1.1. Use of biosimilar treatments (E-4)

1.1.1. Documentation sheet

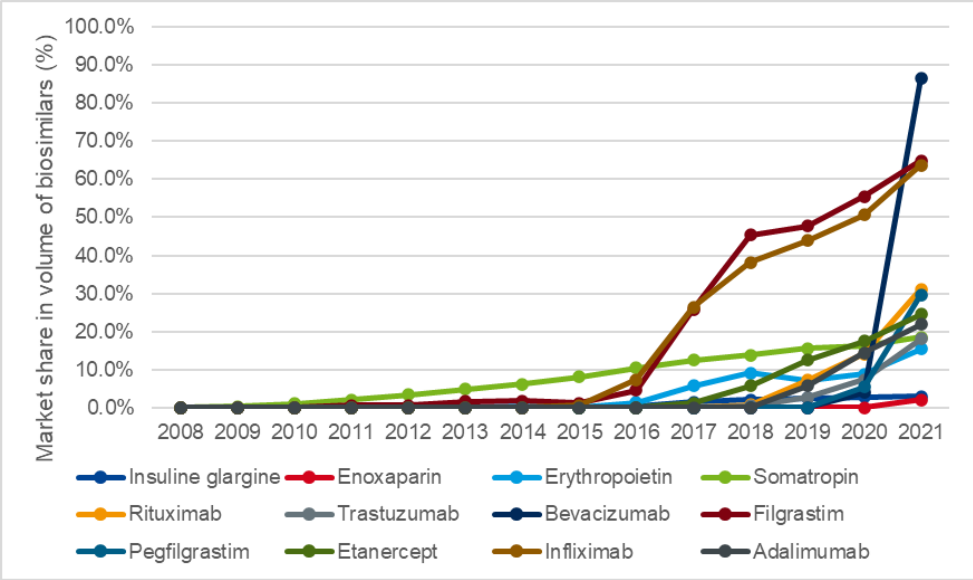
Description	Proportion of biosimilars (DDDs) delivered in biologicals
Calculation	**Numerator**: total DDDs of biosimilar drugs delivered **Denominator**: total DDDs biologicals delivered for the 6 therapeutic classes with reimbursed biosimilars on the Belgian market.[1]
Rationale	A biological medicinal product or biological is a product that contains a biological substance, a substance produced by or derived from a living organism. The expiration of patents of first biologics opened new hopes for affordable copies and increased competition, in the same way that generics are produced from medicines once the patent has expired. Nevertheless, replicate versions of biologicals are not identical, but similar to their original counterparts, hence the name *biosimilars*. Biosimilars have been used in clinical practice in Europe since 2006, some are reimbursed in Belgium since 2008.[2] Promoting the prescription of biosimilars is a way to reduce expenditures, for the patient as well as for the authorities. Currently, biosimilars are not included in the reference price system (cf. E-3 use of low-cost drugs in ambulatory setting).
Data source	Doc PH, Pharmanet (RIZIV – INAMI)
Technical definitions	Reference files from RIZIV – INAMI have a variable for biologicals (unique key = CNK) that defines whether a product is a biosimilar or not
International comparability	Comparison with other countries is possible, but sources are scarce
Limitations	The region of the patient is unknown for the inpatient consumption
Dimension	Efficiency
Related indicators	E-3 prescription of low-cost drugs in ambulatory setting
Reviewer	Joos Tielemans (RIZIV – INAMI)

