LBP Opleidingsinstituut voor Care & Cure: Biosimilars in the Market; what does it mean for us?

Rotterdam, June 18, 2014.

What is a biosimilar and how does sound biosimilar use look like?

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Agenda

LBP OPLEIDINGSINSTITUUT
VOOR CARE & CURE

1. What are we talking about: only real biosimilars
2. The hot patato
3. Some definitions: Interchangeability and Substitution

   formal and informal frameworks
4. “The“ biosimilar does not exist: three generations of biosimilars
5. The science of switching and substitution
6. Five criteria for acceptance of a drug
7. The information gap
8. In summary

Conflict of Interest

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

- I declare no personal financial interest in any pharmaceutical bussiness
- I entertain friendly relationships with all innovative and generic / biosimilar companies
- As a co-founder I have a societal – but not financial - interest in the advocacy of cost-effective treatments via the Generics & Biosimilar Initiative (GaBI)
- My employer – Erasmus University Hospital - receives any speakers honoraria if they let me speak at scientific or commercial meetings.

What are we talking about?

- *The only true definition of a biosimilar as of June 2014:*
  - A biosimilar is a pharmaceutical product, that as such has been licensed via the WHO regulatory pathway (=minimum global standard)
- *What does that mean?*
  - It is a copy of an already licensed biotech-drug, 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*.

The hot patatoe

- When will a physician prescribe a biosimilar and / or when will a pharmacist dispense a biosimilar product?
  - If the physician has sufficient trust in the sameness of the biosimilar
  - If the pharmacist is allowed to dispense a biosimilar
  - And if both have sufficient incentive to do so

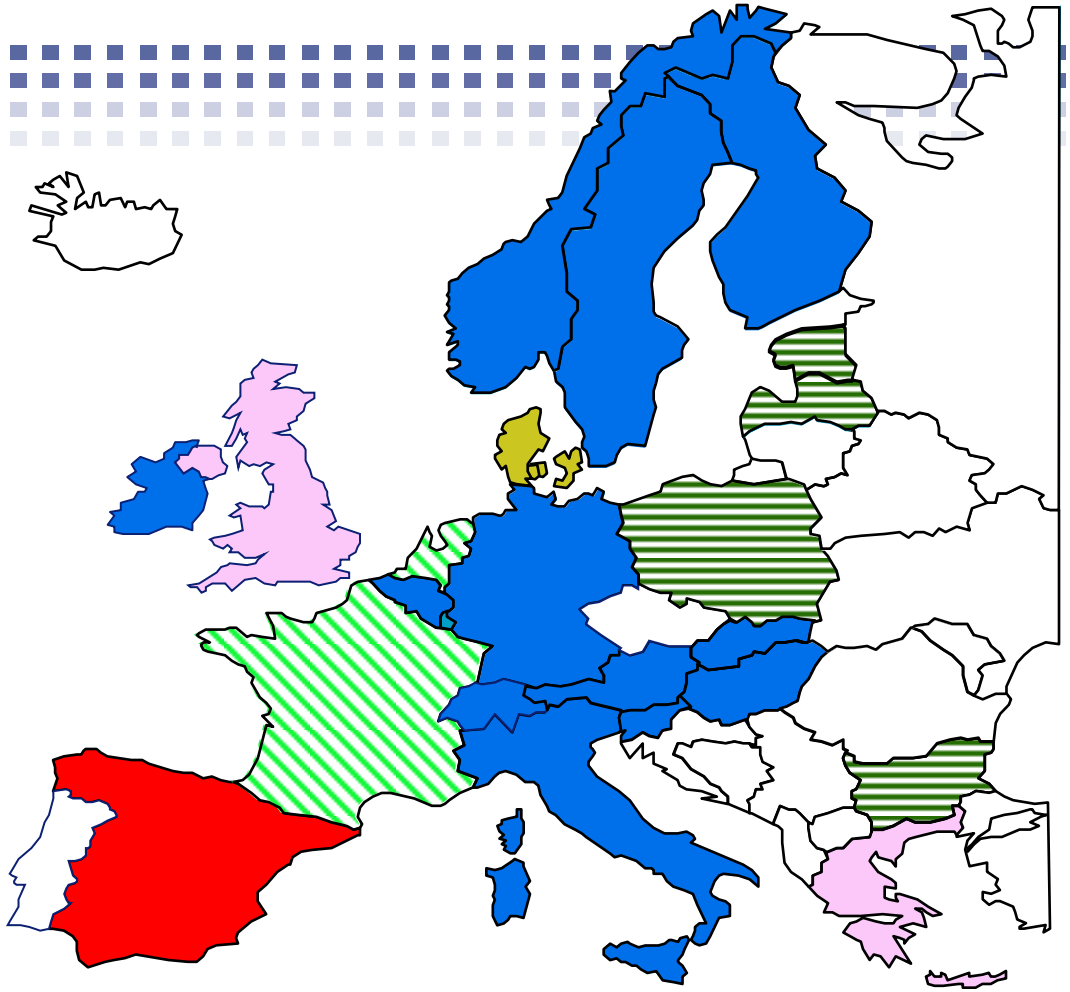
More definitions: Interchangeability and substitution

- **Interchangeability** is a product property: the alternative product will achieve the same clinical effect
  - At the population level: both products can be used for treatment for the same condition in the same population.
  - At the individual level: the biosimilar can be used instead of the innovator product.
- **Substitution** is an act, where an interchangeable medicinal product is replaced by a similar / equivalent product at the pharmacy level without consulting the prescriber
- **Interchangeability** is a product characteristic and is a condition for **substitution**.

