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Improving healthcare decisions

ISPOR BIOSIMILARS SPECIAL INTEREST GROUP AND ISPOR CENTRAL AND EASTERN EUROPE CONSORTIUM:

BIOSIMILARS: AN OPPORTUNITY FOR COUNTRIES WITH RESTRICTED RESOURCES TO IMPROVE PATIENT ACCESS?

Tuesday, 5 November 2019; 12:30 – 1:45 PM CET

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ISPOR The session

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- **Purpose:**
  - To present an overview of the goals, barriers and facilitators of biosimilar adoption in countries with limited resources, from HTA and policy perspective
- **We are interested in your view:**
  - Interactive session after presentation through poll questions - be prepared with your mobile
- **Moderator:**
  - Vera Pataki, MD, MBA,
    - Head of International Market Access, Egis, Budapest, Hungary
    - Chair of CEE Network, Medicines for Europe, Brussels, Belgium

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ISPOR Speakers

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András Inotai

Associate Professor, Semmelweis University, Budapest, Hungary

Evelien Moorkens

PhD Researcher KU Leuven, Leuven, Belgium

Iga Lipska

Project Manager, Strategic research grant, NHF HQ, Warsaw, Poland

Dalia Dawoud

Scientific Adviser, Science Policy and Research,NICE, London, UK

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Access to biological medicines
- big differences across Europe

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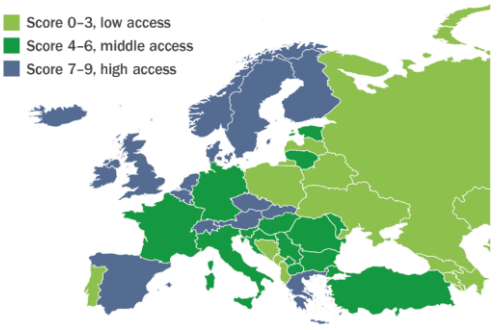
- Compared with Western Europe, Central and Eastern Europe have experienced reduced access to biological medicines[1,2]

Percentage of patients with rheumatoid arthritis (RA) treated with a biological medicine:

Western Europe*	Central & Eastern Europe**
11–12%	1–5%

Level of access to biological treatments for RA across Europe[3]



This difference in access to biological medicines is largely due to general economic conditions[2]

5 **Footnotes:** *Based on values from 2009; **Based on values from 2011.
References: 1. Kobelt G, Kasteng F. Access to innovative treatments in rheumatoid arthritis in Europe. Available at: http://bit.ly/Shamf8. Accessed July 2017; **2.** Orlewska L, *et al. Med Sci Monit.* 2011;17:SR1-13; **3.** Putrik P, *et al. Ann Rheum Dis.* 2014;73:198–206.

Increased patient access to biologicals
– thanks to biosimilar medicines

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- According to WHO, biosimilar medicines provide a good opportunity to **expand access** and to become a **game-changer** for access to medicines for certain complex conditions[1]

Product/Country	Treatment days per capita[2] (Year before biosimilar entrance)	Volume change of treatment days following introduction of biosimilar[2]
HGH		
Romania	0.02	**152%**
Czech Rep	0.08	**68%**
Poland	0.04	**82%**
G-CSF		
Romania	0.02	**2542%**
Bulgaria	0.02	**581%**
Slovakia	0.05	**509%**
Anti-TNF		
Bulgaria	0.10	**190%**
Czech Rep	0.24	**59%**
Slovakia	0.49	**93%**

Biosimilar medicines allow access to highly innovative treatments

6 **Abbreviations:** G-CSF, granulocyte-colony stimulating factor; HGH, human growth hormone; TNF, tissue necrosis factor; WHO, World Health Organisation.
Reference: 1. WHO. WHO to begin pilot prequalification of biosimilars for cancer treatment. Available at: http://bit.ly/2q1WOtp. Accessed July 2017; **2.** QuintilesIMS. The impact of biosimilar competition on price, volume and market share - update 2017. Available at: http://bit.ly/2rpB1rW Accessed July 2017.

CEE – still huge gap

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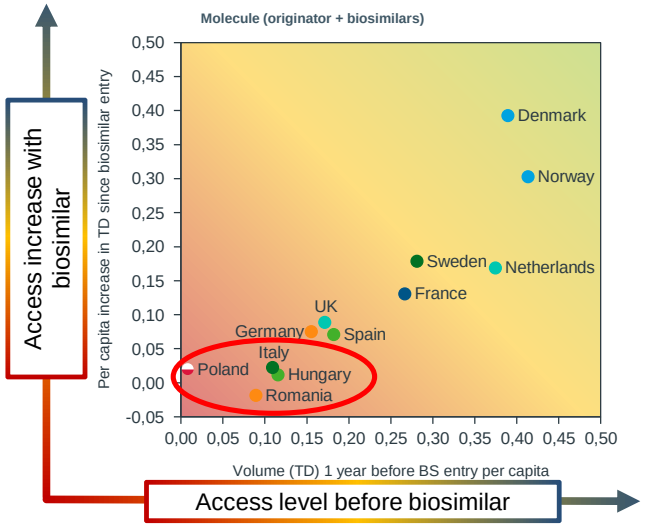

***Molecules included**: Insulin Lispro, Insulin Glargine, Infliximab, Etanercept, Rituximab, Trastuzumab*

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Source: IQVIA MIDAS Restricted MTH October 2018

Biosimilar penetration
- differencies among molecules and countries

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	infliximab	insulin glargine	etanercept	rituximab	trastuzumab	adalimumab
UK	92.2	9.0	82.0	91.5	60.7	
Germany	51.3	13.3	56.8	60.9	28.3	1.4
France	59.1	14.6	17.9	63.6	27.5	0.08
Italy	78.5	19.2	45.6	74.5	9.2	0.01
Spain	55.8	12.0	30.2	27.8	10.6	0.02
Denmark	98.5	9.3	90.6	67.2	99.3	
Finland	17.8	6.0	6.1	6.2	-	
Netherlands	76.1	10.8	24.1	93.4	95.0	3.2
Norway	97.6	5.8	90.1	0.0	81.2	
Poland	95.2	35.6	36.6		34.4	

High uptake

Low uptake

Notes: trastuzumab and rituximab subcutaneous form excluded from calculations

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Source: IQVIA MIDAS Restricted MTH October 2018

Good biosimilar uptake
-does not guarantee better patient access without further actions

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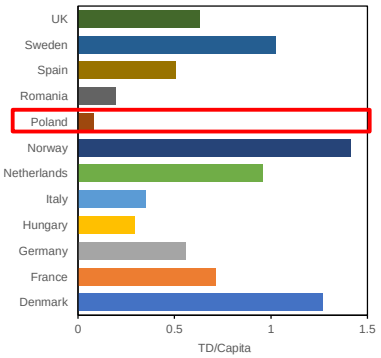

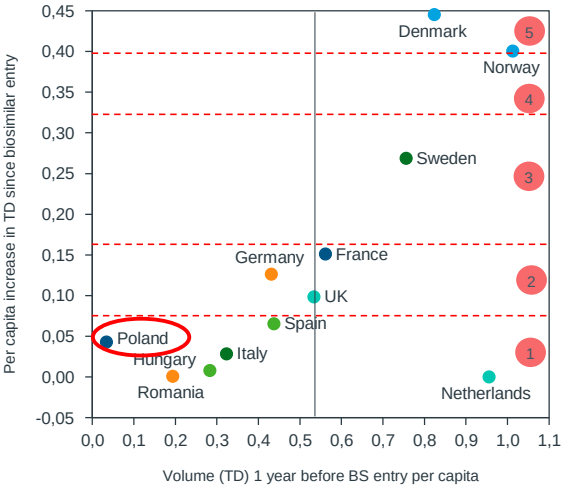

Line shows average volume (TD) 1 year before BS entry per capita, across all countries in scope
Sustainability for Biosimilars in Europe - Policies evaluation report ; Sustainability Score 1 = low; Score 5 = high