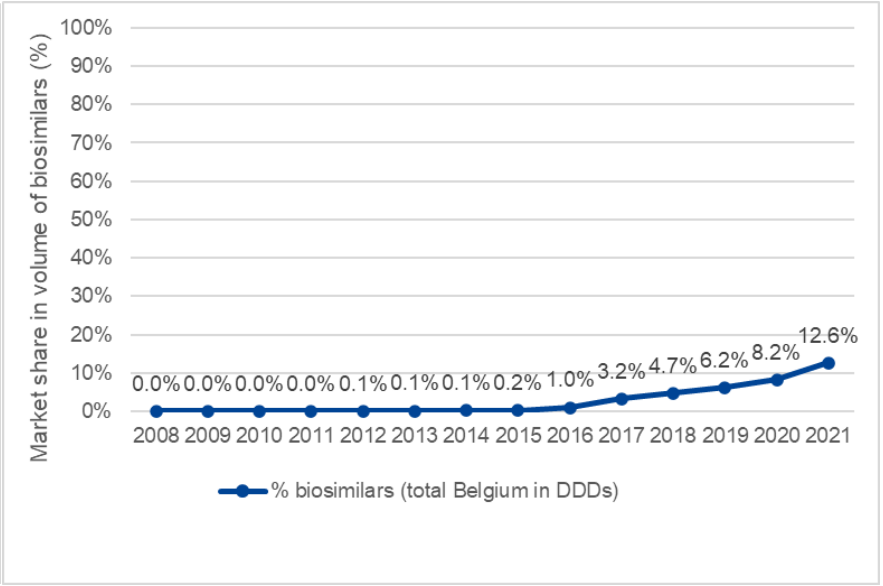
1.1.2. Results

Belgium

Biosimilars are available for 12 molecules in 2021 in Belgium, with the market share in volume growing steadily since 2016 to reach 12.6% in 2021 (Figure 1). This has allowed RIZIV – INAMI to decrease its expenses in biological treatments while the volume has been very slow since 2017 (3.7% between 2017 and 2021) (Figure 2).

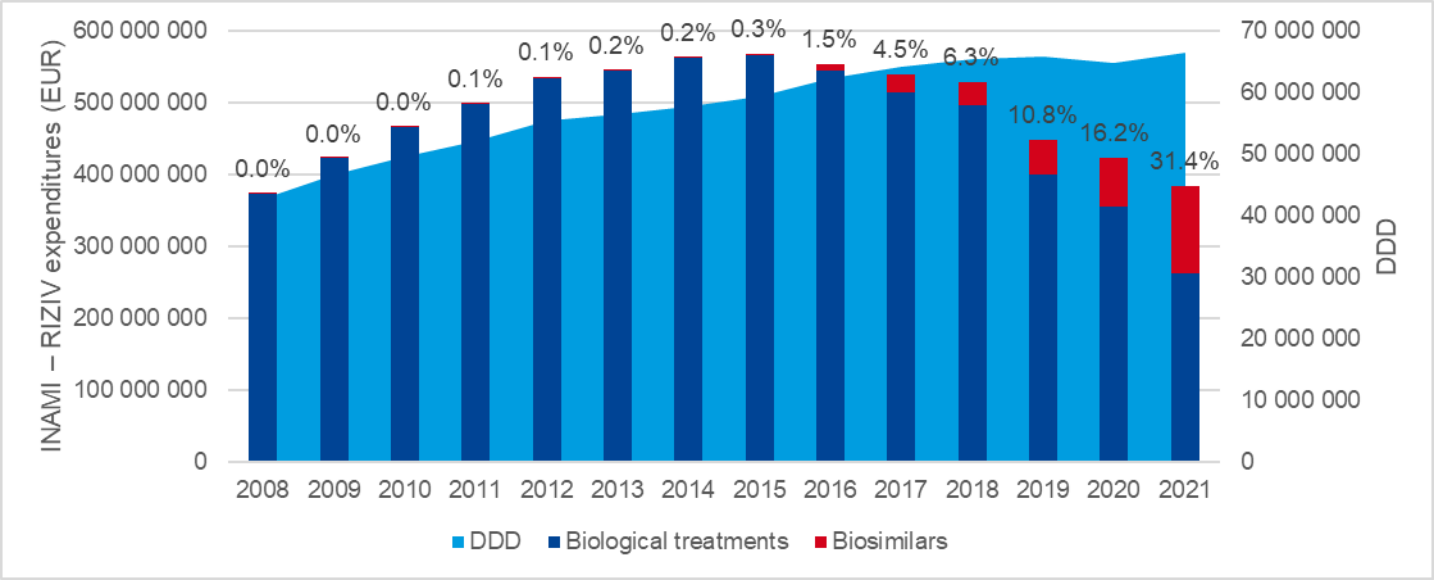
Figure 1 – Shares of biosimilars in volume for available Belgian biological pharmaceuticals





