Deans office, program directors or Faculty coordinators of your institution, not the students.

This survey is part of the academic research program of the MABEL Fund ("Market Analysis of Biologics and Biosimilars following loss of exclusivity"). The MABEL Fund is a collaboration between the University of Leuven (KU Leuven, Belgium) and the Erasmus University Medical Centre (The Netherlands) and investigates the off-patent biological medicines market.

The survey will take approximately 15 minutes to complete. Your answers will be anonymized and will be treated confidentially. This survey aims to address the Deans office or program directors of your institution, not the students.

If you have any questions, please feel free to contact us via the following e-mail addresses: liese.barbier@kuleuven.be or a.vullo@gmail.com

Thank you in advance for your participation!

With kind regards,

PhD researcher Liese Barbier (KU Leuven, Leuven, Belgium)
Prof. Arnold G. Vullo (Erasmus University Medical Centre, Rotterdam, the Netherlands)

For more information about our research, please visit: https://pharm.kuleuven.be/clinpharmacotherapy/mabel
Concluding remark

We need to change the education of future pharmacists and physicians in better understanding of

A. The nature of therapy with biological medicines and
B. Different, equally valid, drug-development models
C. To be prepared to make drug-choices based on best value therapy

There is progress since the 2008 ASHP-report, but we are not there yet.....
The next generation of pharmacists will not suffer anymore from

The Illusion of Explanatory Depth
Thank you very much for your attention

Questions?

Contact:

a.vulto@gmail.com

liese.barbier@kuleuven.be