Substitution and Interchangeability approach by EMA

- Interchangeability is assessed during the licensing process
  - EMA assumes biosimilarity (equivalence)
    - Has no say over substitution or switching, that is a national matter (subsidiarity principle)
    - (and now we have a new confusing definition for *interchangeability* from the EU commission)
- At a national level a variety of conditions affect prescribing:
  - Legislation (at least 8 EU countries prohibit substitution)
  - National (professional) guidelines
  - INN-prescribing required under brandname / EU directive

Substitution / Prescribing policies in several EU countries (2014)



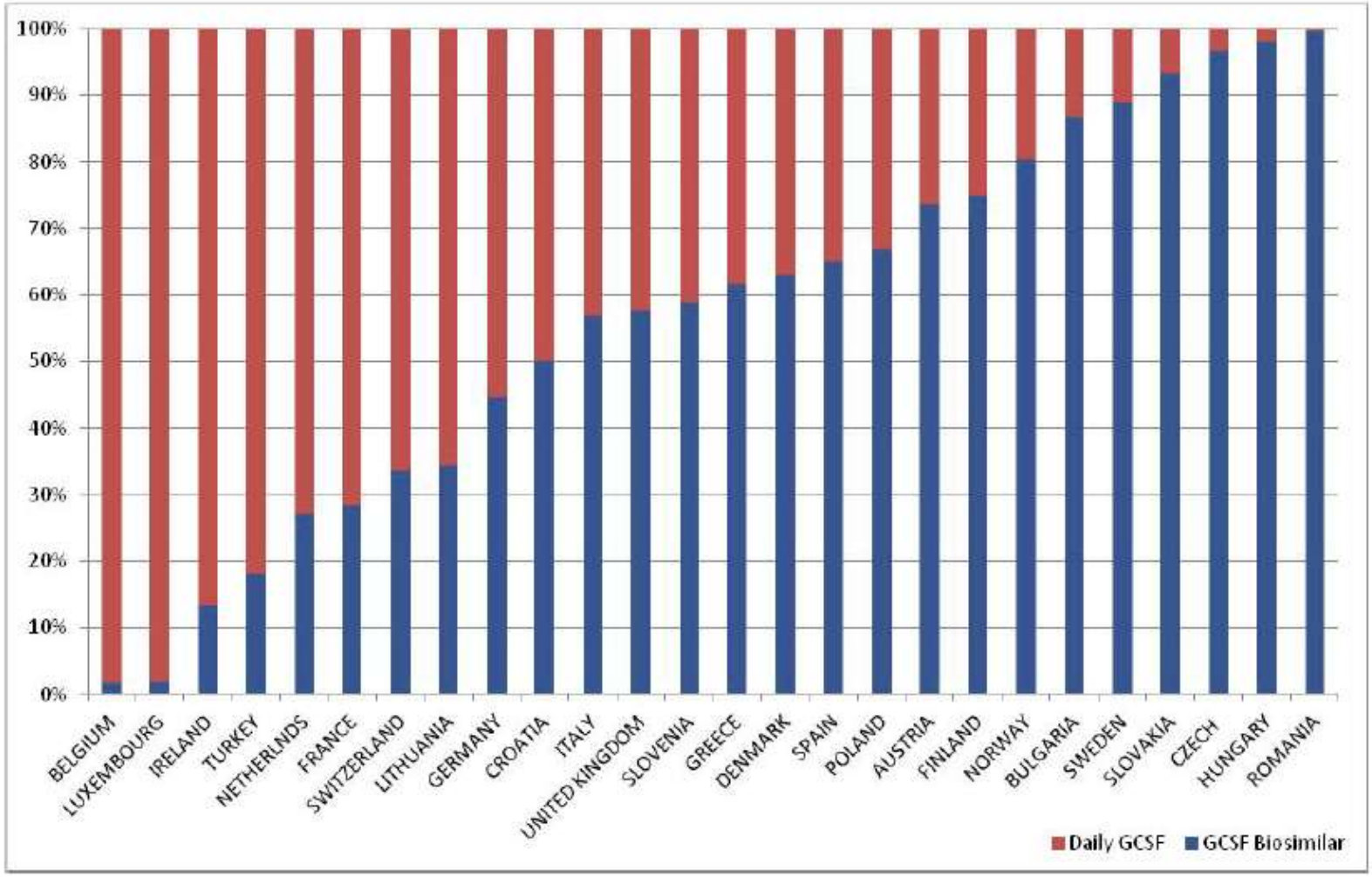
- Substitution possible only for patients starting treatment
- Biological substitution prohibited by law
- Biologicals/biosimilars not considered substitutable (or not on national substitution list) (Germany special case)
- Substitution only for other biosimilars
- All substitution (including small molecule generics) prohibited
- No guidance, but substitution happening (no official figures)

DIRECTIVE 2012/52/EU requires brand name prescribing for biologicals

Niederwieser Eur J of Haematology 2011;86:(277–288)
Courtesy Dr. Hans Ebbers, Utrecht University

And a result as could be expected (example: GCSF)