Anti-TNFs: Adalimumab, Certolizumab pegol, Etanercept, Golimumab, Infliximab

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Source: IQVIA MIDAS Restricted MTH October 2018

SECTION

1

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Biosimilars' uptake from a CEE perspective – theory vs. Practice

András Inotai PhD, DrHabil[1,2,3]

1 Associate Professor, Semmelweis University, Budapest, Hungary;
2 Co-chair, ISPOR SIG on Biosimilars Key Project;
3 Principal Researcher, Syreon Research Institute, Budapest, Hungary

Policy objectives of biosimilar medicines

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- Biologicals at Western European price level are usually not cost effective in CEE
- Off-patent biologicals with price erosion after patent expiry provides more affordable treatment alternatives
- The policy objective of off-patent pharmaceuticals can be approached in two different ways:
  - Disinvestment aspect: Reduce health care expenditure without compromising health outcomes
  - Investment aspect: Increase population health gain by improved patient access without increasing health expenditure

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Ref: Inotai A et al. BioMed Research International. 2018. 9597362. 9.

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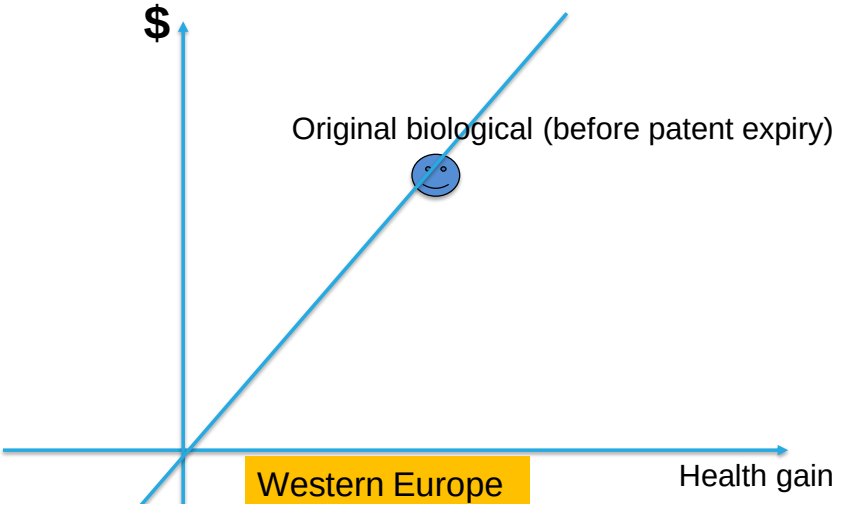
C/E plan for biologicals before and after patient expiry



Ref: Inotai A, Csanádi M, Vitezic D, Francetic I, Tesar T, Bochenek T, Lorenzovici L, Dylst P, Kaló Z. Policy Practices to Maximise Social Benefit from Biosimilars. Journal of Bioequivalence & Bioavailability. 2017. 9. 467-472.

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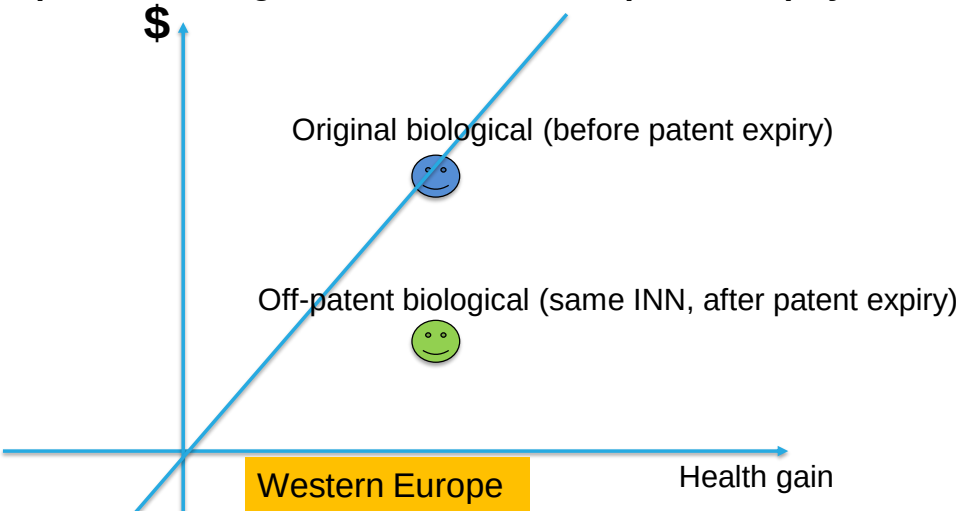

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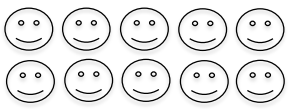
Before patent expiry

After patent expiry



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Before patent expiry After patent expiry

Western Europe:

All eligible patients have access to the original biological prior patent expiry

Ref: Inotai A, Csanádi M, Vitezic D, Francetic I, Tesar T, Bochenek T, Lorenzovici L, Dylst P, Kaló Z. Policy Practices to Maximise Social Benefit from Biosimilars. Journal of Bioequivalence & Bioavailability. 2017. 9. 467-472.

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Before patent expiry After patent expiry **$** ☺ **$/**☺

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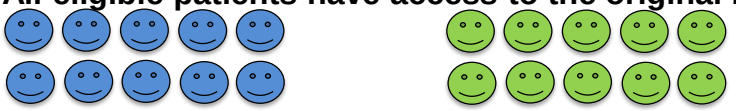

↓ N/C ✓ (CMA)

Ref: Inotai A, Csanádi M, Vitezic D, Francetic I, Tesar T, Bochenek T, Lorenzovici L, Dylst P, Kaló Z. Policy Practices to Maximise Social Benefit from Biosimilars. Journal of Bioequivalence & Bioavailability. 2017. 9. 467-472.

Research on hidden access barriers
Methods

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- Volume restrictions are implemented by payers to ensure financial sustainability of reimbursing high-cost pharmaceuticals
- Aim: to reveal these transparent and hidden access barriers in CEE
- Methods:
  - Disease: RA
  - Scope: TNFa inhibitor bDMARDs
  - 3-3 interviews with 4 stakeholder groups (payers, patients, rheumatologists, industry) in each country
  - Participating countries: CZ, HU, PL, RO, SK
  - 3x4x5=60 interviews
  - Results aggregated at country level

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Research on hidden access barriers
Results

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- TNFa bDMARDs are on the reimbursed list in CEE, but...
- ...the following barriers were reported the most frequently:

Barrier	Number of reporting countries (out of 5)
limited number of RA **centers** with prescribing rights	5
uneven budget allocation among RA centers	3
maximised patient number on reimbursed biologics / RA center	3
insufficient **human** resource **capacities** to administer IV bDMARDs	4
more **restrictive financial protocols** compared to EULAR guidelines in prescribing bDMARDs	4
significant **administrative burden** of prescribing biologics	3
significant **travelling time and cost** for patients to RA centers	5

- Alltogether 33 different types of access barriers were reported

Consequence: Not all eligible patient may have access to bDMARDs in RA in CEE

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Before patent expiry After patent expiry $ $/

Western Europe:

