

Issues of biological therapies in Central and Eastern Europe

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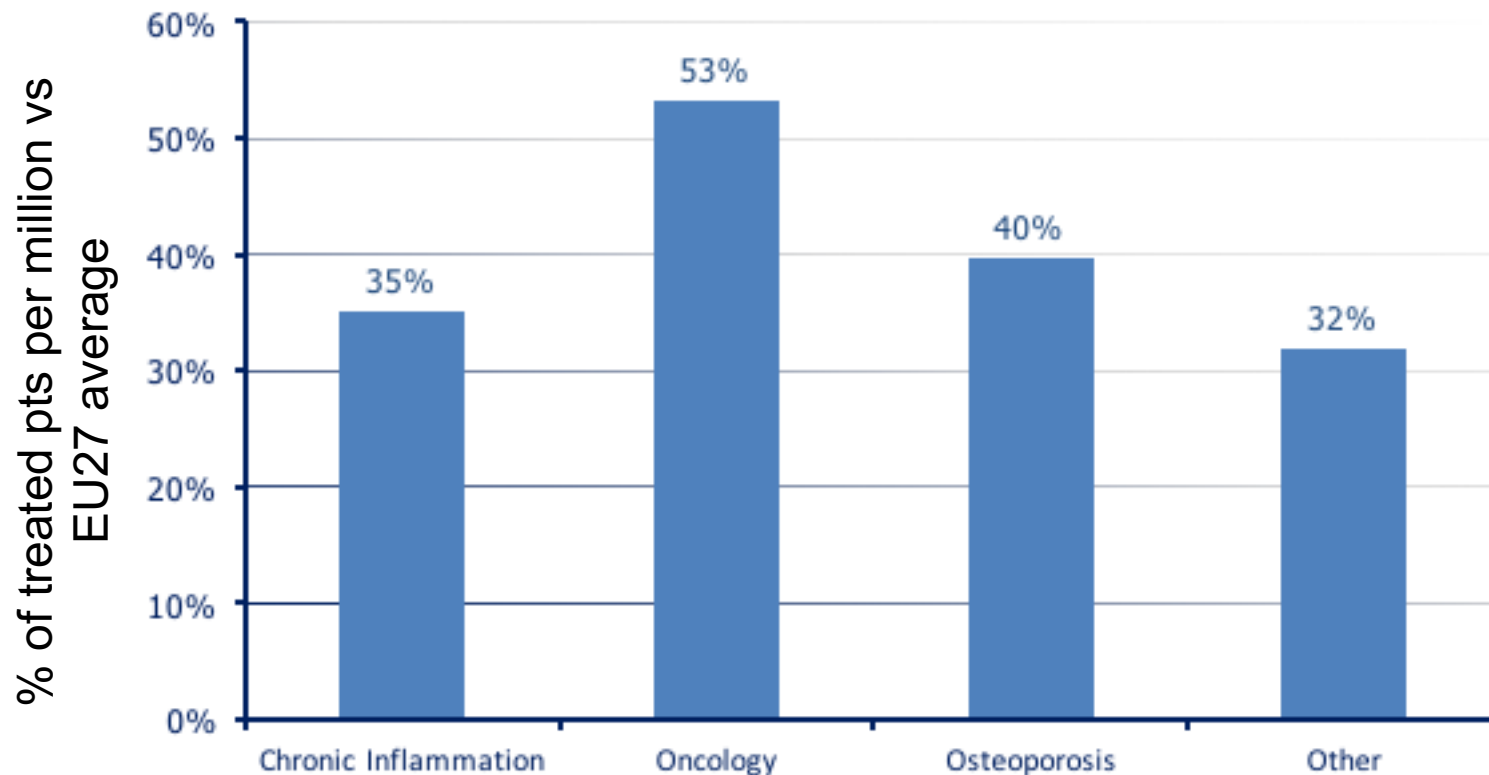
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Outline

- Inequalities of access to biological medicines in 6 CEE countries
- Effect of interchange on potential savings with biosimilar infliximab
- Overview of biosimilar penetration and reimbursement policies in 6 CEE countries

Access to mAb therapies in 6 CEE countries

(BG, CZ, HU, PL, RO, SK)



mAb: monoclonal antibody

Chronic Inflammation: ABATACEPT, ADALIMUMAB, BELIMUMAB, CANAKINUMAB, CERTOLIZUMAB PEGOL, ECULIZUMAB, ETANERCEPT, GOLIMUMAB, INFILIXIMAB, TOCILIZUMAB, USTEKINUMAB