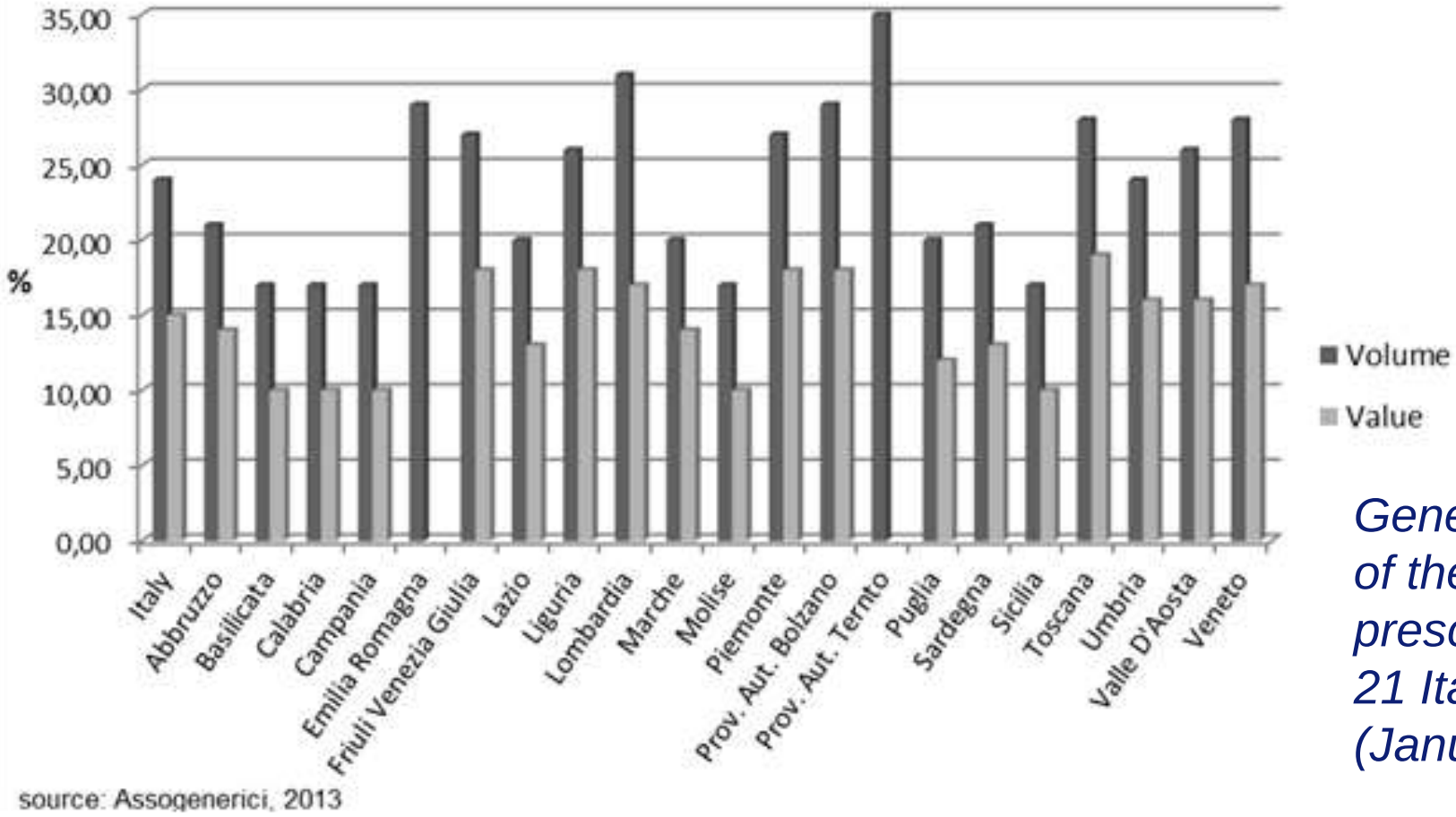
Volume uptake of GCSF biosimilars in standard units vs. daily GCSF available market products



