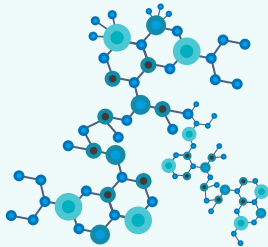


Facts & Figures

BIOSIMILAR MEDICINES IN
BELGIUM: UNMET POTENTIAL
05/2022

CHARACTERISTICS OF A BIOSIMILAR MEDICINE

Biosimilar medicine



Biological molecule



Therapeutic
equivalence with
reference medicine



After patent expiry,
35,80% - 47,18%
cheaper than initial price
of reference medicine*

Generic medicine



Chemical molecule



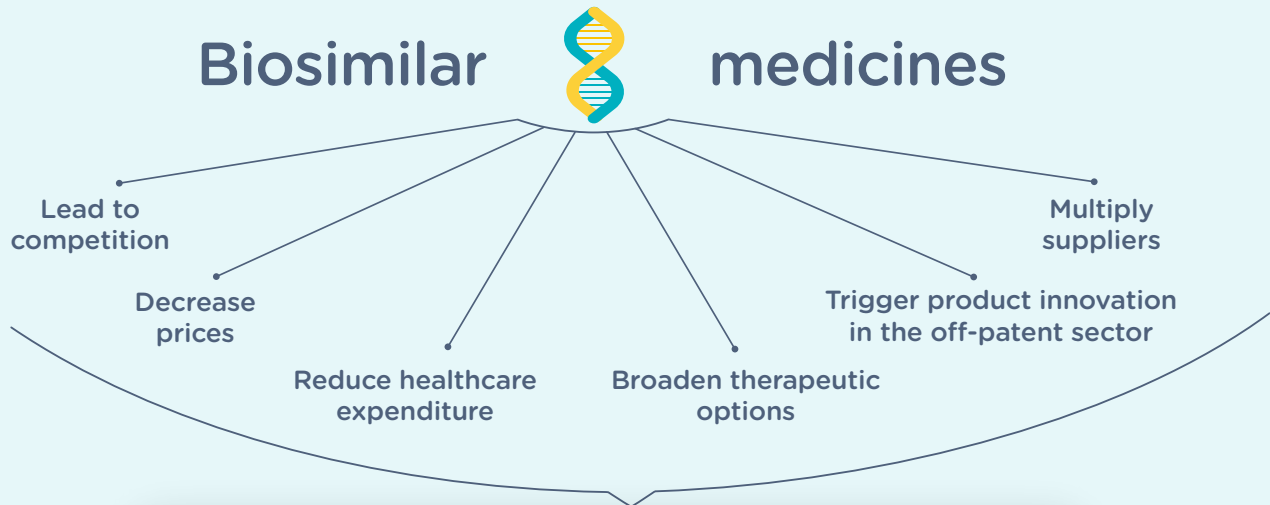
Therapeutic
equivalence with
reference medicine



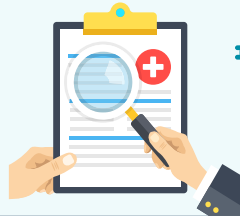
After patent expiry,
44,75% - 67,99%
cheaper than initial price
of reference medicine*