All eligible patients have access to the original biological prior patent expiry

N/C ✓ (CMA)

Central Eastern Europe:

Volume restrictions to the original biological prior patent expiry

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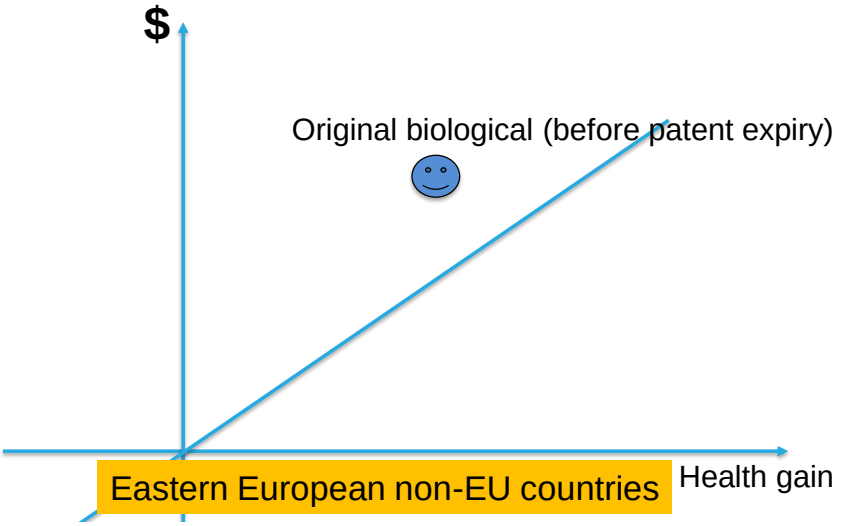
C/E plan for biologicals for low income countries



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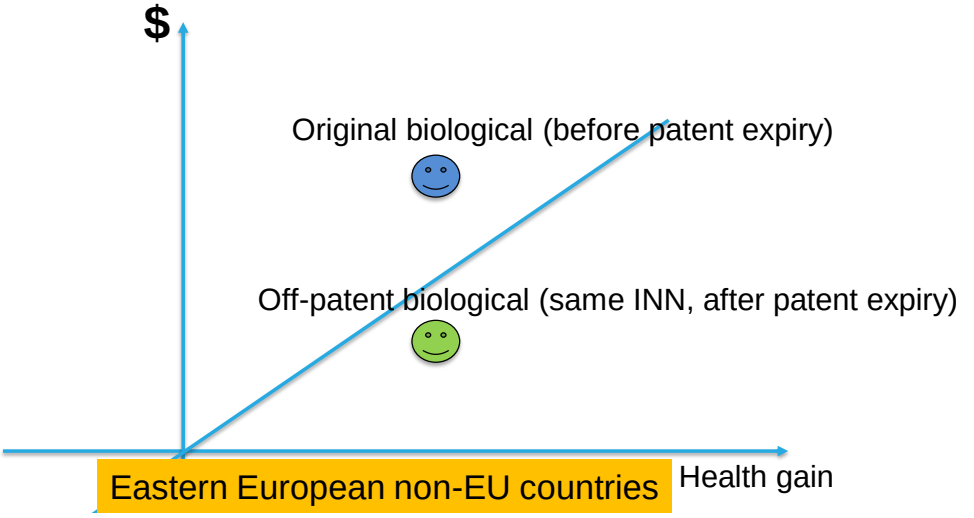

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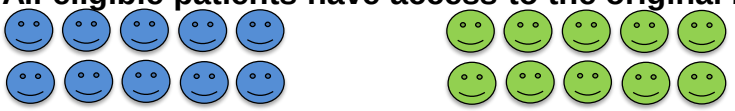
Before patent expiry | After patent expiry | $ | ☺ | $/☺

Western Europe:

All eligible patients have access to the original biological prior patent expiry



N/C ✓ (CMA)

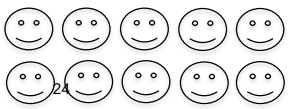
Central Eastern Europe:

Volume restrictions to the original biological prior patent expiry

✓

Eastern European non-EU countries:

Original biological is not cost effective prior patent expiry



Ref: Inotai A et al. Journal of Bioequivalence & Bioavailability. 2017. 9. 467-472.

Before patent expiry After patent expiry $ $/

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N/C ✓ (CMA)

Central Eastern Europe:

Volume restrictions to the original biological prior patent expiry


N/C ✓

Eastern European non-EU countries:

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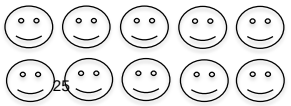
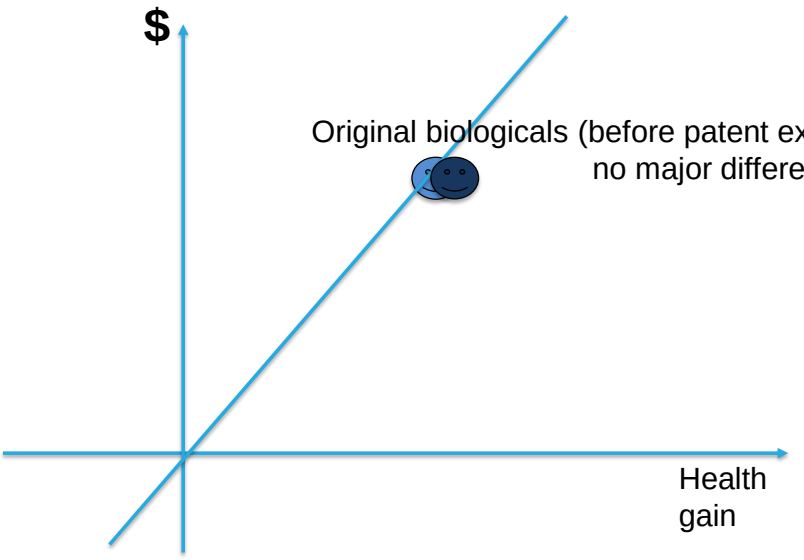



✓ (CEA)

Ref: Inotai A et al. Journal of Bioequivalence & Bioavailability. 2017. 9. 467-472.

How to select first line treatment of compounds with no or limited differential value?



How to select first line treatment of compounds with no or limited differential value?

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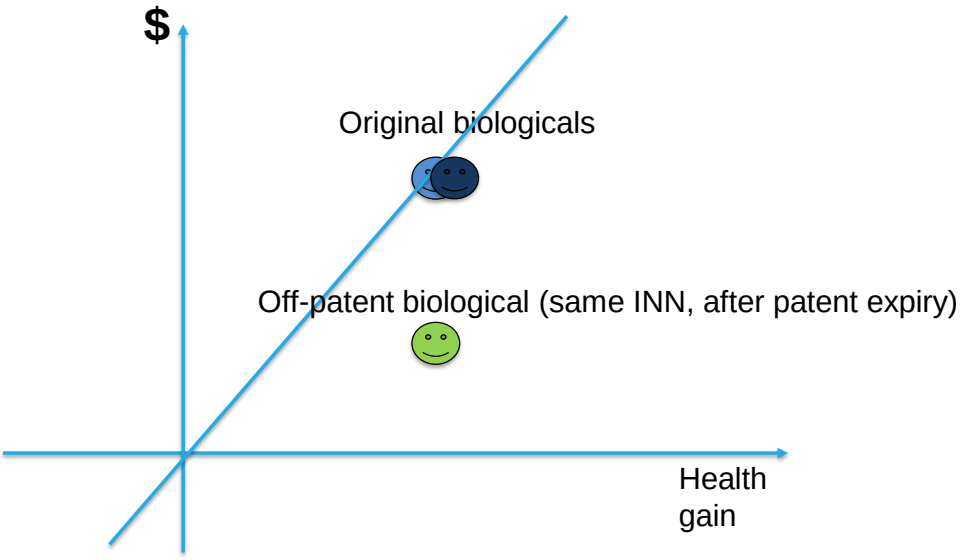

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How to select first line treatment of compounds with no or limited differential value?