Source: IMS Health, MIDAS, July 2013 MAT

But even within countries large differences exist

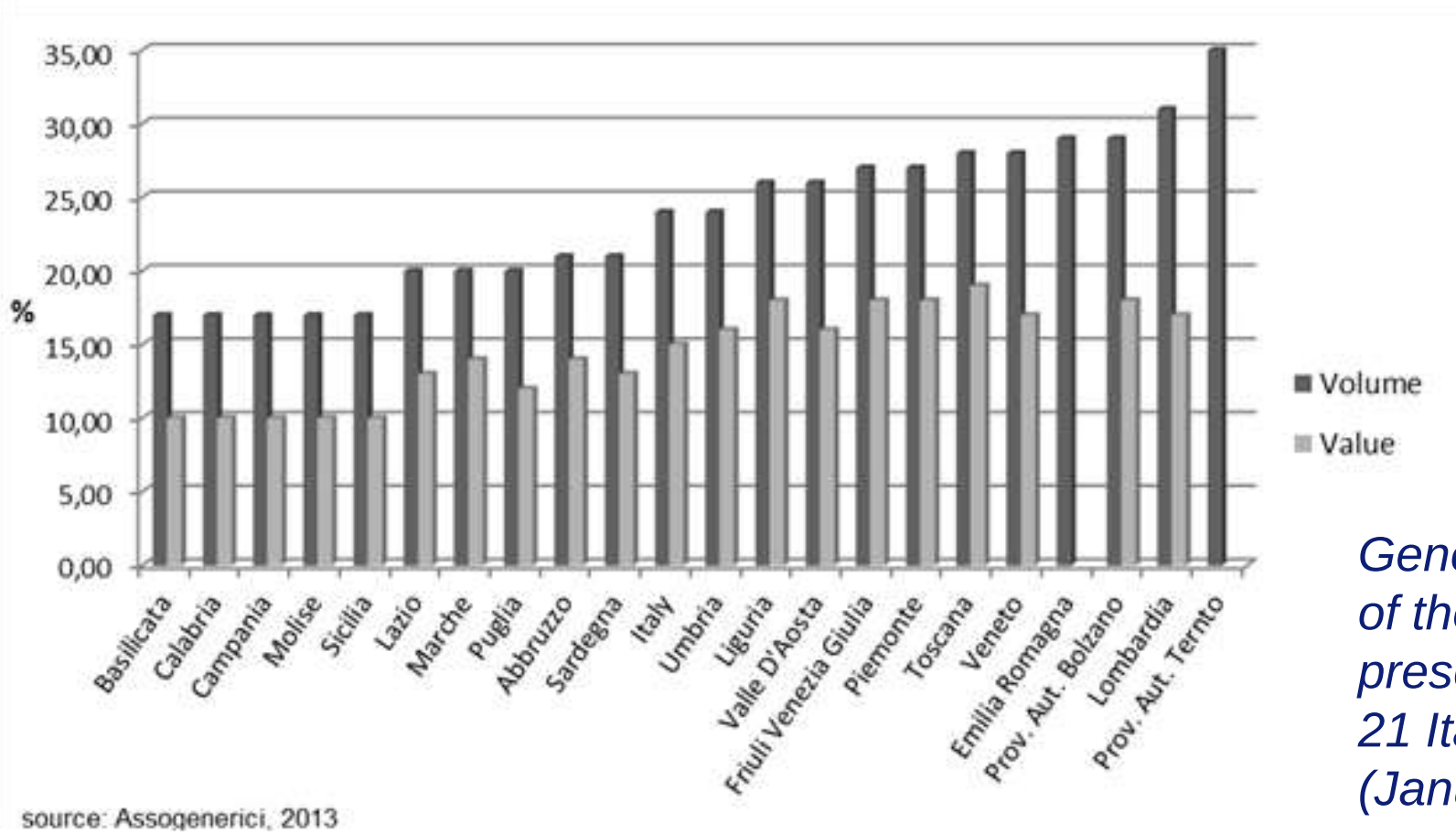
The case of Generic Medicines in Italy: The rules are the same, but practice is different (1/2)



Generic market shares of the 100% reimbursed prescription market in 21 Italian regions (January – July 2013)

Dylst et al. Exp Rev PharmacoEcon 2014, submitted

The case of Generic Medicines in Italy: The rules are the same, but practice is different (2/2)



Generic market shares of the 100% reimbursed prescription market in 21 Italian regions (January – July 2013)

Dylst et al. Exp Rev PharmacoEcon 2014, submitted

- Which means that legislation is only part of the story
  - There exists a formal legal framework
  - Versus a less formal local interpretation with many variations
- Acceptance of a biosimilar is dependent on how different stakeholders act.
- Essential to buy in “ownership” from prescribers (e.g. via guidelines)
- *“The”* biosimilar does not exist

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4. Three Generations of Therapeutic Proteins / biosimilars

- Generation 1: substitution products (“replacement therapy”)
  - Like hormones, growth factors
- Generation 2: proteins with a distinct pharmacologcial effect
  - Like TNF-alfa inhibitors
- Generation 3: proteins with a more remote clinical effect
  - Targeted therapies in oncology

First generation: proteins mimicking biological functions

- Mostly hormones
  - Insulin
  - Follicle stimulating hormone
  - Growth hormone
  - Coagulation factors and thrombolytic agents
  - Hematopoietic growth factors

- Pharmacological effects:
  - almost instantaneous or visible within days
  - Mostly a simple dose-effect relationship

First generation biosimilar replacement therapy

- Examples of such effects
  - Insulin: glucose goes down
  - FSH: ovulation occurs
  - Growth hormone
    - Initially effect on “biomarkers”
    - On the longer term: increased length growth
  - Coagulation factors: stop bleeding
  - Thrombolytic agents: dissolve blood clots
  - Hematopoietic growth factors:
    - increase in white or red blood cell count

First generation biosimilars licensed in the EU (2013)

Class	Product	Medicine Name	Active Substance (INN)	EU approval
Epoetins	HX575	Abseamed	epoetin alfa	28/08/2007
		Binocrit	epoetin alfa	28/08/2007
		Epoetin alfa Hexal	epoetin alfa	28/08/2007
	SB-309	Retacrit	epoetin zeta	18/12/2007
		Silapo	epoetin zeta	18/12/2007
Granulocyte-colony stimulating factor (G-CSF)	XM02	Biograstim	filgrastim	15/09/2008
		Ratiograstim	filgrastim	15/09/2008
		Tevagrastim	filgrastim	15/09/2008
	EP2006	Filgrastim Hexal	filgrastim	06/02/2009
		Zarzio	filgrastim	06/02/2009
	PLD108	Nivestim	filgrastim	08/06/2010
Human growth Hormone	NA	Omnitrope	somatropin	12/04/2006
	~~NA~~	~~Valtropin~~	~~somatropin~~	Withdrawn
		Somatropin Biopartners	somatropin	5/8/2013
Follicle stimulating hormone	XM17	Ovaleap	Follitropin alpha	27/9/2013

2nd generation: Therapeutic proteins with a pharmacological action

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

- The clinical effect may be visible and measurable within days or weeks

- Example: TNF-alpha inhibitors like infliximab and etanercept.