* Numbers valid from 01/01/2022

BIOSIMILAR MEDICINES: ADDED VALUE






What if there were **no biosimilar medicines?**



€310 million
extra expenditure
for NIHDI in 2021*

Source: IQVIA LMPB & BHA 12/2021 year 2021, reimbursed medicines

BIOSIMILAR MEDICINES IN BELGIUM IN A NUTSHELL


Molecule 	Number of biosimilar medicine manufacturers on the market*	Biosimilar medicine turnover Public pharmacies** (in €) 	Biosimilar medicine turnover Hospitals** (in €) 	Biosimilar medicine turnover Total** (in €)
Adalimumab	6	18.266.595	569.064	18.835.659
Bevacizumab	3	NA	9.587.520	9.587.520
Enoxaparin	2	649.727	NA	649.727
Epoetin	1	NA	1.132.558	1.132.558
Etanercept	3	7.413.783	114.999	7.528.782
Filgrastim	3	4.294	1.656.800	1.661.094
Infliximab	4	993.469	59.551.212	60.544.681
Insulin glargine	1	583.965	47.106	631.071
Pegfilgrastim	3	NA	5.767.512	5.767.512
Rituximab	3	NA	9.121.242	9.121.242
Somatropin	1	3.837.724	11.610	3.849.334
Trastuzumab	6	NA	8.120.708	8.120.708
TOTAL		31.749.557	95.680.331	127.429.888

* Source: NIHDI, SSP file, 03/2022

** Source: IQVIA LMPB & BHA 12/2021, ex-factory prices

BIOSIMILAR MEDICINES: BELGIUM IS LAGGING BEHIND


Market share in volume: Belgium compared to other EU countries (1/3)

Molecule 	Originator or Biosimilar	Belgium (%)	France (%)	Germany (%)	Italy (%)	UK (%)
Adalimumab	Originator	75,38	64,88	14,93	27,54	17,33
Adalimumab	Originator (PI)	0,00	0,00	11,78	0,00	0,00
Adalimumab	Biosimilars	24,62	35,12	73,29	72,46	82,67
Bevacizumab	Originator	73,30	7,33	32,51	36,99	96,50
Bevacizumab	Originator (PI)	0,00	0,00	1,28	0,00	0,00
Bevacizumab	Biosimilars	26,70	92,67	66,21	63,01	3,50
Enoxaparin sodium	Originator	97,54	94,11	64,71	33,44	39,41
Enoxaparin sodium	Originator (PI)	0,00	0,00	1,71	0,00	0,00
Enoxaparin sodium	Biosimilars	2,46	5,89	33,59	66,56	60,59
Epoetin alfa	Originator	89,71	52,82	8,61	12,47	100,00
Epoetin alfa	Originator (PI)	0,00	0,00	0,00	0,00	0,00
Epoetin alfa	Biosimilars	10,29	47,18	91,39	87,53	0,00
Epoetin zeta	Originator	0,00	0,00	0,00	0,00	0,00
Epoetin zeta	Originator (PI)	0,00	0,00	0,00	0,00	0,00
Epoetin zeta	Biosimilars	0,00	100,00	100,00	100,00	100,00
Etanercept	Originator	76,97	60,91	15,10	31,11	16,12
Etanercept	Originator (PI)	0,00	0,00	7,50	0,00	0,00
Etanercept	Biosimilars	23,03	39,09	77,41	68,89	83,88
Filgrastim	Originator	68,78	3,85	15,55	2,62	14,05
Filgrastim	Originator (PI)	0,00	0,00	1,47	0,00	0,00
Filgrastim	Biosimilars	31,22	96,15	82,98	97,38	85,95

Source: IQVIA MAT Q4 2021

BIOSIMILAR MEDICINES: BELGIUM IS LAGGING BEHIND


Market share in volume: Belgium compared to other EU countries (2/3)

Molecule 	Originator or Biosimilar	Belgium (%)	France (%)	Germany (%)	Italy (%)	UK (%)
Follitropin alfa	Originator	35,86	46,02	48,47	61,93	57,34
Follitropin alfa	Originator (PI)	0,00	0,00	11,10	0,00	0,00
Follitropin alfa	Biosimilars	64,14	53,98	40,42	38,07	42,66
Infliximab	Originator	56,29	23,64	31,54	6,58	3,96
Infliximab	Originator (PI)	0,00	0,00	4,27	0,00	0,00
Infliximab	Biosimilars	43,71	76,36	64,19	93,42	96,04
Insulin glargine	Originator	96,33	72,14	82,11	79,54	85,07
Insulin glargine	Originator (PI)	0,00	0,00	1,20	0,00	0,00
Insulin glargine	Biosimilars	3,67	27,86	16,69	20,46	14,93
Insulin aspart	Originator	100,00	100,00	98,44	100,00	100,00
Insulin aspart	Originator (PI)	0,00	0,00	1,56	0,00	0,00
Insulin aspart	Biosimilars	0,00	0,00	0,00	0,00	0,00
Insulin lispro	Originator	100,00	100,00	92,98	87,37	100,00
Insulin lispro	Originator (PI)	0,00	0,00	1,19	0,00	0,00
Insulin lispro	Biosimilars	0,00	0,00	5,83	12,63	0,00
Insulin human base	Originator	100,00	100,00	89,21	100,00	100,00
Insulin human base	Originator (PI)	0,00	0,00	10,79	0,00	0,00
Insulin human base	Biosimilars	0,00	0,00	0,00	0,00	0,00