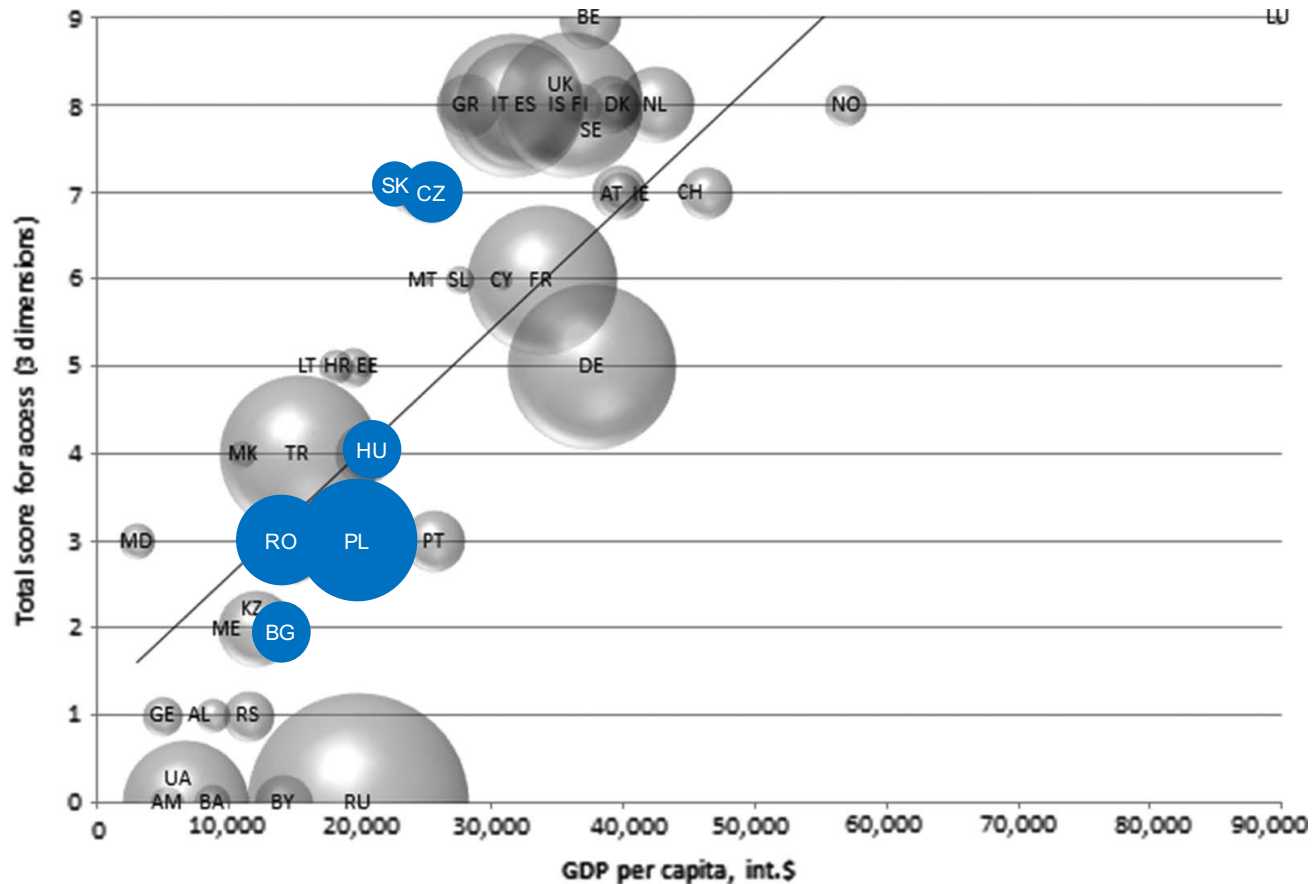
Oncology mAbs: BEVACIZUMAB, BRENTUXIMAB VEDOTIN, CATUMAXOMAB, CETUXIMAB, IBRITUMOMAB TIUXETAN, IPIILIMUMAB, OFATUMUMAB, PANITUMUMAB, RITUXIMAB, TRASTUZUMAB