Second generation of EU licensed biosimilar

Active Substance	Brand Name	Approval Date
Infliximab (CT-P13)	Inflectra Remsima	September 2013 September 2013

Approved indications

Supported by clinical research:

- Ankylosing spondylitis
- Rheumatoid arthritis

Extrapolated indications:

- Psoriatic arthritis
- Psoriasis
- Crohn's Disease
- Ulcerative colitis

GENERICS AND BIOSIMILARS INITIATIVE
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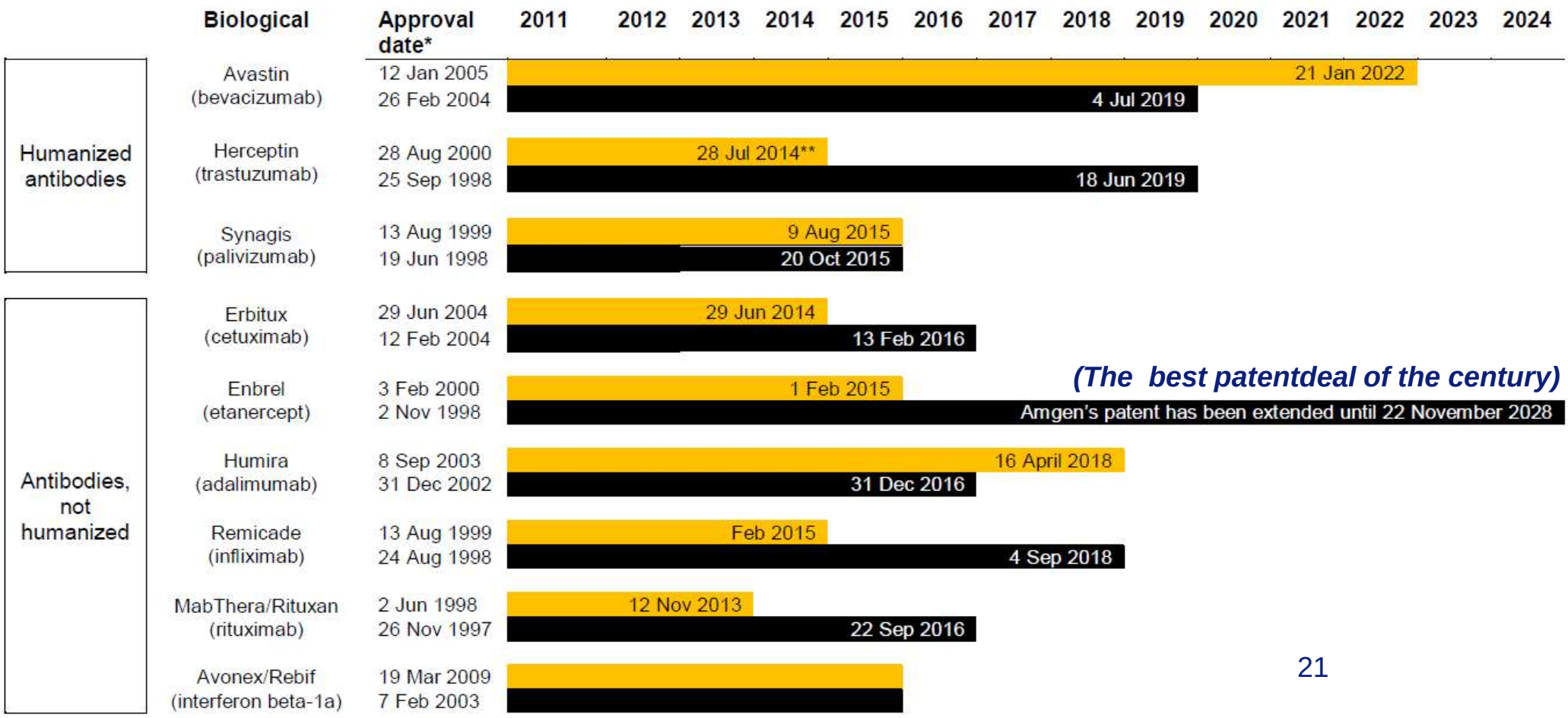
(1/10/2013)

GaBI Online: US$67 billion worth of biosimilar patents expiring before 2020

Figure 1: Expiry dates for major patents on best-selling biologicals



(The best patentdeal of the century)

3rd generation: 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).
- Now 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”)

- As yet, these are theoretical questions: as yet no biosimilar of this type has been granted marketing authorization.

More complex molecules require also deeper understanding of the similarity principles

- Different generations are confronted with different emotions
- ***First generation biosimilars are a no-brainer***
  - They work, and have a proven safety track record
- ***Second generation biosimilars:***
  - Will become available in 2015 in the greater part of Europe
  - The current knowledge base looks promising
  - Extrapolation of indications under debate among professionals
- ***Third generation biosimilars:***
  - Difficult to say: as yet no product in registration
    - (as far as we know May 2014)

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EXPERT OPINION

The safety of switching between therapeutic proteins

Hans C Ebbers, Michael Muenzberg & Huub Schellekens†
†*Utrecht University, Utrecht Institute for Pharmaceutical Sciences (UIPS), Department of Pharmaceutics, TB Utrecht, The Netherlands*

6. Expert opinion

We were not able to identify direct safety risk associated with substituting biopharmaceuticals in any of the data sources we analyzed. Although there may be valid reasons to be prudent with switching between biopharmaceuticals, including traceability of adverse events or concerns about patient anxiety, thus far there is no evidence that the process of switching in itself poses a risk to patients. Currently, there is limited clinical data that specifically studied the effects of switching, but they mostly concluded that patients can be safely switched from one product to the other. However, most clinical trials

Interchangeability, immunogenicity and biosimilars

VOLUME 30 NUMBER 12 DECEMBER 2012 NATURE BIOTECHNOLOGY

Hans C Ebbers, Stacy A Crow, Arnold G Vulto & Huub Schellekens

For authorized biosimilars to achieve full acceptance in the marketplace, it is crucial that they are considered to be therapeutically equivalent and interchangeable with the brand reference product.