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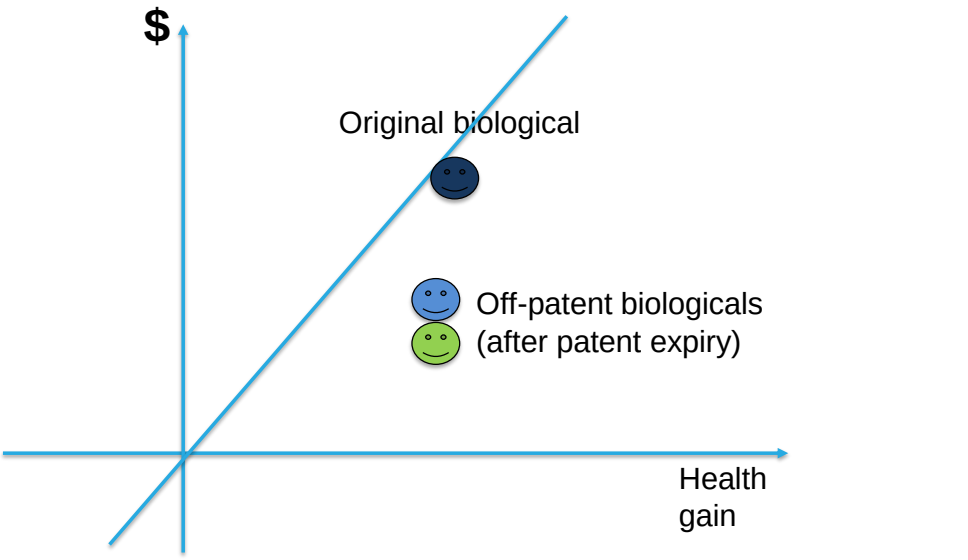

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Before patent expiry After patent expiry $ $/

Western Europe:

All eligible patients have access to the original biological medicine prior patent expiry

N/C ✓ (CMA)

29

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Before patent expiry After patent expiry $ $/

Western Europe:

All eligible patients have access to the original biological medicine prior patent expiry

N/C ✓ (CMA)

30

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Before patent expiry | After patent expiry | $ | ☺ | $/☺

Western Europe:

All eligible patients have access to the original biological medicine prior patent expiry



N/C ✓ (CMA)

Central Eastern Europe:

Volume restrictions to the original biological medicine prior patent expiry


N/C  ✓

31

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Before patent expiry | After patent expiry | $ | ☺ | $/☺

Western Europe:

All eligible patients have access to the original biological medicine prior patent expiry



N/C ✓ (CMA)

Central Eastern Europe:

Volume restrictions to the original biological medicine prior patent expiry


N/C  ✓

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Before patent expiry After patent expiry $ $/

Western Europe:

All eligible patients have access to the original biological medicine prior patent expiry

Central Eastern Europe:

- Opportunity cost: reduced opportunity for savings

Volume restrictions to the original biological medicine prior patent expiry

- Opportunity cost: reduced opportunity to treat additional patients

New patients should start on more affordable off patent biologicals

Using other patented biologicals w/o added benefit if off patent biologicals are available has opportunity cost

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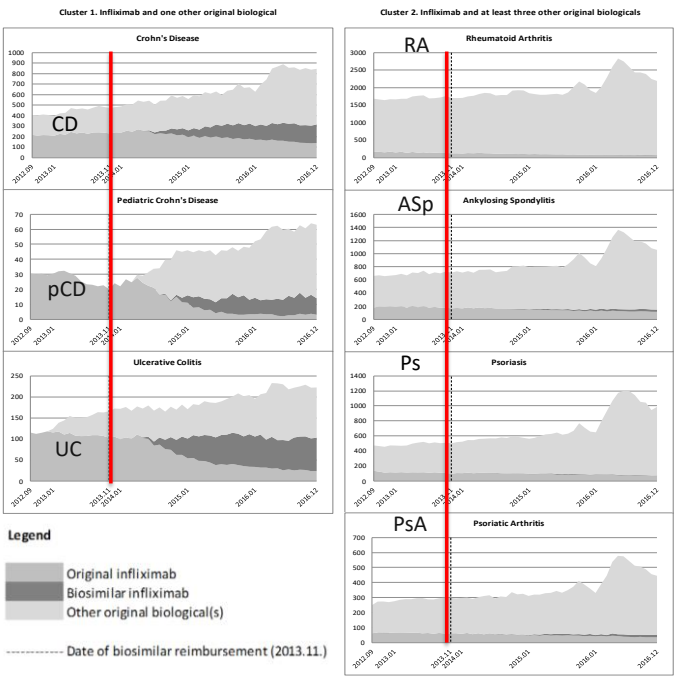
The case of infliximab in Hungary

- Increasing utilisation of biologicals implicitly confirms hidden barriers



Ref: Harsányi A, Csanádi M, Márky K, Vinczickzki AZ, Kaló Z, Inotai A (2019) Influence Of Biosimilar Infliximab Launch On The Utilization Pattern Of Biological Medicines. Expert Rev PharmacoeconOutcomes Res. https://doi.org/10.1080/14737167.2019.1667232

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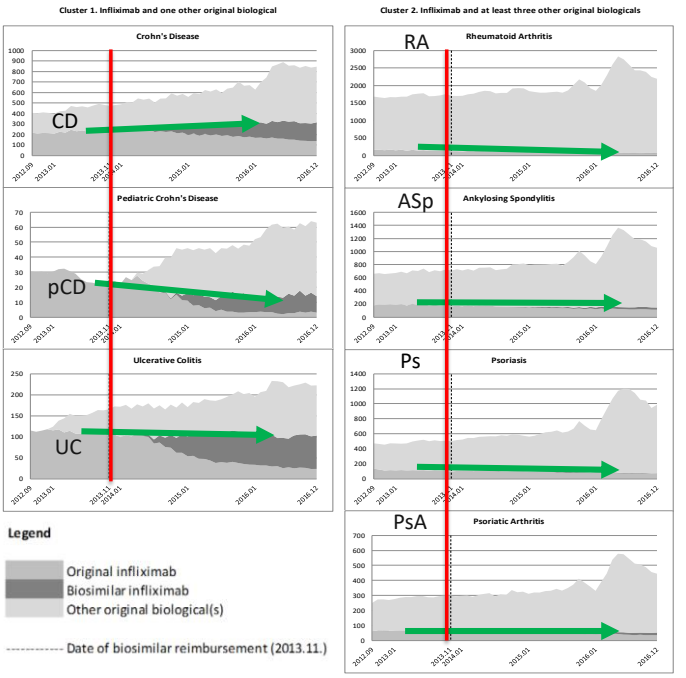
The case of infliximab in Hungary

- Increasing utilisation of biologicals implicitly confirms hidden barriers
- After patent expiry the market share of off-patent infliximab showed a decrease



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The case of infliximab in Hungary