Source: IQVIA MAT Q4 2021

BIOSIMILAR MEDICINES: BELGIUM IS LAGGING BEHIND

Market share in volume: Belgium compared to other EU countries (3/3)

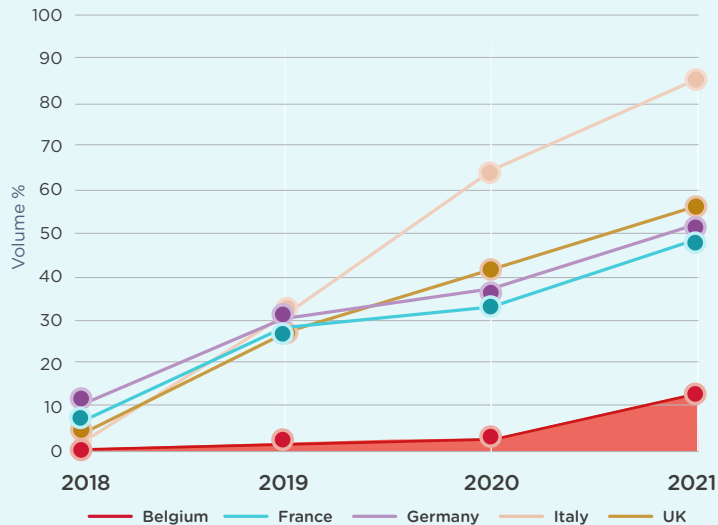
Molecule 	Originator or Biosimilar	Belgium (%)	France (%)	Germany (%)	Italy (%)	UK (%)
Pegfilgrastim	Originator	76,69	26,23	56,90	18,98	19,35
Pegfilgrastim	Originator (PI)	0,00	0,00	3,22	0,00	0,00
Pegfilgrastim	Biosimilars	23,31	73,77	39,89	81,02	80,65
Ranibizumab	Originator	100,00	100,00	93,90	100,00	100,00
Ranibizumab	Originator (PI)	0,00	0,00	6,10	0,00	0,00
Ranibizumab	Biosimilars	0,00	0,00	0,00	0,00	0,00
Rituximab	Originator	75,67	16,33	15,00	12,10	10,17
Rituximab	Originator (PI)	0,00	0,00	2,21	0,00	0,00
Rituximab	Biosimilars	24,33	83,67	82,79	87,90	89,83
Somatropin	Originator	73,83	83,91	64,17	87,80	84,46
Somatropin	Originator (PI)	0,00	0,00	16,88	0,00	0,00
Somatropin	Biosimilars	26,17	16,09	18,95	12,20	15,54
Teriparatide	Originator	100,00	76,20	47,40	57,05	32,88
Teriparatide	Originator (PI)	0,00	0,00	17,08	0,00	0,00
Teriparatide	Biosimilars	0,00	23,80	35,52	42,95	67,12
Trastuzumab	Originator	87,12	51,92	41,49	14,99	44,50
Trastuzumab	Originator (PI)	0,00	0,00	7,07	0,00	0,00
Trastuzumab	Biosimilars	12,88	48,08	51,44	85,01	55,50