If a product is approved as a biosimilar in Europe, this should be interpreted to mean that the product is deemed both therapeutically equivalent and interchangeable with the reference product and similar biosimilars.

Automatic substitution at the pharmacy level will be a legal challenge

GaBiJournal
Generics and Biosimilars Initiative Journal

REVIEW ARTICLE

Biosimilarity and Interchangeability

Interchangeability. An insurmountable 5th hurdle?

Hans C Ebbers[1], PhD; Paul Chamberlain[2], BSc

The arrival of biosimilars has led to considerable debate on how they can be used in clinical practice. A particular concern is related to the question of whether a biosimilar can be safely interchanged with the originator product or other biosimilars. Here we will discuss challenges to the regulatory approach for establishing interchangeability, in the sense of considering biosimilar versions as therapeutic equivalents that could – depending on National or Federal Law – be substituted at the pharmacy level, and compare these to the weight of real-world evidence of the risks of potential differences that could modify longer-term clinical benefit-to-risk. Our discussion will be mainly focused on monoclonal antibodies. We conclude that it will be highly challenging to establish interchangeability of biosimilars, and it should be questioned whether the 'higher' standard required for designation of interchangeability adds to the benefit for patients.

Keywords: Biosimilars, immunogenicity, interchangeability, monoclonal antibodies, substitution, switching

In Press: GaBI Journal 3(2014)No.2

For a decision to prescribe a drug, information is needed

- Biosimilars are not *identical* but *similar*
- What are then the differences and what could be the consequence?
- A deep understanding of bioequivalence and “biosimilarity” is not easy
- Interchangeability / substitutability needs to be addressed in a large scale – and thus costly - blinded clinical trial to avoid bias.
- We have to accept that at the time of licensing there is always a certain degree of uncertainty – as with every other new drug.
  - How will the new drug – innovative or biosimilar – stand the test of use in everyday practice in your patients?

Physicians don’t like uncertainty

In doubt do not cross!

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5 criteria that play a role in adoption of a new drug

Adoption: "a decision to make full use of an innovation as the best course of action available"

1. Relative advantage

* Is the innovation perceived as better?

* What is the added value?

Effectiveness, quality, safety, ease of use, economic factors

2. Compatibility

* Perception of consistency with past experience and current needs

Does it fit expectations?

Moors EHM, Eur J Hosp Pharmacy Practice 13(2007)No.5, 57-58

5 criteria that play a role in adoption of biosimilars

3. Complexity

* Perception of degree of difficulty in using the innovation

* Proving similarity is a serious barrier to biosimilar drug development (when is enough, enough?)

4. Trial data

* Overall clinical experience before drug is adopted

* How reliable, informative and convincing are the proof-of-bioequivalence studies?