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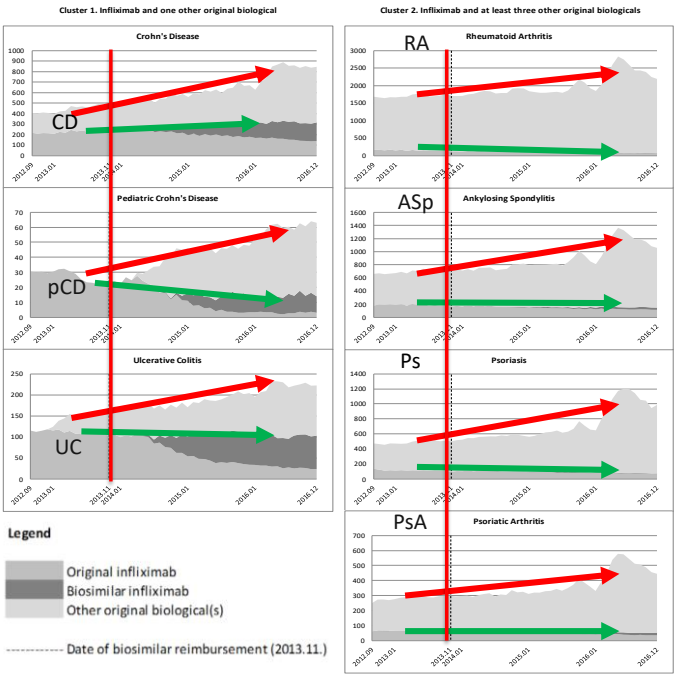
- After patent expiry the market share of off-patent infliximab showed a decrease

- Market share of other patented biologics shows an increase



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Utilisation pattern of treatment naive patients after patent expiry

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Indication	Originator infliximab	Biosimilar infliximab	Other patent protected biological(s)
Ulcerative Colitis	13.5%	50.3%	36.3%
Adult Crohn's Disease	14.3%	37.0%	48.7%
Paediatric Crohn's Disease	17.1%	18.4%	64.6%
Rheumatoid Arthritis	**0.4%**	**1.2%**	**98.4%**
Ankylosing Spondylitis	**1.1%**	**4.1%**	**94.8%**
Psoriasis	**1.4%**	**1.6%**	**97.0%**
Psoriatic Arthritis	**1.5%**	**5.4%**	**93.1%**

Despite of the economic rationale, in many indications phyisicans did not even try the more affordable off patent biologicals for new patients

Ref: Harsányi A, Csanádi M, Márky K, Vinczickzki AZ, Kaló Z, Inotai A (2019) Influence Of Biosimilar Infliximab Launch On The Utilization Pattern Of Biological Medicines. Expert Rev PharmacoeconOutcomes Res. https://doi.org/10.1080/14737167.2019.1667232

Conlusion

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- Using patented biologicals with no added value if off-patent biologicals are also available has opportunity cost:
  - In case of disinvestment: reduced opportunity for savings
  - In case of investment (e.g. volume restriction): reduced opportunity to treat additional patients

In case of limited access, if naive patients start on orignal bDMARDs when off patent biologicals are available, some patients will be denied treatment

Are lower income countries rich enough not to use off patent biologicals as first line treatments?

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SECTION

2

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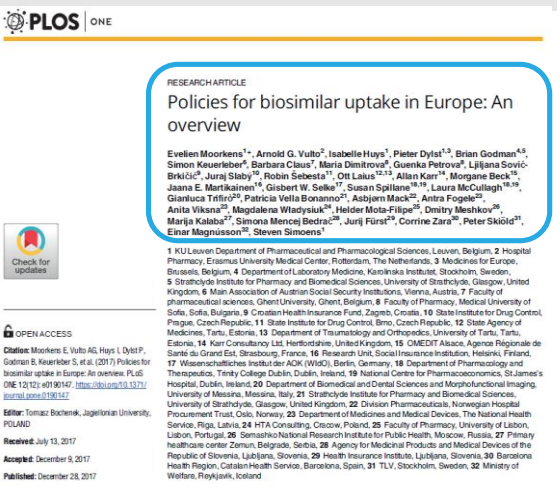
Policies on biosimilars: What can we learn from the European experience?

Evelien Moorkens

PhD researcher, KU Leuven, Leuven, Belgium



Supply-side and demand-side policies fo
biosimilars: an overview in 10 European
states

Cécile Rémuzat, Anna Kapuśniak, Aleksandra Caban, Dan Io
Radière, Cyril Mendoza & Mondher Toumi

To cite this article: Cécile Rémuzat, Anna Kapuśniak, Aleksandra Caban, Dan Ionescu, Guerric Radière, Cyril Mendoza & Mondher Toumi (2017) Supply-side and demand-side policies for biosimilars: an overview in 10 European member states, Journal of Market Access & Health Policy, 5:1, 1307315, DOI: 10.1080/20016689.2017.1307315

To link to this article: http://dx.doi.org/10.1080/20016689.2017.1307315

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List prices

Pricing of biosimilars:
often **different pricing mechanisms**
- % below price of originator
- Maximum price
- …

Pricing of off-patent biologicals:
- Price cuts for originators

VS

Tenders

Often by INN → no difference between treatment-naïve patients and on treatment

National – regional – hospital level

Multiple winners – single winner

Reimbursement

Approximately half of European countries use internal reference pricing

41
Moorkens *et al.* (2017). Policies for biosimilar uptake in Europe: An overview. *PLoS ONE*

ISPOR *Demand-side policies*

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➢ **Policies tend to target physicians, …** **rather than pharmacists and patients**

Quotas
Recommendations
Economic prescribing
Switching
Education

42
Moorkens *et al.* (2017). Policies for biosimilar uptake in Europe: An overview. *PLoS ONE*

ISPOR *Impact of policies on market dynamics?*

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Case study in Sweden

- Study local/regional level: 21 counties in Sweden
- Focus on infliximab and etanercept

Infliximab (Hospital setting)	**Etanercept (Outpatient setting)**
Biosimilar market shares: 18-96% (2017)	Biosimilar market shares: 40-82% (2017)
Regression analysis: 59% of variability explained by relative difference in discounted price between originator and biosimilar	Small differences in actual costs between products for regions after MEA on national level and gainsharing arrangements Prescription provided for a year: Active pull-back or wait?
→ **Uptake influenced by regional tender contracts**	→ **Uptake influenced by KOLs, guidelines, gainsharing**

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Moorkens *et al.* (2019). Different policy measures and practices between Swedish counties influence market dynamics. *BioDrugs*

ISPOR *Impact of policies on market dynamics?*

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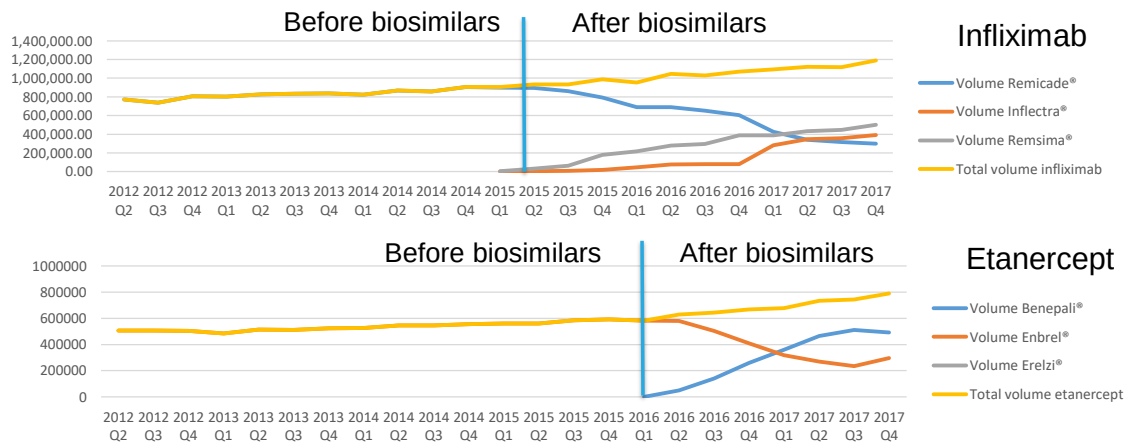
Case study in Sweden: Rate of volume growth accelerates (AND cost savings)