Source: IQVIA MAT Q4 2021

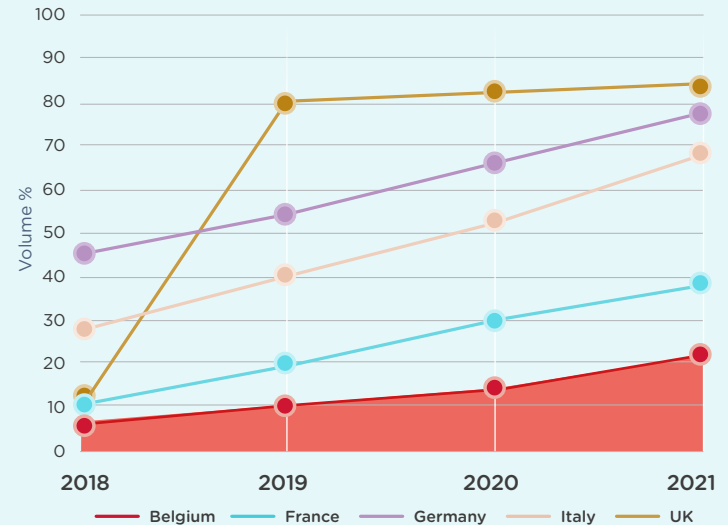
BIOSIMILAR MEDICINES: RECENT LAUNCHES SLOW MARKET PENETRATION

Belgium compared to other countries (1/3)

Biosimilar trastuzumab: market share in volume



Biosimilar etanercept: market share in volume



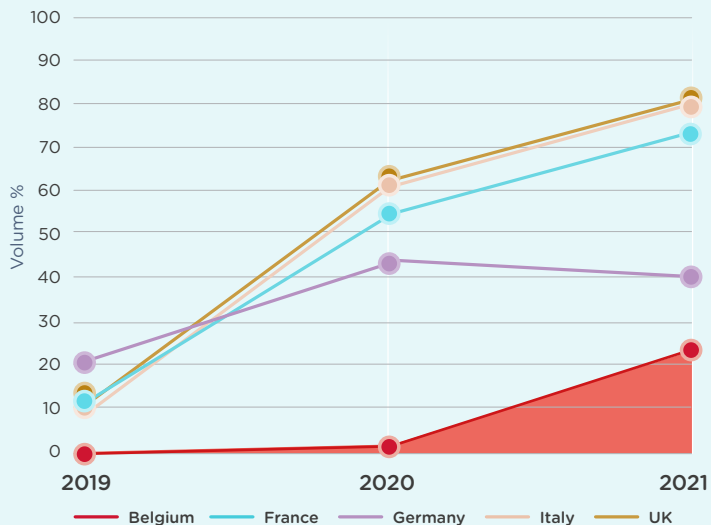
Source: IQVIA MAT Q3 2018-2019-2020 & MAT Q4 2021

BIOSIMILAR MEDICINES: RECENT LAUNCHES

SLOW MARKET PENETRATION

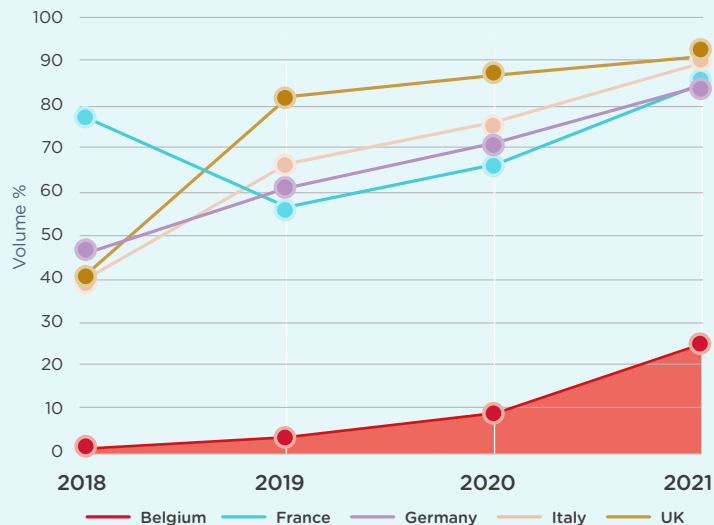
Belgium compared to other countries (2/3)