Source: INAMI – RIZIV

Figure 2 – Shares of biosimilars in expenditures for available Belgian biological pharmaceuticals

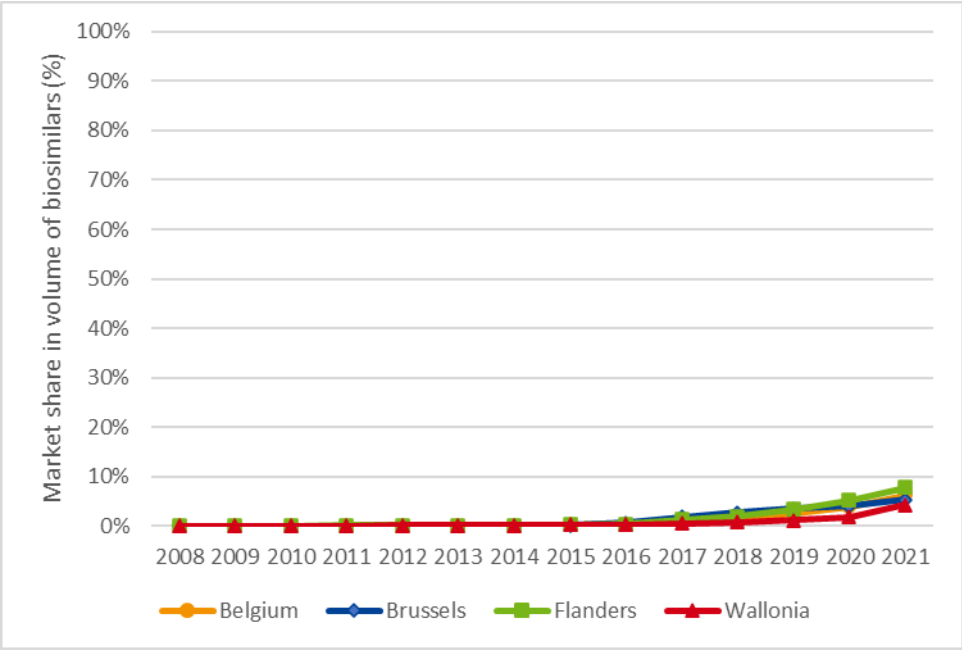


Source: INAMI – RIZIV

Regional comparison

Regional comparison is currently only available for ambulatory prescriptions. Figure 3 shows that while Flanders patients have more biosimilars prescribed in 2021 (7.8%) than Brussels and Wallonia (5.3% and 4.2% respectively), it is well below the 27.6% reached in inpatient setting at the Belgian level the same year.

