November 14th, 2018
ISPOR Europe, Barcelona

KU LEUVEN

Competition in the off-patent biological market:

Policies for biosimilars in Europe

Evelien Moorkens
PhD researcher Market access biosimilars

Promotors: prof. I Huys, prof A Vulto, prof P Declerck

Barriers to entry and use of biosimilars

- Lack of incentives
- Lack of knowledge
- No substitution
- IP rights
- Innovator's reach
- Complex development

KU LEUVEN

Moorkens *et al.* (2016). Overcoming Barriers to the Market Access of Biosimilars in the European Union: The Case of Biosimilar Monoclonal Antibodies. *Frontiers in Pharmacology*

Market potential incentivized companies and countries

Supply side:
Investment by companies

Demand side:
European countries implemented various policies

No country has high penetration in all biosimilars

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

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

High uptake

Low uptake

Moorkens *et al.* (2017). The Market of Biopharmaceutical Medicines: A Snapshot of a Diverse Industrial Landscape. *Frontiers in Pharmacology*
Per Troein (2018). Trends in the development of the biosimilar market. 16th Biosimilar Medicines Conference.

KU LEUVEN

biosimilar medicines
better access, better health.

MARKET REVIEW – BIOSIMILAR ME

Payers' price & market access policies supporting a sustainable biosimilar medicines market

Final report

Supply-side and de
biosimilars: an ove
states

Cécile Rémuzat, Anna Kapu
Radière, Cyril Mendoza & M

PLOS ONE

Check for updates

OPEN ACCESS

Citation: Moorkens E, Vulto AG, Huys I, Dylst P, Godman B, Keuerleber S, et al. (2017) Policies for biosimilar uptake in Europe: An overview. PLoS ONE 12(12): e0190147. https://doi.org/10.1371/journal.pone.0190147

Editor: Tomasz Bochenek, Jagiellonian University, POLAND

Received: July 13, 2017

Accepted: December 9, 2017

Published: December 28, 2017

RESEARCH ARTICLE

Policies for biosimilar uptake in Europe: An overview

Evelien Moorkens[1]*, Arnold G. Vulto[2], Isabelle Huys[1], Pieter Dylst[1,3], Brian Godman[4,5], Simon Keuerleber[6], Barbara Claus[7], Maria Dimitrova[8], Guenka Petrova[8], Ljiljana Sović-Brkičić[9], Juraj Slaby[10], Robin Šebesta[11], Ott Laius[12,13], Allan Karr[14], Morgane Beck[15], Jaana E. Martikainen[16], Gisbert W. Selke[17], Susan Spillane[18,19], Laura McCullagh[18,19], Gianluca Trifirò[20], Patricia Vella Bonanno[21], Asbjørn Mack[22], Antra Fogele[23], Anita Viksna[23], Magdalena Wladysiuk[24], Helder Mota-Filipe[25], Dmitry Meshkov[26], Marija Kalaba[27], Simona Mencej Bedrač[28], Jurij Fürst[29], Corrine Zara[30], Peter Skiöld[31], Einar Magnússon[32], Steven Simoens[1]

1 KU Leuven Department of Pharmaceutical and Pharmacological Sciences, Leuven, Belgium, 2 Hospital Pharmacy, Erasmus University Medical Center, Rotterdam, The Netherlands, 3 Medicines for Europe, Brussels, Belgium, 4 Department of Laboratory Medicine, Karolinska Institutet, Stockholm, Sweden, 5 Strathclyde Institute for Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow, United Kingdom, 6 Main Association of Austrian Social Security Institutions, Vienna, Austria, 7 Faculty of pharmaceutical sciences, Ghent University, Ghent, Belgium, 8 Faculty of Pharmacy, Medical University of Sofia, Sofia, Bulgaria, 9 Croatian Health Insurance Fund, Zagreb, Croatia, 10 State Institute for Drug Control, Prague, Czech Republic, 11 State Institute for Drug Control, Brno, Czech Republic, 12 State Agency of Medicines, Tartu, Estonia, 13 Department of Traumatology and Orthopedics, University of Tartu, Tartu, Estonia, 14 Karr Consultancy Ltd, Hertfordshire, United Kingdom, 15 OMEDIT Alsace, Agence Régionale de Santé du Grand Est, Strasbourg, France, 16 Research Unit, Social Insurance Institution, Helsinki, Finland, 17 Wissenschaftliches Institut der AOK (WIdO), Berlin, Germany, 18 Department of Pharmacology and Therapeutics, Trinity College Dublin, Dublin, Ireland, 19 National Centre for Pharmacoeconomics, St James's Hospital, Dublin, Ireland, 20 Department of Biomedical and Dental Sciences and Morphofunctional Imaging, University of Messina, Messina, Italy, 21 Strathclyde Institute for Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow, United Kingdom, 22 Division Pharmaceuticals, Norwegian Hospital Procurement Trust, Oslo, Norway, 23 Department of Medicines and Medical Devices, The National Health Service, Riga, Latvia, 24 HTA Consulting, Cracow, Poland, 25 Faculty of Pharmacy, University of Lisbon, Lisbon, Portugal, 26 Semashko National Research Institute for Public Health, Moscow, Russia, 27 Primary healthcare center Zemun, Belgrade, Serbia, 28 Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, Ljubljana, Slovenia, 29 Health Insurance Institute, Ljubljana, Slovenia, 30 Barcelona Health Region, Catalan Health Service, Barcelona, Spain, 31 TLV, Stockholm, Sweden, 32 Ministry of Welfare, Reykjavik, Iceland

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

4

KU LEUVEN

Pricing of off-patent biologicals – List prices

Pricing of biosimilars:

- % below price of originator
- Maximum price
- …

→ often combination of **different pricing mechanisms**

Pricing of off-patent biologicals/reference products:

- Price cuts for originators

E.g. Iceland: -20% on original ex-factory price after entry of biosimilar

Influence of mandatory price cuts on originator for sustainability of biosimilar market?

