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Budget impact and cost-effectiveness of oncology biosimilars

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Health economist

Conflict of interest

I am one of the founders of the KU Leuven Fund on Market Analysis of Biologics and Biosimilars following Loss of Exclusivity (MABEL)
https://gbiomed.kuleuven.be/english/research/50000715/52577001/mabel

I was involved in a stakeholder roundtable on biologics and biosimilars sponsored by Amgen, Pfizer and MSD, and I have participated in advisory board meetings for Amgen, Pfizer and Sandoz

I have contributed to studies on biologics and biosimilars for Hospira, Celltrion, Mundipharma and Pfizer

I had speaking engagements for Amgen, Celltrion and Sandoz

I am member of the leadership team of the ISPOR Special Interest Group on Biosimilars

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Biosimilar competition ensures access to biologic therapy at lower cost

Oncology biosimilar competition can generate savings from lower-priced biosimilars and from reduced prices of reference biologics

Table 1. Examples of policies that aim to make biologic therapy available to patients at the lowest cost.

Country	Biopharmaceutical policy
Austria	When multiple products are on the market, physicians are encouraged to prescribe the most cost-effective product [14]
Belgium	Policy is geared at promoting the use of a 'cheap' biologic medicine, be it a biosimilar medicine or the reference biologic with a reduced price [18]
Denmark	Amgros organizes national tenders for hospital medicines, selecting the cheapest product [19]
England	NHS England has set targets for the uptake of 'best-value biologics' in specialized services for both new and applicable existing patients [20]
Ireland	The Health Service Executive Medicines Management Programme identifies 'best-value biologics' based on 13 criteria (including cost), and Prescribing and Cost Guidance is published to support clinicians in prescribing these medicines [21]
Italy	If more than three biologic/biosimilar products using the same active substance are available, physicians need to prescribe one of the three cheapest products as identified in a regional tender (law 232/2016)
Slovakia	A reference-pricing system groups biologic and biosimilar medicines based on the same active substance and administration form, and sets the reference price at the level of the cheapest product [22]

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Simoens S. and Vulto A. A health economic guide to market access of biosimilars. Expert Opinion on Biological Therapy 2021, 21:1, 9-17.

Oncology biosimilars, savings and treatment access

Conversion from reference to biosimilar pegfilgrastim in hypothetical panel of 20,000 US cancer patients, assuming various discount and conversion rates

Table 1. Cost savings by conversion from reference pegfilgrastim to biosimilar pegfilgrastim-bmez by scenarios (in US$) utilizing ASP.

Biosimilar Discount	Conversion Rate									
	100%	90%	80%	70%	60%	50%	40%	30%	20%	10%
15%	$12,749,439	$11,474,495	$10,199,551	$8,924,607	$7,649,663	$6,374,720	$5,099,774	$3,824,832	$2,549,888	$1,274,944
20%	$16,999,252	$15,299,327	$13,599,402	$11,899,477	$10,199,551	$8,499,626	$6,799,701	$5,099,776	$3,399,850	$1,699,925
25%	$21,249,065	$19,124,159	$16,999,252	$14,874,346	$12,749,439	$10,624,533	$8,499,626	$6,374,720	$4,249,813	$2,124,907
30%	$25,498,878	$22,948,990	$20,399,103	$17,849,215	$15,299,327	$12,749,439	$10,199,551	$7,649,663	$5,099,776	$2,549,888
35%	$29,748,691	$26,773,822	$23,798,953	$20,824,084	$17,849,215	$14,874,346	$11,899,477	$8,924,607	$5,949,738	$2,974,869

Table 2. Expanded access to biosimilar pegfilgrastim-bmez by scenarios (number of patients) utilizing ASP.

Biosimilar Discount	Conversion Rate									
	100%	90%	80%	70%	60%	50%	40%	30%	20%	10%
15%	3,529	3,176	2,823	2,470	2,117	1,764	1,411	1,058	705	352
20%	5,000	4,500	4,000	3,500	3,000	2,500	2,000	1,500	1,000	500
25%	6,666	6,000	5,333	4,666	4,000	3,333	2,666	2,000	1,333	666
30%	8,571	7,714	6,857	6,000	5,142	4,285	3,428	2,571	1,714	857
35%	10,769	9,692	8,615	7,538	6,461	5,384	4,307	3,230	2,153	1,076

Table 4. Expanded access to pembrolizumab by scenarios (number of patients) utilizing ASP.