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Moorkens *et al.* (2019). Different policy measures and practices between Swedish counties influence market dynamics. *BioDrugs*

Case study in UK

- Study local/regional level: England (10 historical regions), Scotland (14 health boards), Wales (7 health boards)
- Focus on infliximab and etanercept: **Early and late adopters** of biosimilars can be seen

UK biosimilar uptake is positively influenced by:

a) **A price difference** between biosimilar and originator product making it worth to switch patients

b) **A good relationship** between commissioner and provider in England resulting in gainsharing agreements

c) **Leadership** on biosimilars in regional NHS offices in England or Scottish and Welsh health boards

d) **Key opinion leaders** or leading hospitals that start using biosimilars early and gain experience

High biosimilar market shares can be reached even without gainsharing! (Scotland, Wales)

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ISPOR Impact of policies on market dynamics? www.ispor.org

Case study in UK: Example of biosimilar adalimumab in Scotland

Before patent expiry:

- Groups on efficient use of high cost medicines were tasked to come up with a **strategy** for biosimilar use
- Health Boards were encouraged to put in place a **switching plan**
- A **case study** on the biosimilar switch for etanercept was made available
- Some Health Boards invested in **additional staffing** ('invest to save principle')

After patent expiry:

- **Statistics** on biosimilar market shares were shared monthly for benchmarking purposes
- Also, for anti-TNFs a national biological medicines **treatment cost comparator** was developed

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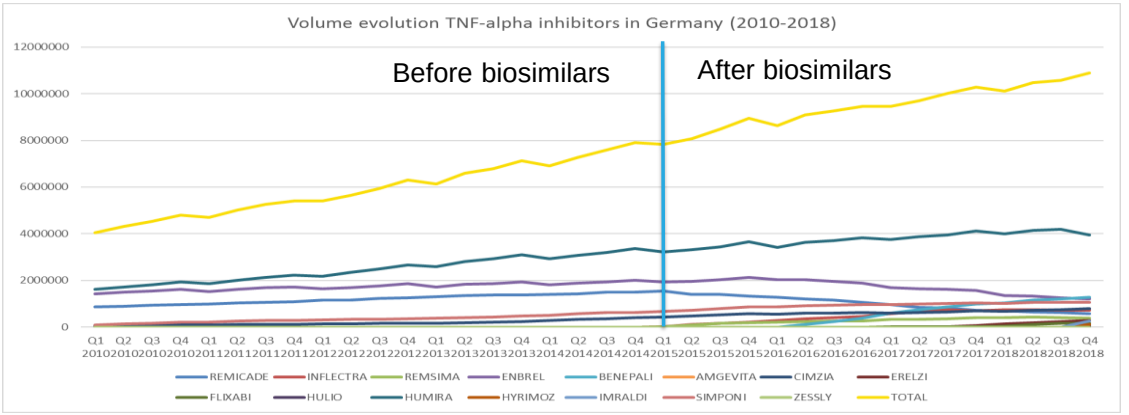
Impact of policies on market dynamics?

Case study in Germany: Constant rate of volume growth (but cost savings)

- **Access to TNF-alpha inhibitors seems to increase at the same rate after introduction of biosimilars**



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Conclusions

- Policies targeting price may not be sustainable in the long term
- Focus on demand-side policies
- Guidelines and recommendations
- Target agreements
- Gainsharing arrangements
- Create an open environment with multi-stakeholder involvement

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SECTION

3

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Biosimilars
CEE public payer perspective

Iga Lipska, MD PhD
National Health Fund HQ
Warsaw, Poland

Policy objectives of biosimilar medicines

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- **Biologicals** are usually not cost effective in CEE
  - Price levels at Western European countries at launch
  - International Reference Pricing
- Creates a financial barrier for patients to have access to effective treatments
- **Biosimilars** create new cost saving opportunities
  - The same clinical effectivenes (patient outcomes)
  - Less costly – better cost – effectiveness
- The policy objective of off-patent pharmaceuticals can be approached in two different ways*:
  - Disinvestment aspect: Reduce health care expenditure without compromising health outcomes
  - Investment aspect: Increase population health gain by improved patient access without increasing health expenditure

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**Ref: Inotai A et al. BioMed Research International. 2018. 9597362. 9.*

ISPOR Public payer perspective

- **Public payer priority:**
  - To provide appropriate health care to the population covered
  - Poland – population of 38 mln
  - Within limited budget / financial resources
- **Whats's specific about CEE countries?**
  - Worse health status of the population
  - Less money invested in health care (5% GDP in Poland, EU average 9%)
    - eg. OECD/European Commission report „Health at glance"
  - Patients are less satisfied with health care services
    - European Health Consumer Index EHCI 2018 (32/35 with 585/1000 points)
- The ongoing discussion about:
  - Value-based health care (VBHC)
  - Michael Porter *Redefinig health care* 2006 & *What is value in healthcare?* NEJM 2010

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ISPOR Medicines Policy for 2018-2022

- **Govermental document approved in Sept 2018**
- Currently in the implementation phase
- **Authors:**
  - M. Czech – Vice Minister responsible for Drug Policy 2017-2019 (chair)
  - J.Adamski, A. Fałek, A. Lech, I. Lipska, I. Skrzekowska-Baran, R. Zyśk

- **The document addresses also:**
- *„Special categories of medicinal products: biological medicines and biosimilars"*

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Ministerstwo Zdrowia

POLITYKA LEKOWA PAŃSTWA 2018-2022

ISPOR Biological medicines in Medicines Policy for 2018-2022

- The market for biological medicines in Poland reached the value of PLN 3.5bn*
- Three groups of medicines accounted for more than **50%** of the market: monoclonal antibodies, human insulin and its analogues and heparins
- Monoclonal antibodies and human insulin and its analogues are also the main areas of development of biosimilars
- In view of the expiry of patent protection of key biological drugs, the biosimilars segment has experienced rapid growth in recent years
- The main biosimilars in Poland were immunomodulating agents (non-interferon) and the highest sales were generated by the biosimilar filgrastim (2016)

* *Between March 2015 and March 2016, QuintilesIMS Institute Report, The potential of biosimilar medicines for healthcare systems. November 2016, http://www.producencilekow.pl/wp-content/uploads/2017/11/potencjal-lekow-biopodobnych-dla-systemowochrony-zdrowia.pdf*

54

ISPOR Public payer perspective on biosimilars

- Challenges in pricing negotiations on biosimilars
- **Pricing negotiations** by the Economic Commission MoH
  - 5 representatives of National Health Fund
- Price reduction
  - by definition 25% when generic or biosimilar enters a market
  - The Act of Law on Drug Reimbursement
- In practice much bigger price reduction has been expected in pricing negotiations
- Sometimes we were successful with substantial price reduction
- **BUT**
- Risk sharing mechanisms were implemented
- Clear financial mechanisms:
  - discounts, payback, price volume agreements
  - to ensure financial sustainability of health care budget (public payer)

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ISPOR Education around biosimilars