⚠ List prices vs actual prices after discounts and rebates

Pricing of off-patent biologicals – Tendering

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

Sustainability considerations:
National – regional – hospital level
Multiple winners – single winner

Sweden

21 county councils

Norway

National tender

England

4 supra regions

Rotation system:
- Next region every 6 months
- Tender duration 2 year

Reimbursement of biosimilars

Approximately half of European countries use internal reference pricing

Limited information on methodology and process from authorities and literature

→ **Questions**

Economic evaluation	Budget impact analysis
Need?	**Need?**
Technique?	**Budget affected?**
What if reference product not reimbursed?	**Consider volume evolution?**
What if 2nd-generation products enter?	**Consider price evolution?**
Which comparator for 2nd-generation products?	**Consider market entry of new products?**

Process often delays market entry of biosimilar

Medicines for Europe. The 2017 Market Review – European Biosimilar Medicines Markets – Policy Overview
Moorkens et al. The design of economic evaluation and budget impact analysis of biosimilars (in preparation)

KU LEUVEN

Demand-side policies

Incentives for physicians

- **Quotas** on biosimilars:


Belgium: 20% biosimilars for treatment-naïve patients (Covenant)


Germany: Target agreements per region

- **Recommendations**:


Sweden: Use most cost-effective product (e.g., for etanercept)

- **Economic prescribing**:


Germany: Prescribing budgets

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

KU LEUVEN

Demand-side policies

Switching policies

- Mostly at discretion of physician
- Some countries issued a position statement e.g., Norway, Sweden

Different approaches possible: discussion with patient, letter to inform patient

Substitution policies

- (Restricted) pharmacist substitution in Estonia, Latvia, Poland and Russia

⚠ France: Legislation introduced for treatment-naïve patients, not implemented

Germany: Groups of bio-identicals

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

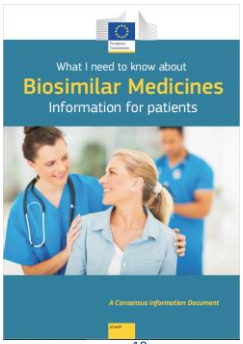
KU LEUVEN

Demand-side policies

Education

- Varies at country level, but tends to target physicians

- Initiatives of the European Commission and EMA



Moorkens *et al.* (2017). Policies for biosimilar uptake in Europe: An overview. *PLoS ONE*
Website EMA. Biosimilar medicines

KU LEUVEN

Impact of policies?

Important to create competition, not just uptake of biosimilars as originator might be the least expensive treatment option. However, biosimilars need to have market share to exert competitive pressure.

Potential drivers for implementation:

- Price difference between originator and biosimilar (Savings!)
- Attitude of key opinion leaders
- Local guidelines/recommendations/quota
- Gainsharing arrangements

→ Need for **multi-stakeholder approach**, **communication** on decisions, and **education** of stakeholders to make policy decision work!

Moorkens *et al.* (2018) Poster presentation ISPOR Barcelona

KU LEUVEN

Conclusions

Policies targeting price not sustainable in the long term

Focus on demand-side policies

- Guidelines and recommendations
- Quota
- Gainsharing arrangements

Moorkens *et al.* (2017). Policies for biosimilar uptake in Europe: An overview. *PLoS ONE*
Rémuzat et al. (2017). Supply-side and demand-side policies for biosimilars: an overview in 10 European member states. Journal of Market Access & Health Policy

KU LEUVEN

Thank you!

Contact

Evelien Moorkens
Clinical Pharmacology & Pharmacotherapy
KU Leuven

evelien.moorkens@kuleuven.be

KU LEUVEN

Polling and Q&A

WiFi Network: ISPORBarcelona | Password: IQVIA2018

https://myispor.cnf.io/

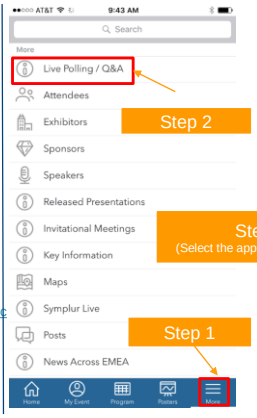
ISPOR **Conference Platform**

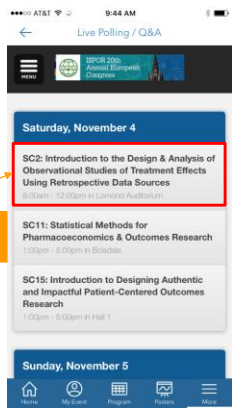
Web Platform

myISPORBarcelona.zerista.com

Mobile App

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





KU LEUVEN

- **For attendees using the mobile app:**

Open the app >> Select “More” >> Select “Live Polling/Q&A” >> Select your session from the list

- **For attendees using the myISPORBarcelona.zerista.com web platform:**

Go to the myISPORBarcelona.zerista.com home page >> Click on **https://myispor.cnf.io/** >> Select your session

- **For those not using the mobile app nor the web platform:**

Go to your web browser and type in: **https://myispor.cnf.io/** >> Select your session

KU LEUVEN

Live Content Slide

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

Social Q&A

Live Content Slide

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

Poll: To what extent is your healthcare system unlocking the biosimilar value proposition and fully utilizing biosimilars to enable broad access?