Biosimilar Discount	Conversion rate									
	100%	90%	80%	70%	60%	50%	40%	30%	20%	10%
15%	38	34	31	27	23	19	15	11	7	3
20%	51	46	41	36	31	25	20	15	10	5
25%	64	58	51	45	38	32	25	19	12	6
30%	77	69	62	54	46	38	31	23	15	7
35%	90	81	72	63	54	45	36	27	18	9

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McBride A., et al. Economic modeling for the US of the cost-efficiency and associated expanded treatment access of conversion to biosimilar pegfilgrastim-bmez from reference pegfilgrastim. Journal of Medical Economics 2020, 23:8, 856-863.

Oncology biosimilars, savings and next-generation biologics

Biosimilars can enter the market in the presence of IV and SC formulations of reference biologic (e.g. trastuzumab)

Net budget impact of introducing IV biosimilar trastuzumab in UK from health care payer perspective

	Year 1	Year 2	Year 3	Year 4	Year 5
Drug acquisition	-£2,418,938	-£6,326,132	-£6,370,415	-£6,415,008	-£6,459,913
Administration	£214,876	£658,440	£663,049	£667,690	£672,364
Total	*- £2,204,061*	*-£5,667,692*	*-£5,707,366*	*-£5,747,318*	*-£5,787,549*

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Jang M., et al. Budget impact analysis of the introduction of rituximab and trastuzumab intravenous biosimilars to EU-5 markets. BioDrugs 2021, vol. 35, no. 1, p. 89-101.

Oncology biosimilars, savings and next-generation biologics

Cost difference between IV biosimilar trastuzumab and SC reference trastuzumab depends on patient body weight

Weight	87.5kg	84kg	75kg	62.5kg	56.25kg	50kg
IV loading dose vials	5	4,5	4	3,5	3	3
IV subsequent dose	3.5	3.5	3	2.5	2.5	2
IV total vials	64.5	64	55	46	45.5	37
SC total vials	18	18	18	18	18	18

	87.5kg	84kg	75kg	62.5kg	56.25kg	50kg
Price IV	€17 858	€17 720	€15 228	€12 736	€12 598	€10 244
Price SC	€15 228	€15 228	€15 228	€15 228	€15 228	€15 228
Difference IV - SC	€2 630	€2 492	€0	-€2 492	-€2 630	-€4 984
SC savings	€907	€907	€907	€907	€907	€907
Total additional cost	€3 537	€3 399	€907	-€1 585	-€1 723	-€4 077

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Simoens S., et al. A cost simulation of intravenous biosimilar trastuzumab versus subcutaneous reference trastuzumab in adjuvant HER2-positive breast cancer in Belgium. Submitted to Pharmaceuticals.

Oncology biosimilars, savings and next-generation biologics

Cost difference between IV biosimilar trastuzumab and SC reference trastuzumab depends on patient body weight, drug discounts and IV vial sharing

Drug costs and health care costs of treating hypothetical sample of 100 patients with IV biosimilar trastuzumab versus SC reference trastuzumab

	Base case	Scenario with discounts* without IV vial sharing	Scenario with discounts* and IV vial sharing
Drug costs			
IV	€1,431,282	€715,641	€697,335
SC	€1,522,809	€1,218,247	€1,218,247
IV-SC	-€91,527	-€502,606	-€520,912
Health care costs			
IV-SC	-€807	-€411,886	-€430,192

* Assuming a discount of 50% on IV biosimilar trastuzumab and 20% on SC reference trastuzumab

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Simoens S., et al. A cost simulation of intravenous biosimilar trastuzumab versus subcutaneous reference trastuzumab in adjuvant HER2-positive breast cancer in Belgium. Submitted to Pharmaceuticals.

How to design tenders for off-patent oncology biologics and biosimilars?