Osteoporosis mAb: denosumab

Other mAbs: ABCIXIMAB, BASILIXIMAB, BELATACEPT, NATALIZUMAB, OMALIZUMAB, PALIVIZUMAB, RANIBIZUMAB

Data source: IMS 2012 Q2, except Cegecim 2012 Q2 for Romania and Pharmexpert 2012 Q2 for Russia

Access to mAb therapies in RA varies greatly across Europe



mAb: monoclonal antibody, RA: Rheumatoid Arthritis

Putrik P, et al. "Inequities in Access to Biologic and Synthetic DMARDs across 46 European Countries." *ARD* 73:1(Jan 2014): 198–206

Budget impact analysis of biosimilar infliximab in 6 CEE countries

Allowing interchange can increase savings or improve patient access to mAb treatment

		# RA patients on biologicals in 2013: 17 300	year 1	year 2	year 3	total
Rheumatoid Arthritis	Budget impact (th €)					
	BSc1 - Interchanging disallowed		-945	-4 782	-9 612	-15 340
	BSc2 - Interchanging allowed		-2 394	-6 968	-11 463	-20 826
	Number of new patients can be treated*					
	BSc1 - Interchanging disallowed		165	672	1205	-
	BSc2 - Interchanging allowed		242	1002	1790	-
		# CD patients on biologicals in 2013: 4 737				
Crohn's Disease	Budget impact (th €, 2013)					
	BSc1 - Interchanging disallowed		-770	-2 647	-4 540	-7 958
	BSc2 - Interchanging allowed		-266	-7 731	-8 913	-16 910
	Number of new patients can be treated*					
	BSc1 - Interchanging disallowed		59	237	426	722
	BSc2 - Interchanging allowed		124	502	904	1 530

* with biological therapy if budget savings would be spent on biosimilar infliximab

BSc1: interchanging of biosimilar and originator infliximab is not allowed

BSc2: interchanging of biosimilar and originator infliximab is allowed 6 months after the initiation of treatment, 80% of patients interchanged during 1st year of treatment

Countries included: Bulgaria, Czech Republic, Hungary, Poland, Romania, Slovakia

mAb: monoclonal antibody, RA: Rheumatoid Arthritis, CD: Crohn's Disease

Brodzsky V et al. "Budget Impact Analysis of Biosimilar Infliximab (CT-P13) for the Treatment of Rheumatoid Arthritis in Six Central and Eastern European Countries." *EJHE* 15 (May 2014): 65–71

Brodzsky V et al. "A Budget Impact Model for Biosimilar Infliximab in Crohn's Disease in Bulgaria, the Czech Republic, Hungary, Poland, Romania, and Slovakia." *Expert Rev Pharmacoecon Outcomes Res* July 10, 2015, 1–7.

Penetration and reimbursement landscape of 4 biosimilars in 6 CEE countries in 2015

% Market Share of Biosimilars	Bulgaria	Czech Rep	Hungary	Poland	Slovakia	Romania
Filgrastim	89%	99%	100%	83%	99%	100%
Erythropoietin	53%	29%	36%	17%	59%	15%
Growth Hormone	13%	8%	4%	99%	0%	27%
Infliximab	100%	14%	16%	51%	6%	8%

Reimbursement of biosimilars:	Bulgaria	Czech Rep	Hungary	Poland	Slovakia	Romania
Filgrastim	Reg/Hosp Tender	Reg/Hosp Tender	Retail	Reg/Hosp Tender	Retail	Retail
Erythropoietin	Reg/Hosp Tender	Reg/Hosp Tender	Retail	Reg/Hosp Tender	Retail	Retail
Growth Hormone	Retail	Retail	Retail	National Tender	National Tender	Retail
Infliximab	Retail	Retail	National Tender	Reg/Hosp Tender	Retail	Retail

Interchange by physicians	Bulgaria	Czech Rep	Hungary	Poland	Slovakia	Romania
Filgrastim	Forced	Forced	Forced	Forced	Allowed	Allowed
Erythropoietin	Forced	Forced	Forced	Forced	Allowed	Allowed
Growth Hormone	Allowed	Allowed	Allowed	Forced	Allowed	Allowed
Infliximab	Allowed	Allowed	Banned	Forced	Allowed	Allowed