Biosimilar pegfilgrastim*: market share in volume



*First biosimilar on the Belgian market launched in 2019

Biosimilar rituximab: market share in volume

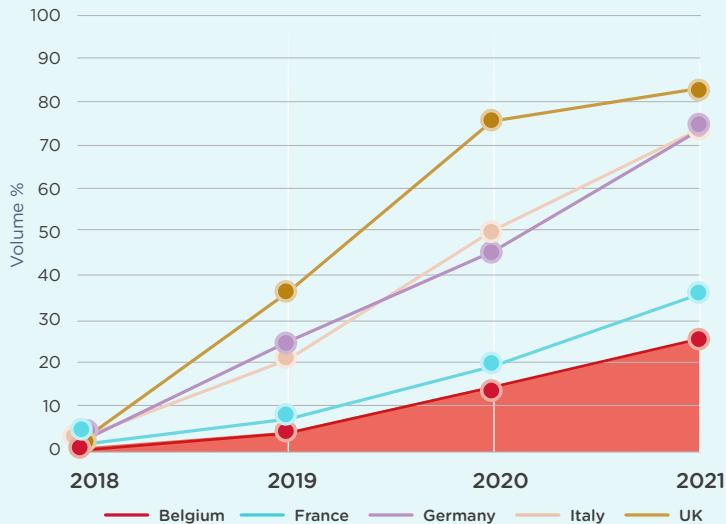


Source: IQVIA MAT Q3 2018-2019-2020 & MAT Q4 2021

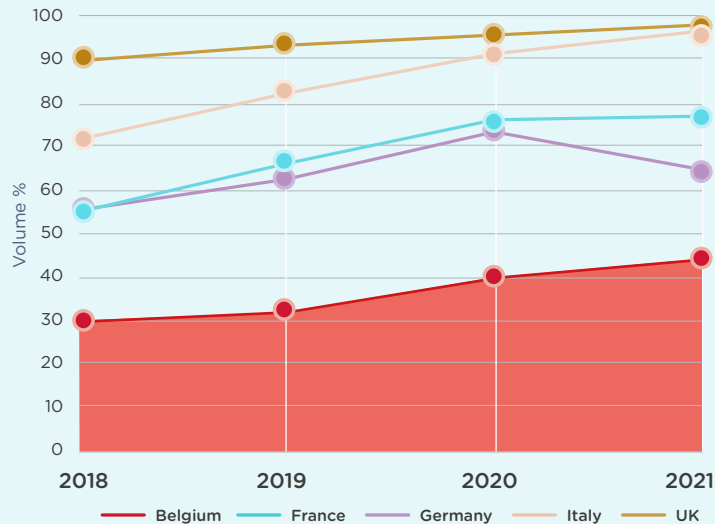
BIOSIMILAR MEDICINES: RECENT LAUNCHES SLOW MARKET PENETRATION

Belgium compared to other countries (3/3)

Biosimilar adalimumab: market share in volume



Biosimilar infliximab: market share in volume



Source: IQVIA MAT Q3 2018-2019-2020 & MAT Q4 2021

BIOSIMILAR MEDICINES: MORE THAN LEGAL PRICE DECREASES

NIHDI



- ▶ Opportunity for additional saving mechanisms, such as invoicing or groupwise revisions
- ▶ Possibility to capitalise on price differentials

€55 million
annual savings for NIHDI
thanks to 85% invoicing mechanism

PATIENTS



- ▶ Improve access

HOSPITALS



- ▶ Benefits from competition between different providers

€343 million
turnover of biological medicines
with biosimilar competition
in hospitals



HEALTHCARE PROFESSIONALS



- ▶ Enlarge therapeutic treatment options
- ▶ Opportunity for 'gain sharing' mechanisms, allowing better patient treatment