Tender design influences:

- Extent of competition
- Market sustainability
- Risk of drug shortages
- Physician freedom of choice

Single-winner tenders may maximize price competition, but exclude other manufacturers from the market, thus increasing supply risks and threatening market sustainability

Multiple-winner tenders may generate largest savings because they attain price decreases on all tendered products for all uses/indications

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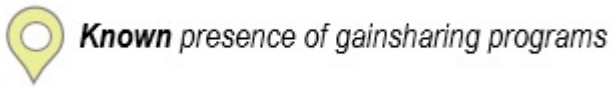
IQVIA Institute for Human Data Science. Advancing biosimilar sustainability in Europe: a multi-stakeholder assessment (2018).

Gainsharing arrangements for off-patent biologics and biosimilars

Arrangement which shares savings generated from reference product and biosimilar competition between stakeholders (e.g. health care payers, hospitals, physicians and patients)



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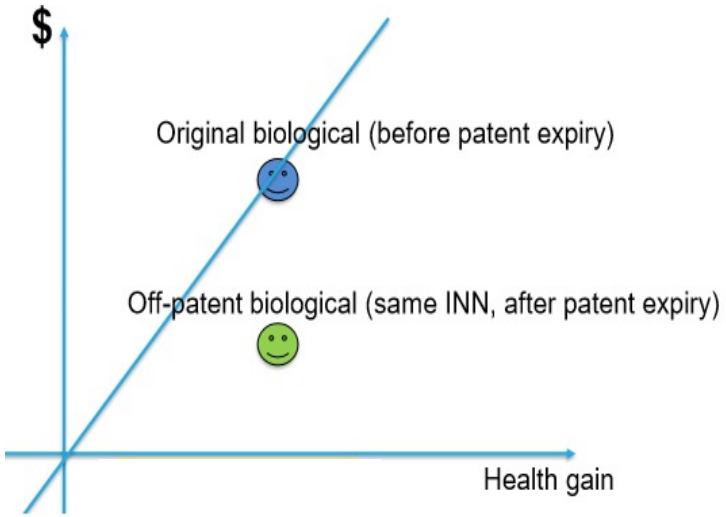
Barcina Lacosta T., et al. Qualitative analysis of the design and implementation of gainsharing programs across Europe. Work in progress.

Biosimilar competition improves cost-effectiveness of oncology therapy



Example:

Cost-effectiveness of cetuximab + best supportive care vs. best supportive care for metastatic colon cancer in Canada

Reference cetuximab: $299,613 / QALY
Biosimilar cetuximab: $261,126 / QALY

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Cheung et al. Current Oncology 2019;26(2),89-93. Inotai et al. J Bioequiv Availab 2017;9: 467-472. Joint forum of ISPOR Special Interest Group on Biosimilars and ISPOR Central Eastern European Consortium. ISPOR Copenhagen, November 2019.

Biosimilar competition improves cost-effectiveness of oncology therapy

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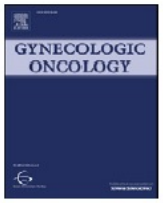

Cost-effectiveness of adding bevacizumab to first line therapy for patients with advanced ovarian cancer

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Reference bevacizumab is not cost-effective

Biosimilar bevacizumab (at 30% price reduction) is not cost-effective in total population

Biosimilar bevacizumab is cost-effective in patients with stage IV disease, in ECOG PS 1 patients, and in patients at high risk of disease progression

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Biosimilar competition supports innovation in oncology therapy

Example:

Cost-effectiveness of pertuzumab + IV trastuzumab + chemotherapy for HER2-positive early stage breast cancer in adults who have lymph node-positive disease

< £20,000 per QALY gained if:

- commercial discount to price of pertuzumab
- weighted average biosimilar trastuzumab discount

were taken into account

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National Institute for Health and Care Excellence. Pertuzumab for adjuvant treatment of HER2-positive early stage breast cancer. www.nice.org.uk/guidance/ta569

Key messages

Budget impact and cost-effectiveness of oncology biologics change through lifecycle

Biosimilars can contribute to value, affordability and patient access to oncology care

Entry of oncology biosimilars can change dynamics in broad market

Gainsharing arrangements can be a tool to deliver benefits of oncology biosimilars to multiple stakeholders

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Simoens S. How do biosimilars sustain value, affordability and access to oncology care? Expert Review of Pharmacoeconomics and Outcomes Research. In press.

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