Comments

Slovakia

Filgrastim 20% tender w forced interchange, 80% retail w allowed interchange

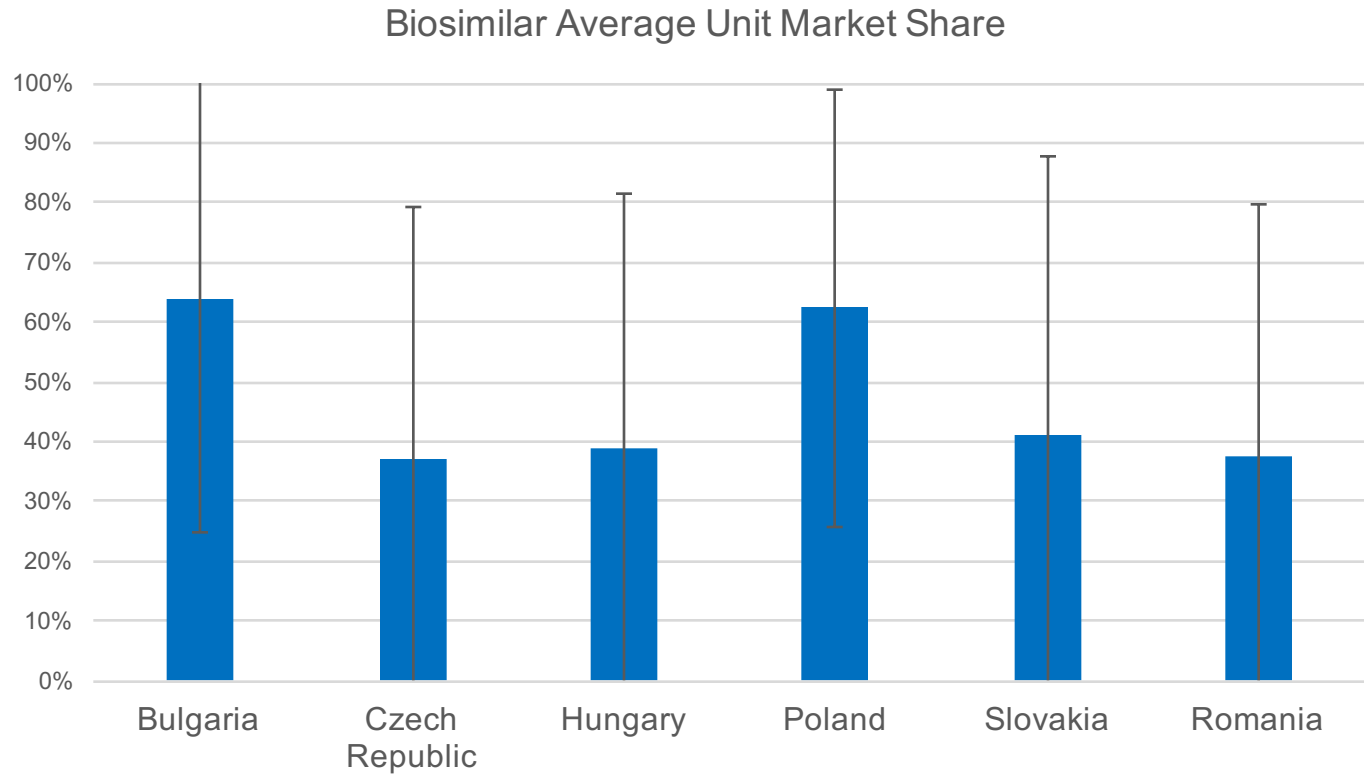
Bulgaria

Erythropoietin 70% hospital tender with forced interchange, 30% retail

Poland