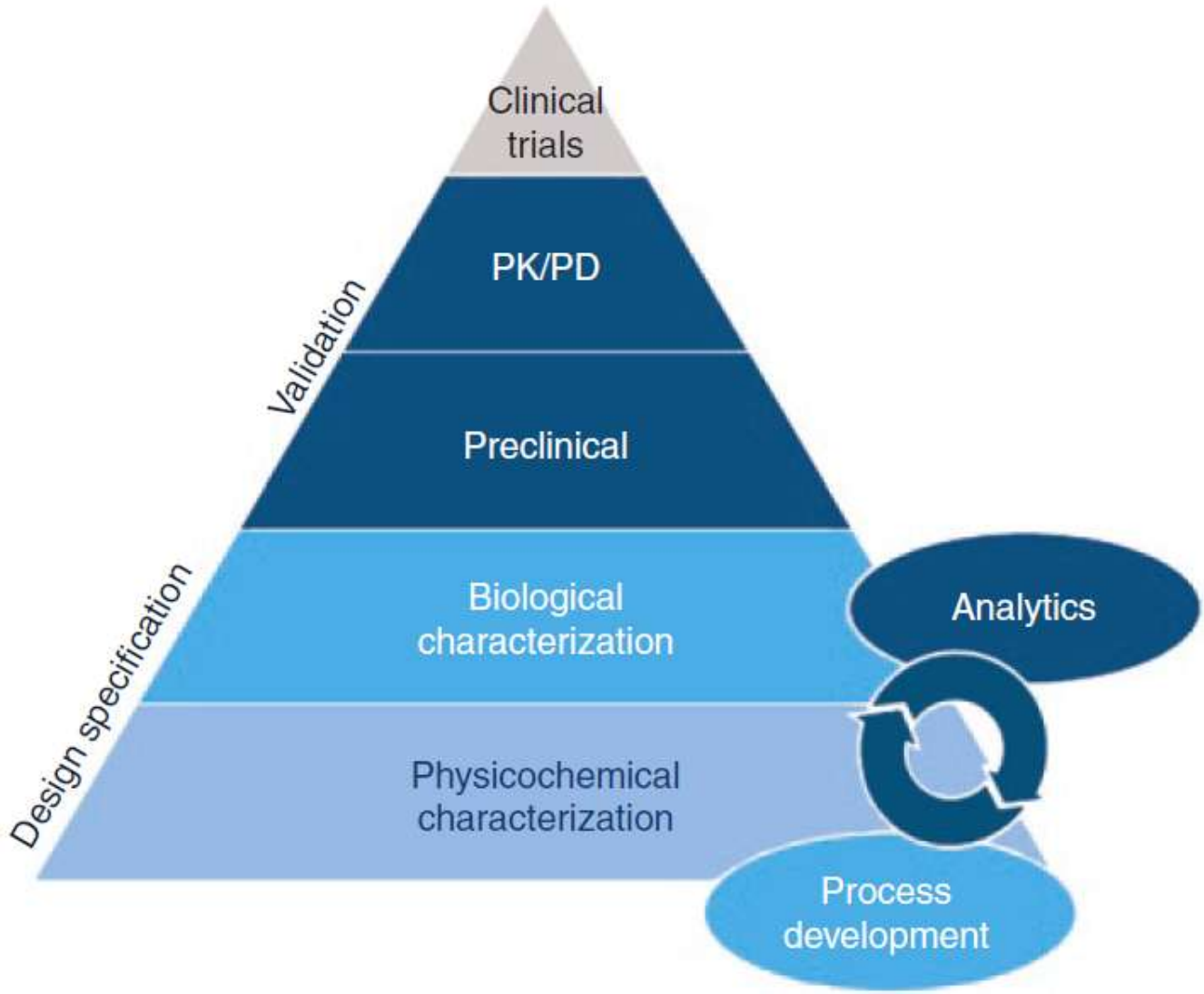
5. Observations

* How observable are the results of the innovation?

Biosimilars hardly offer ground breaking research results

Knowledge base *looks* rather small vs. innovative product

The Biosimilar Principle: reversed engineering and reversed body of evidence



- Similarity is proven with analytics and only confirmed in a small clinical trial
- Evidence comes from the lab and not from the clinical trial
- Clinical trials are notoriously insensitive for small differences in treatment

What to choose?

Acceptance of a new drug dependent on

Affinity with the existing brand-product

(= current value, including habit)

Versus

Atrractiveness of the alternative (biosimilar)

(= it implies a change with uncertain outcome)

Without an incentive for change,

A physician will not change it's prescribing habits

Drug prescribing is highly emotion and information driven

Where to obtain convincing information?

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

The market place makes it even more confusing

- Innovative companies have high stakes
  - Are seeding doubt among prescribers and patients with “you never know”.
  - Have invested for years in a strong prescriber relationship

- The biosimilar industry was reluctant with high quality scientific information; it came too late or it was impossible to find
  - Smaller marketing budgets
  - Traditionally, they do not have – as yet – a relationship with prescribers.

It is an uneven playing field

To prescribe and substitute is an issue of trust

- Some observations on the European market after the introduction of the first biosimilars
  - Licensing authorities have build very robust evaluation procedures, but neglected to collaborate with the medical community and the public
  - They behaved in the defence towards the lobby of innovative companies
  - Biosimilar companies underestimated doctors loyalty
  - They went for licensing and price competition
  - There was insufficient education of doctors and the public to raise trust and reduce uncertainty

Lesson learned: it's more an issue of communication than science

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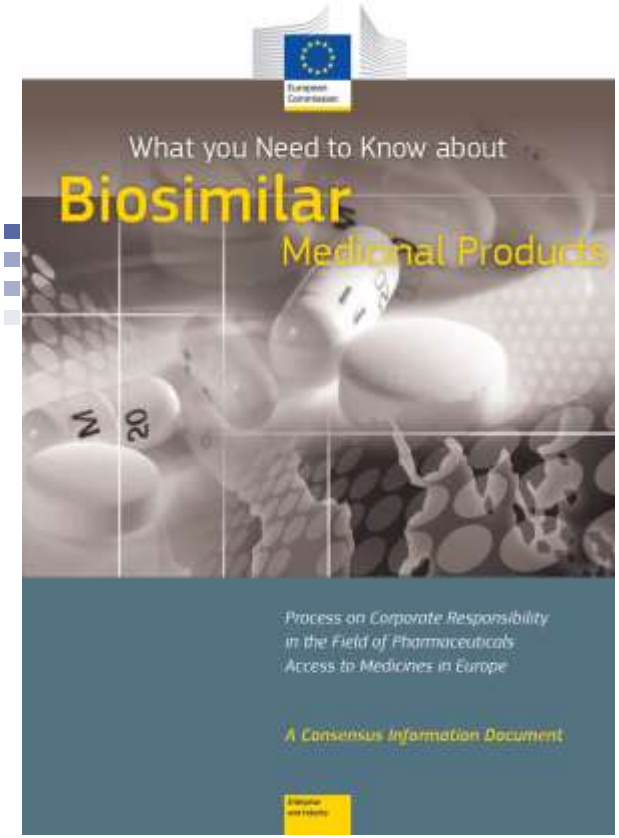
The information gap

- EMA's Public Assessment Reports (EPAR; 50+ pages) are difficult to read / understand for a healthcare professional
  - Need support to understand the *"comparability excercise"*
    - Is 3% antibodies in a Nivestim comparative trial a problem?
  - As yet no public access to risk management / safety information

- Research findings should be published and made accesible

- Clinical trials are scattered and not easily accesible

How to build trust in biosimilars?



- **Reduce the information gap**
  - Regulators can communicate their knowledge actively to medical professionals:
    - “The past 6 year there has not been a single incident with biosimilars”
    - The assessment system worked as expected
    - Raised mistrust was not justified and we learned better in the meantime
- **Avoid trouble around substitution**
  - Convince prescribers on the (financial) advantages for the society, without compromising quality of treatment.

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

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J&J adds its opinion to biosimilars naming debate

posted 10/01/2014

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DISCOVER THE SCIENTIFIC ADVANCEMENT OF GENERICS AND BIOSIMILARS

ORIGINAL ARTICLE

Eur J Hosp Pharm 2013

How to select a biosimilar

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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.