- **Education around biosimilars highly needed**
- For different stakeholders
  - **Clinicians, patients, decision-makers**
  - **Perhaps also media? Journalists?**
- **Clinicians** need to be informed on the entry and use of biosimilars
  - In order to create trust
- There is a framework in place in Poland
  - **Top-down approach**
  - Including incentives for health care providers by a public payer
- Still the uptake of biosimilars is very low
- Bottom-up approach would be helpful
  - Including **education**

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Conlusions

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- Extensive use of biosimilars creates cost-saving opportunity for health care systems
  - Everywhere but in particular in CEE countries
- But more importantly provides **more value** (health gain) for patients
  - Creates potential to cover patients in need
  - More patients can be treated as compared to very expensive biologics
- By investing in biosimilars public payers are able to provide clinically-effective and cost-effective treatments for patients in need
  - Incentives for health care providers
- **Education** around biosimilars is needed

SECTION

4

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HOW THE OUTPUTS OF THE SPECIAL INTEREST GROUP CAN PROVIDE GUIDANCE FOR BIOSIMILARS' HTA AND POLICY DECISION-MAKING

Dalia Dawoud, PhD[1,2]

[1]Scientific Adviser, National Institute for Health and Care Excellence (NICE), UK

[2]Chair, ISPOR Biosimilars SIG

Disclaimer

- The views expressed in this presentation are those of the author not the Institute

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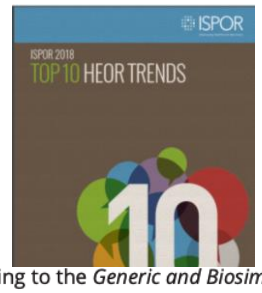
Why Biosimilars?



According to the *Generic and Biosimilars Initiative Journal*, the use of biosimilars is expected to result in overall savings from €11.8 billion and €33.4 billion between 2007 and 2020, with the largest savings expected for France, Germany, and the United Kingdom.[21]

The challenge is how to provide optimal health outcomes for patients without bankrupting individual patients or the healthcare system.

New cost-saving opportunities **without** adversely affecting patient outcomes

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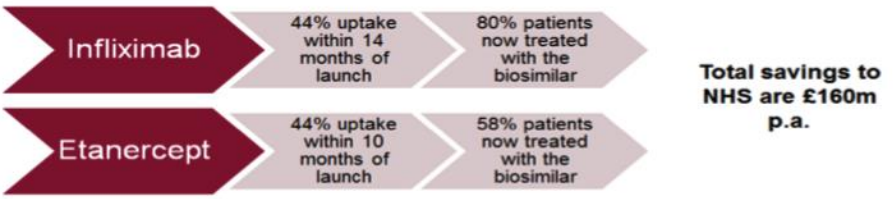
Opportunities

"As the biosimilar market develops, increased competition between biological medicines has the potential to deliver significant savings of at least £200m to £300m per year by 2020/21 through increased uptake of the best value biologic medicine, including biosimilars." *[NHS England, Commissioning framework for biological medicines (including biosimilar medicines), 2017]*



61 Source: Rx-InfoDefine (Infliximab isused to treat rheumatology conditions and inflammatory bowel disease; etanercept is used for rheumatology conditions. These biosimilars came onto the UK market in March 2015 and April 2016 respectively)

Opportunities

- Improved patient access
- Increased choice for patients and clinicians,
- Enhanced value propositions for individual medicines
- Releasing valuable resources to be invested elsewhere in the healthcare system

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Challenges

- Lack of clear guidance around how to assess their actual value
- Uncertainty around data extrapolation from one indication to another
- Uncertainty around immunogenicity and long-term safety
- Slow uptake
- Switching back

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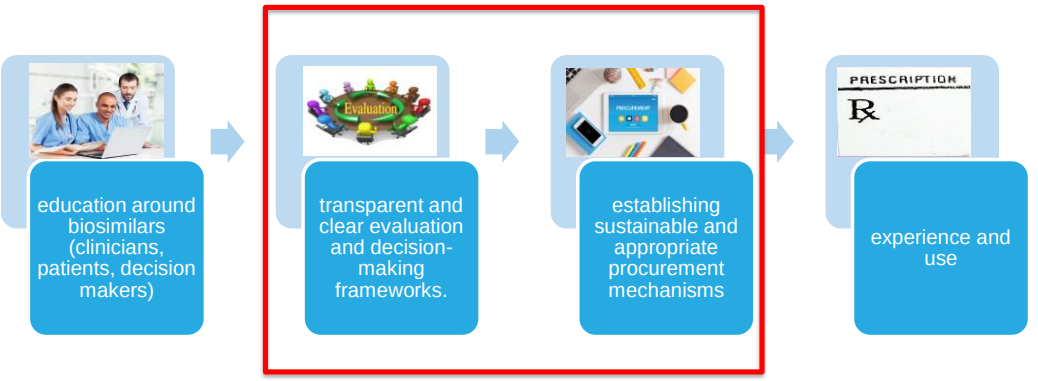
How to address these challenges?



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NICE's position statement

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

NICE's biosimilars position statement

a. Published Appraisals

2. NICE has decided that normally all relevant published guidance that includes the originator molecule will apply to the biosimilar medicinal product at the time it is made available for use in the NHS. A funding direction will apply to a new biosimilar if the active drug substance has already been recommended by NICE.

5. NICE will consider appraising the evidence for any new relevant biosimilar product(s) when a published Technology Appraisal is considered for review; the introduction of a biosimilar would not automatically trigger an earlier consideration for review or an automatic decision to update the guidance.

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a. Published appraisals

TA323

Epoetins in treatment of **chemotherapy induced anaemia** - new clinical data supporting enhanced efficacy when combining epoetin with IV iron (2014)
https://www.nice.org.uk/guidance/ta323/chapter/1-Guidance

TA383

Infliximab for treatment of **severe ankylosing spondylitis and severe non-radiographic axial spondyloarthritis**. Previously the originator was not supported due to high price (whereas other originator TNFs were supported). (2016)
https://www.nice.org.uk/guidance/ta383

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NICE's position statement

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

NICE's biosimilars position statement

b. Future appraisal topics (before invitation to participate or scoping)

- Intervention

- Comparator

10. Biosimilar medicines will be considered to differ from the originator product only in terms of price.

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TA569

Pertuzumab combined with biosimilar trastuzumab for the treatment of **HER-2 positive, node positive, early breast cancer patients** (2019) https://www.nice.org.uk/guidance/TA569/chapter/1-Recommendations

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NHS England and NHS Improvement Commissioning framework

- Best Value Biologic Medicine (BVBM)
  - Ambition **90% of new patients** prescribed a BVBM within **3 months of product launch**
  - **80% of existing patients** switched to BVBM **within 12 months, or sooner if possible**

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Latest success story

- **Adalimumab** (Humira; AbbVie) came off patent in October 2018 and was projected to achieve savings of £300m by 2021
- The rate of uptake of best-value adalimumab has varied across different regions across England, ranging from around **20%** to approximately **90%**
- The switch program will achieve the projected savings by the **beginning of 2020**