Figure 3 – Market share in volume of biosimilar in ambulatory setting by region

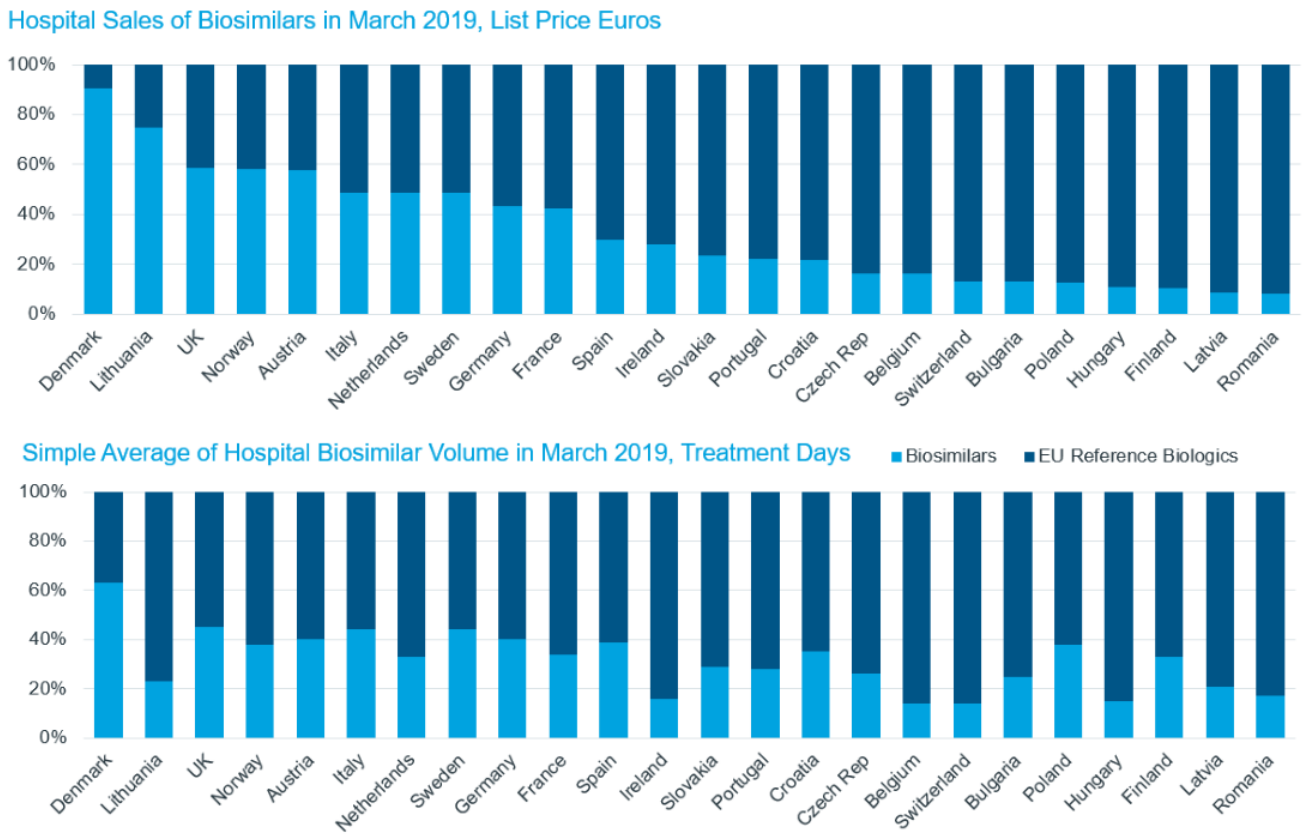


Source: INAMI – RIZIV

International comparison

Based on 2018 figures, Belgium has a low proportion of biosimilars compared to other European countries in hospital setting (Figure 4 and Figure 5):[3] less than 20% in expenses and 14% in volume (compared to >90% and 63% for Denmark, respectively).

Figure 4 – Market shares (value and volume) of biosimilars in the European hospital setting



Hospital sales and volume of biosimilars and biologics in 2018, expressed in Euros (list price) and treatment days, respectively. These analyses are based on list prices and therefore do not take into account the (often confidential) discounts that manufacturers give to hospitals and other buying entities.
Source: IQVIA European Thought Leadership, IQVIA MIDAS MTH March 2019, cited in [3].

Figure 5 – Proportion in volume of biosimilar by molecule in the European hospital setting