Source: Internal calculations based on IQVIA LMPB & BHA 12/2021

BIOSIMILAR MEDICINES: FUTURE OPPORTUNITIES (1/3)

Active substance	Originator(s)	Turnover originator(s) year 2021 (€)
Abatacept	Orencia	15.843.592
Aflibercept 	Eylea	70.367.209
Alglucosidase alfa	Myozyme	12.518.895
Atezolizumab	Tecentriq	50.424.351
Brentuximab vedotin	Adcetris	9.337.779
Certolizumab pegol	Cimzia	20.097.224
Cetuximab	Erbitux	16.180.077
Daratumumab	Darzalex	80.292.136
Darbepoetin alfa	Aranesp	55.063.169
Denosumab	Xgeva, Prolia	36.079.621
Eculizumab 	Soliris	9.947.834
Evolocumab	Repatha	4.456.682
Glucagon	Glucagen hypokit	479.339
Golimumab	Simponi	24.932.276



under evaluation EMA



EMA approval



EMA approval, commercialised in other EU member states but not Belgium

Source: IQVIA year 12/2021

BIOSIMILAR MEDICINES: FUTURE OPPORTUNITIES (2/3)

Active substance	Originator(s)	Turnover originator(s) year 2021 (€)
Insulin aspart ✓	Novorapid, Novomix, Fiasp	3.934.866
Insulin human ✓	Multiple	1.567.352
Insulin lispro ✓	Humalog	780.286
Interferon alfa-2a ✓	Roferon	1.564
Interferon beta-1a	Avonex, Rebif	9.705.754
Interferon beta-1b	Betaferon	1.563.761
Ipilimumab	Yervoy	25.278.108
Liraglutide	Victoza, Saxenda*	5.217.766
Natalizumab	Tysabri	13.927.319
Nivolumab	Opdivo	173.349.350
Obinutuzumab	Gazyvaro	6.505.833
Octocog alpha	Advate	-
Omalizumab	Xolair	32.949.066
OnabotulinumtoxinA	Botox	-
Palivizumab	Synasis	6.388.196



under evaluation EMA



EMA approval



EMA approval, commercialised in other EU member states but not Belgium

Source: IQVIA year 12/2021

* not reimbursed, turnover not taken into account

BIOSIMILAR MEDICINES: FUTURE OPPORTUNITIES (3/3)

Active substance	Originator(s)	Turnover originator(s) year 2021 (€)
Panitumumab	Vectibix	9.784.566
Pegaspargase	Oncaspar	481.985
Pembrolizumab	Keytruda	304.210.408
Pertuzumab	Perjeta	53.552.916
Ramucirumab	Cyramza	4.461.202
Ranibizumab ✓	Lucentis	47.576.079
Recombinant human interferon alfa-2a ✓	Pegasys	-
Secukinumab	Cosentyx	23.927.739
Teriparatide ✓	Forsteo	580.963
Tocilizumab	Actemra	23.245.996
Trastuzumab emtansine	Kadcyla	18.246.271
Ustekinumab	Stelara	57.452.183
Vedolizumab	Entyvio	91.590.475
Total		1.322.300.187



under evaluation EMA



EMA approval



EMA approval, commercialised in other EU member states but not Belgium

Source: IQVIA year 12/2021

Disclaimer: The information provided has been drawn by Medaxes from various sources, both public and non-public. Even though this information was gathered and established with due care, the data provided are for information purposes only and remain indicative.

ABOUT MEDAXES

Our mission

Medaxes is the Belgian association of pharmaceutical companies that want to contribute to making healthcare accessible to all.

Medaxes focuses on generic and biosimilar medicines, as well as on other off-patent medicines and self-care products.

Medaxes aims to provide high quality solutions for efficient and sustainable healthcare in a well-regulated environment.

Medaxes strives to build a dialogue and work in partnership with other healthcare stakeholders. For its members, Medaxes acts as a representative platform, offering a wide range of services in support of their individual activities and common interests.