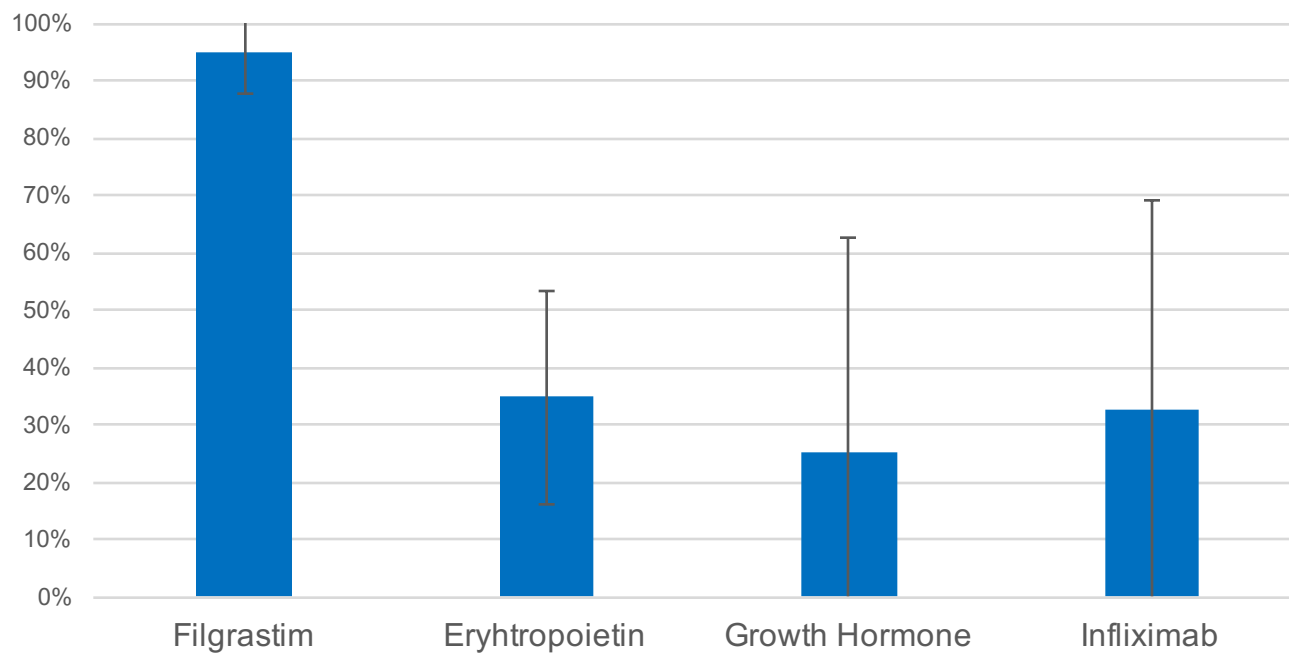
Poland filgrastim 80% hospital tender with forced interchange, 20% retail

Average Unit Market Share of 4 biosimilars



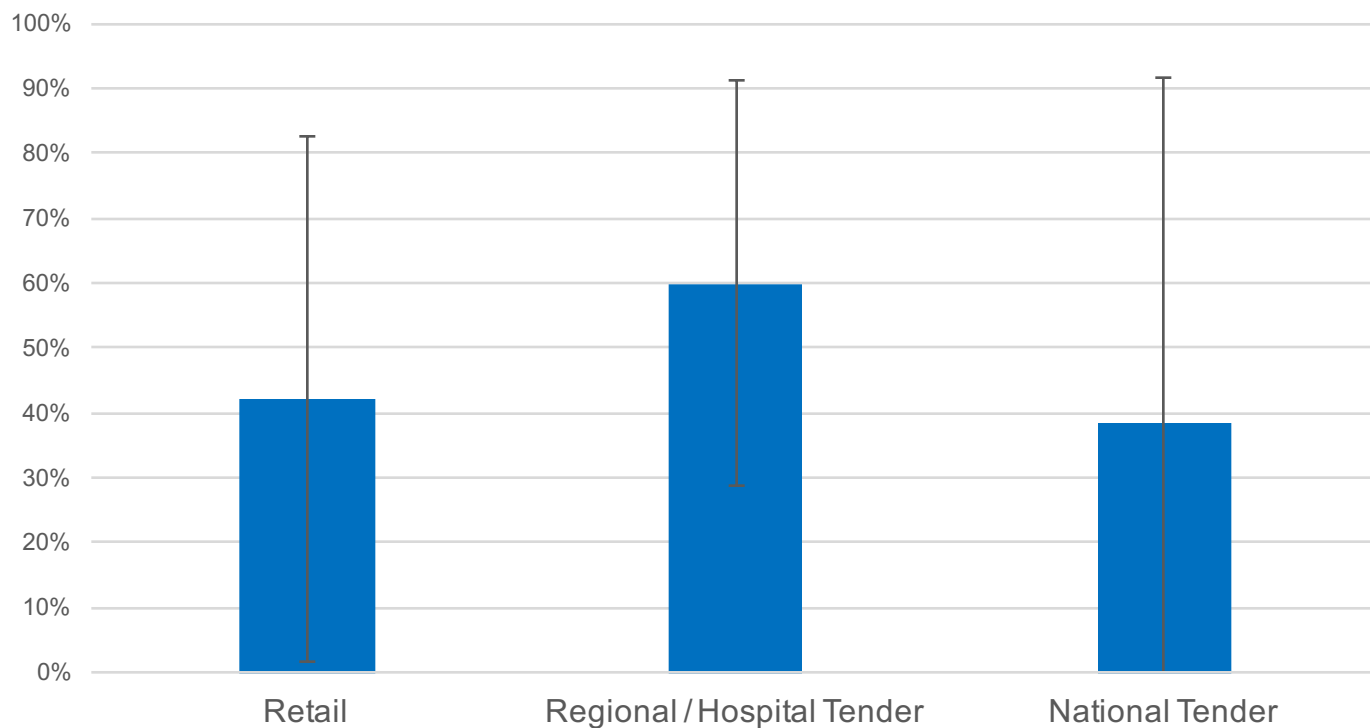
Average unit market share of 4 biosimilars by molecule