	Simple Average*	Adalimumab	Enoxaparin Sodium	Epoetin	Etanercept	Filgrastim	Follitropin Alfa	Infliximab	Insulin Glargine	Insulin Lispro	Pegfilgrastim	Rituximab	Rituximab IV only	Somatropin	Trastuzumab	Trastuzumab IV only
EU Weighting		6%	48%	9%	3%	0.5%	0.3%	12%	12%	2%	0.5%	2%		2%	2%	
Denmark	63%	96%	0%	53%	89%	93%	26%	97%	8%	0%	100%	78%	93%	78%	98%	99%
UK	45%	39%	53%	6%	81%	96%	52%	93%	16%	0%	12%	79%	90%	22%	32%	81%
Italy	44%	25%	35%	84%	48%	97%	26%	84%	16%	21%	1%	70%	88%	25%	42%	66%
Sweden	44%	55%	0%	81%	65%	99%	16%	81%	33%	50%	21%	22%	58%	2%	43%	90%
Germany	40%	81%	3%	80%	96%	94%	0%	24%	23%	0%	3%	71%	77%	2%	47%	58%
Austria	40%	9%	12%	80%	52%	99%	0%	91%	0%	0%	22%	83%	95%	0%	67%	89%
Spain	39%	12%	41%	77%	39%	94%	85%	59%	24%	0%	2%	43%	59%	20%	17%	40%
Poland	38%	1%	0%	100%	40%	86%	0%	97%	21%	35%	8%	0%	0%	100%	11%	50%
Norway	38%	0%	0%	100%	100%	86%	0%	98%	4%	0%	15%	80%	94%	0%	7%	76%
Croatia	35%	8%	0%	100%	24%	100%	64%	67%	10%	0%	28%	30%	62%	25%	5%	12%
France	34%	28%	0%	42%	49%	99%	0%	61%	47%	0%	13%	62%	76%	0%	36%	80%
Netherlands	33%	25%	0%	19%	22%	39%	0%	82%	30%	0%	15%	95%	97%	16%	80%	99%
Finland	33%	10%	0%	100%	14%	91%	0%	11%	29%	10%	0%	43%	54%	100%	19%	88%
Slovakia	29%	0%	0%	100%	0%	100%	0%	33%	25%	0%	67%	29%	40%	0%	26%	80%
Portugal	28%	4%	0%	96%	29%	93%	0%	61%	0%	0%	3%	51%	78%	12%	13%	35%
Czech Rep.	26%	8%	0%	85%	22%	100%	4%	60%	8%	0%	27%	21%	31%	7%	1%	7%
Bulgaria	25%	0%	0%	100%	0%	100%	0%	100%	0%	0%	0%	19%	21%	0%	0%	1%
Lithuania	23%	0%	0%	0%	0%	100%	92%	0%	2%	0%	0%	0%	0%	0%	100%	100%
Latvia	21%	0%	0%	0%	0%	100%	74%	0%	0%	100%	0%	0%	0%	0%	0%	0%
Romania	17%	0%	0%	100%	0%	100%	0%	0%	17%	0%	2%	7%	7%	0%	0%	0%
Ireland	16%	0%	0%	100%	0%	41%	0%	47%	0%	0%	0%	23%	23%	0%	2%	3%
Hungary	15%	0%	0%	0%	0%	100%	0%	0%	0%	0%	0%	73%	87%	0%	27%	78%
Belgium	14%	0%	0%	14%	0%	32%	47%	33%	6%	0%	0%	2%	4%	40%	2%	5%
Switzerland	14%	0%	0%	21%	23%	83%	0%	24%	1%	0%	0%	14%	15%	11%	0%	0%

*Hospital volume of biosimilars and biologics in 2018, expressed in treatment days. * Simple average calculated including subcutaneous formulation for rituximab and trastuzumab.*
Source: IQVIA European Thought Leadership, IQVIA MIDAS MTH March 2019, cited in [3].

Impact of COVID-19 pandemic

Unknown.

Key points

- **Improvements in the share in biosimilars have been sharp in recent years concerning bevacizumab, infliximab and filgrastim**
- **Thanks to the increase in biosimilars market shares, the expenses have been reducd while the volume has been stable**
- **Substitution in biological treatments from orginal drugs to biosimilars in hospital setting has a low uptake in Belgium compared to other European countries; measures have been taken in October 2023 to improve the uptake[a], there will be an assessement every two year**
- **At the regional level, biosimilars market share in ambulatory setting is as follows in 2021 (in volume): Flanders 7.8%, Brussels 5.3% and Wallonia 4.2%**

References

1. INAMI – RIZIV. Analyse de l'utilisation des médicaments biosimilaires dans le cadre de la "convention sur la relance des médicaments biosimilaires en Belgique". RIZIV - INAMI; 2018.
2. Lepage-Nefkens I, Gerkens S, Vinck I, Piérart J, Hulstaert F, Farfan-Portet M-I. Barriers and opportunities for the uptake of biosimilar medicines in Belgium. Health Services Research (HSR). Brussels: Belgian Health Care Knowledge Centre (KCE); 2013. KCE Reports 199 (D/2013/10.273/13)
3. KPMG Advisory N.V. Improving healthcare delivery in hospitals by optimized utilization of medicines; 2019

[a] https://www.ejustice.just.fgov.be/eli/arrete/2023/09/13/2023045282/moniteur