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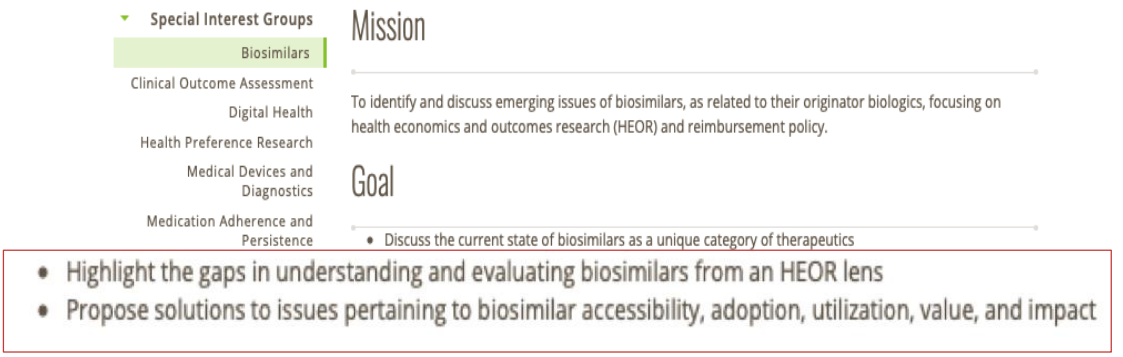
Pharmaceutical Journal. "NHS savings from adalimumab biologic switching hit earlier than expected. 11 June 2019. Available at: https://www.pharmaceutical-journal.com/news-and-analysis/news-in-brief/nhs-savings-from-adalimumab-biologic-switching-hit-earlier-than-expected/20206658.article?firstPass=false

Biosimilars

Special Interest Group



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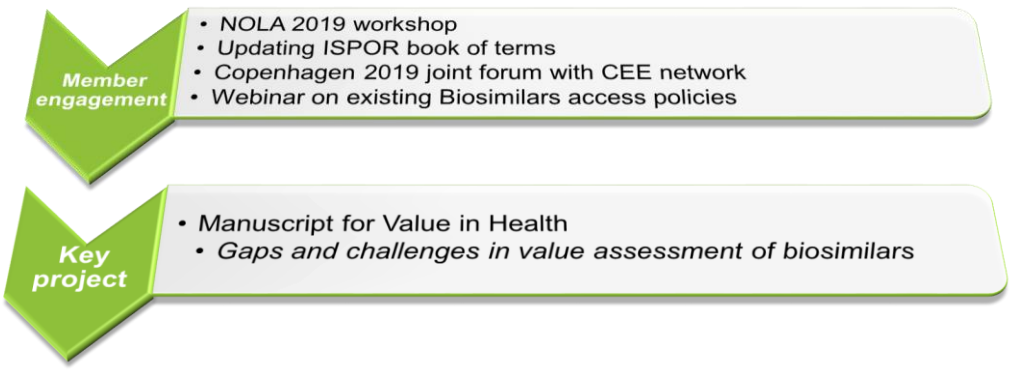
ISPOR Biosimilars SIG



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ISPOR Biosimilars SIG

Key Project Co-Chairs

Steven Simoens

Andras Inotai

Evelien Moorkens

Leadership

Dalia Dawoud
Chair
&
Jackie Vanderpuye-Orgle
Chair-elect

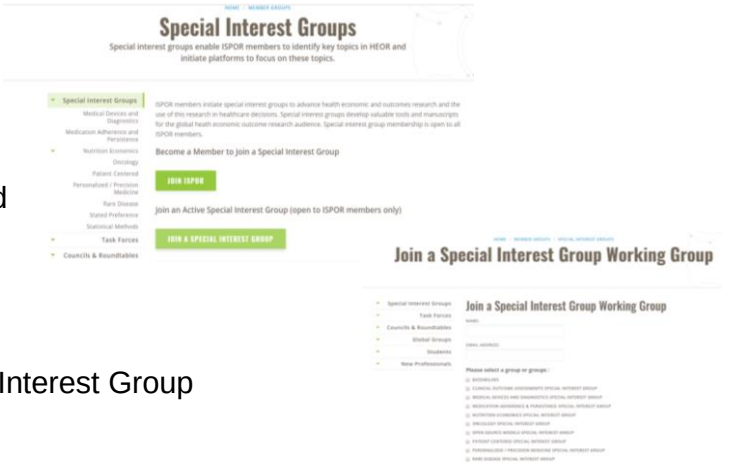
Member Engagement Co-Chairs

Catarina Lopes Pereira
&
Liese Barbier

ISPOR Leads
Amy Pavlock
Associate Director, Scientific and Health Policy Initiatives
&
Theresa Tesoro
Associate Director, Scientific and Health Policy Initiatives

ISPOR Special Interest Group

How to JOIN our Special Interest Group



- Sign up now
  - Sign up sheet
  - Provide a business card
- Go to the Website
  - Members groups
  - Special Interest Groups
  - Click on Join A Special Interest Group

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SECTION

5

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BIOSIMILARS: AN OPPORTUNITY FOR COUNTRIES WITH RESTRICTED RESOURCES TO IMPROVE PATIENT ACCESS?

DISCUSSION

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Q&A

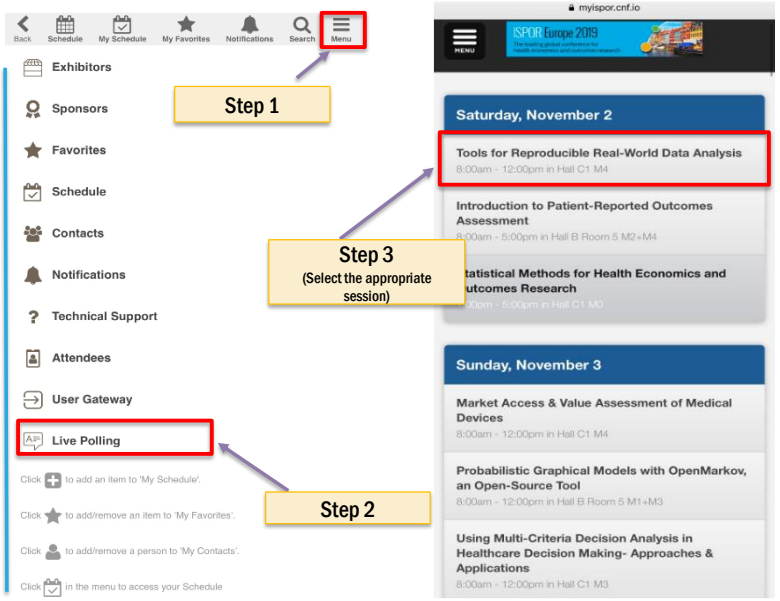
ISPOR **Conference Platform**

Web Platform

https://myispor.cnf.io/

Mobile App

Search "**ISPOR Europe 2019**" in the App Store or on Google Play!



1. Preferred therapy
- for patients already treated with biologicals

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In case of volume restrictions (i.e. not all eligible patients can have access to biologicals), **what do you consider more important:**

Options:

- Promote mandatory switch of patients treated with original biological medicine to lower priced biosimilars with the same active compound to release funds to treat additional patients (i.e. maximise access)
- Allow patients staying on the original biological medicine after patient expiry even if lower priced biosimilars are available (i.e. maximise patient preference)

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Live Content Slide

When playing as a slideshow, this slide will display live content

Poll: In case of volume restrictions (i.e. not all eligible patients can have access to biologicals), what do you consider more important:

2. Preferred approach
- to increase uptake of off-patent biologicals

How would you incentivise increased uptake of off-patent biologicals?

Options:

- Via top-down approach, mainly driven by regulation of payers
- Via bottom-up approach, mainly driven by incentivising and educating physicians

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Live Content Slide

When playing as a slideshow, this slide will display live content

Poll: How would you incentivise increased uptake of off-patent biologicals?

SECTION

5

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BIOSIMILARS: AN OPPORTUNITY FOR COUNTRIES WITH RESTRICTED RESOURCES TO IMPROVE PATIENT ACCESS?

DISCUSSION

THANK YOU

- Please come to the front to leave your business card and/or use the sign-up sheet to provide your information if you are interested in joining and/or participating in our SIG!
- **Questions?** Please email **biosimilarsig@ispor.org.**