Biosimilar Penetration by Molecule



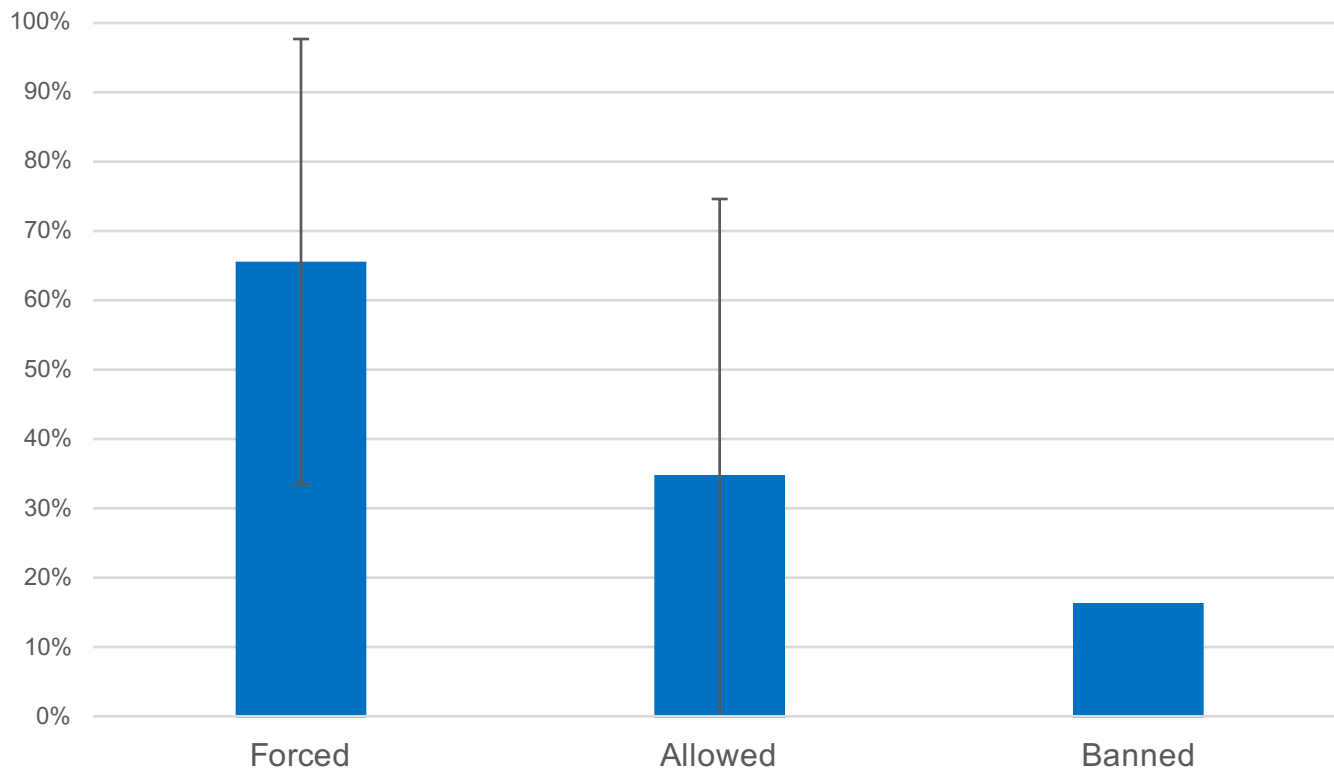
Penetration of 4 biosimilars in different reimbursement settings