INTRODUCTION

Selection of biosimilars in hospitals is a relatively

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-

Has anything changed?

- Biosimilar companies now are more active in communication
- Presentation trial results at congresses (oral, poster)
- Publication of comparative trials in peer-reviewed journals (> 850 patients)

- What was the setback?
  - J&J extended Infliximab patent protection in Europe with 6 months (→ februari 2015) (result of licensing paediatric indication)
  - (In US patent expected to expire September 2018)

EXTENDED REPORT

A randomised, double-blind, multicentre, parallel-group, prospective study comparing the pharmacokinetics, safety, and efficacy of CT-P13 and innovator infliximab in patients with ankylosing spondylitis: the PLANETAS study

Won Park,[1] Pawel Hrycaj,[2] Slawomir Jeka,[3] Vo
Pedro Miranda,[6] Helena Mikazane,[7] Sergio Gu
Yeon-Ah Lee,[9] Sang Joon Lee,[10] HoUng Kim,[1

2 x 125 patients
Result: biosimilar almost indentical

EXTENDED REPORT

A randomised, double-blind, parallel-group study to demonstrate equivalence in efficacy and safety of CT-P13 compared with innovator infliximab when coadministered with methotrexate in patients with active rheumatoid arthritis: the PLANETRA study

Dae Hyun Yoo,[1] Pawel Hrycaj,[2] Pedro Miranda,[3] Edgar Ramiterre,[4] Mariusz Piotrowski,[5] Sergii Shevchuk,[6] Volodymyr Kovalenko,[7] Nenad Prodanovic,[8] Mauricio Abello-Banfi,[9] Sergio Gutierrez-Ureña,[10] Luis Morales-Olazabal,[11] Michael Tee,[12] Renato Jimenez,[13] Omid Zamani,[14] Sang Joon Lee,[15] HoUng Kim,[16] Won Park,[17] Ulf Müller-Ladner[18]

2 x 300 patients
Result: biosimilar at least equal to reference product
Total: 54 weeks

Remsima extension study demonstrate long term efficacy and safety over 2 years

JUNE 12, 2014 9:10 AM

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Celltrion EULAR infliximab Press Release Remicade Remsima South Korea

Bi

Results presented yesterday at the Celltrion Healthcare satellite symposium during EULAR 2014 confirm that patients with rheumatoid arthritis (RA) and ankylosing spondylitis (AS) benefit from taking the newly licensed infliximab Remsima for up to two years.

In addition, the open-label studies reported by Professor Dae Hyun Yoo (Hanyang University Hospital for Rheumatic Diseases, Republic of Korea) demonstrate that those patients who switched from the originator therapy after 12 months, experienced comparable treatment benefits for a further year.

The studies were designed to evaluate efficacy and safety over 12 months following on from PLANETRA2 and PLANETAS3 (Remsima marketing approval studies), for a total of 24 months. This enabled investigators to compare the benefits for RA and AS patients maintained on Remsima and those switched from the originator drug. The study in RA, led by Professor Yoo, carried on from PLANETRA. It included a total of 302 patients in the maintenance arm and 144 who switched to Remsima . All patients gave informed consent and were treated every eight weeks. They also received methotrexate and folic acid.

For people with AS included in the study following on from PLANETAS, 88 patients continued with Remsima and 86 switched from the originator drug. This study was directed by Professor Won Park (Inha University Hospital, Republic of Korea).

Biosimilar companies take their task very serious:

- *Celltrion / Hospira follow-up study*
- *Sandoz has ongoing a phase-III biosimilar etanercept (GP2015) multiple switch study in psoriasis (530 pat enrolled; 70 centres, 12 countries, 52 weeks)*

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
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The NOR-SWITCH Study

This study is not yet open for participant recruitment. (see Contacts and Locations)

Verified May 2014 by Diakonhjemmet Hospital

Sponsor:
Diakonhjemmet Hospital

Collaborator:
South-Eastern Norway Regional Health Authority

Information provided by (Responsible Party):
Tore K Kvien, Diakonhjemmet Hospital

ClinicalTrials.gov Identifier:
NCT02148640

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History of Changes

Norway is taking the lead in a publicly funded infliximab biosimilar switch study in all indications

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Purpose

The purpose of this study is to assess the safety and efficacy of switching from Remicade to the biosimilar treatment Remsima in patients with rheumatoid arthritis, spondyloarthritis, psoriatic arthritis, ulcerative colitis, Crohn's disease and chronic plaque psoriasis

Condition	Intervention	Phase
Rheumatoid Arthritis Spondyloarthritis Psoriatic Arthritis Ulcerative Colitis Crohn's Disease Psoriasis Chronic	Drug: Innovator infliximab Drug: Biosimilar infliximab	Phase 4

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study

In summary

- Biosimilars once licensed, fulfill very high quality requirements, equal to any other biotech drug. Thus, they can be prescribed without reservation
  - For new patients
  - To change patients from innovator to biosimilar in a stable way
- There exist formal and informal barriers towards market acceptance
  - These barriers need to be removed to make it a sustainable market
- Critical to have support from stakeholders; requires a lot of education
- Biosimilars may contribute to an affordable health care market for all

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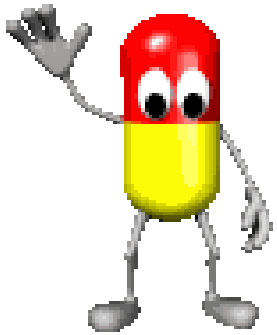
Thank you for your attention



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