Biosimilar Penetration by Reimbursement Type

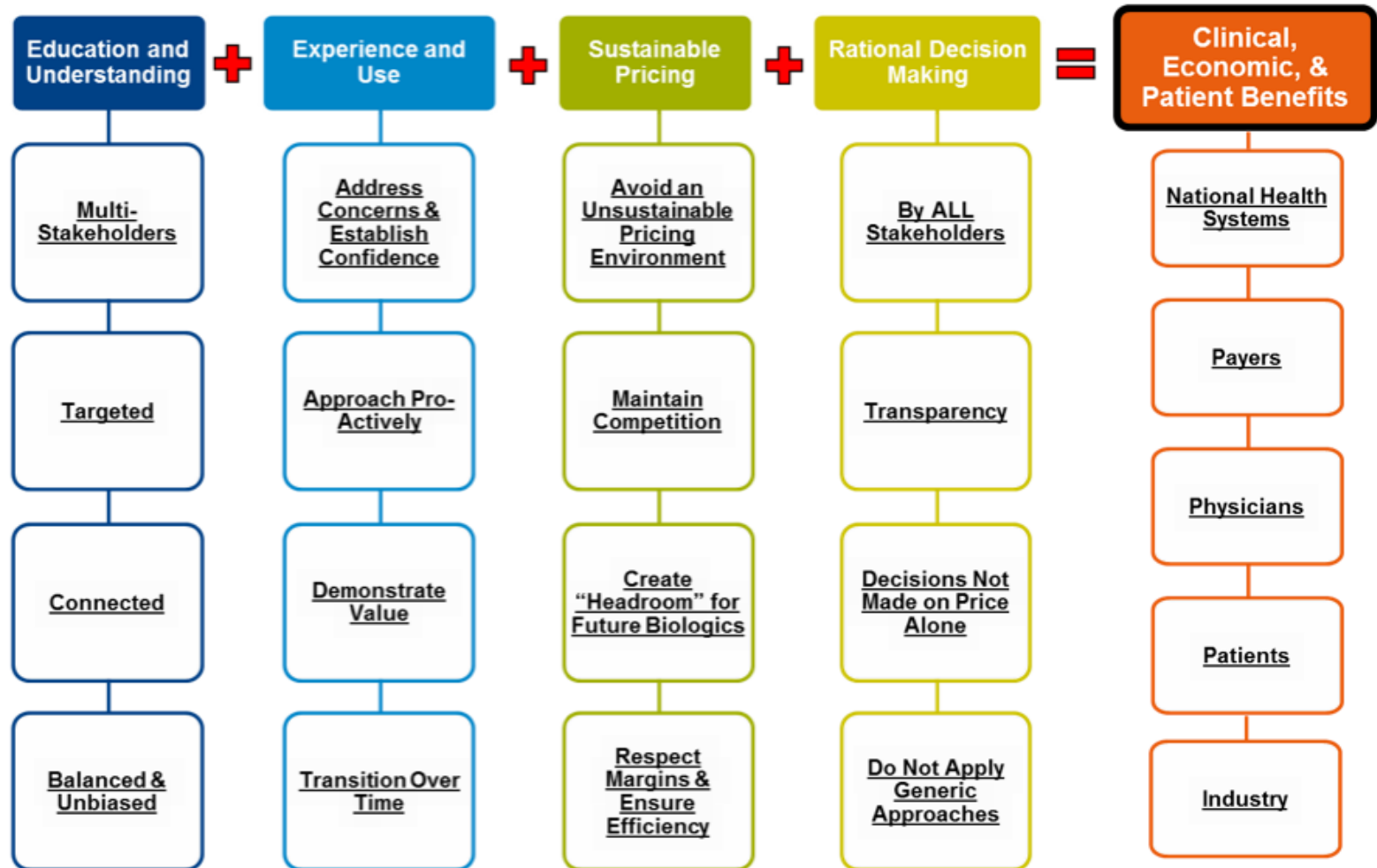


Penetration of 4 biosimilars in different interchange policies

Biosimilar Penetration by Interchange Policy



Factors supporting a sustainable biosimilar medicines market in Europe



Conclusion

- Biosimilar reimbursement policies and market penetration vary greatly among CEE countries
- Filgrastim had unanimously the highest market share, growth hormone and infliximab penetration were most diverse
- Greater biosimilar penetration was observed in hospital / regional tender settings and where forced interchange policies are applied
- Suggestions of the sustainability framework could be considered for further developing the biosimilar reimbursement policies in CEE countries

Thank you for your attention!

