7.3. Biosimilar treatments (E-4)

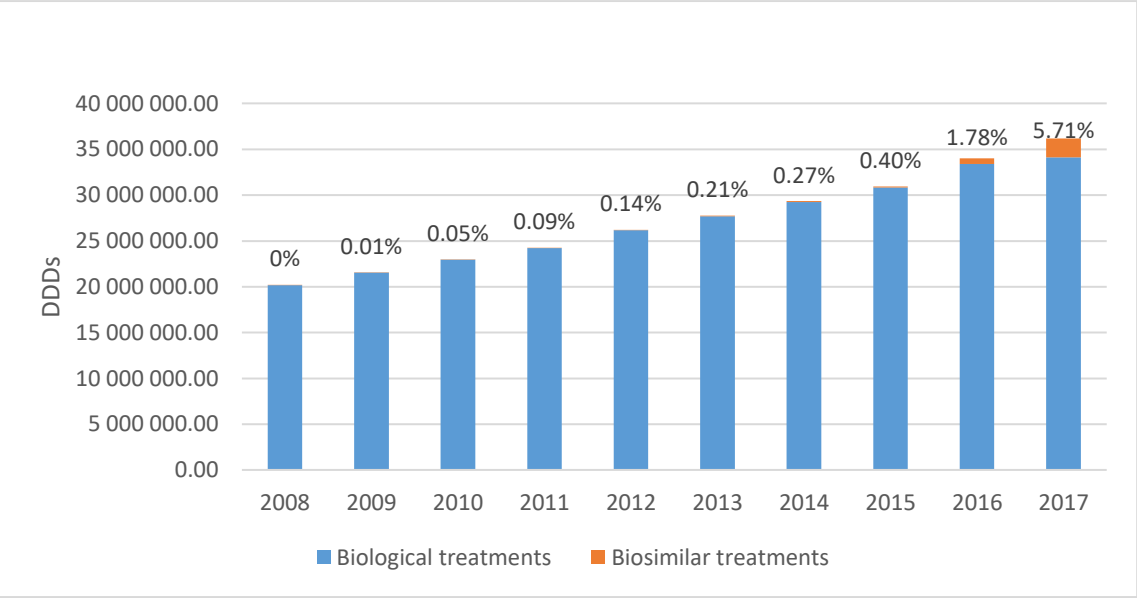
7.3.1. Documentation sheet

Description Proportion of biosimilars (DDD) prescribed in biologicals.
Calculation Numerator: total DDD of biosimilar drugs delivered Denominator: total DDD 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 prescription of low drugs in ambulatory setting).
Primary 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.
Limitation The region of the patient is unknown for the inpatient consumption.
Dimensions Efficiency
Related indicators E-3 prescription of low-cost drugs in ambulatory setting

7.3.2. Results

Between 2008 and 2017, the total of DDDs prescribed biologicals (original drugs and biosimilars) in Belgium rose from 20 to 34 million; in the meantime, the share of biosimilars went from 0 to 5.71 %, with a big increase in 2017.

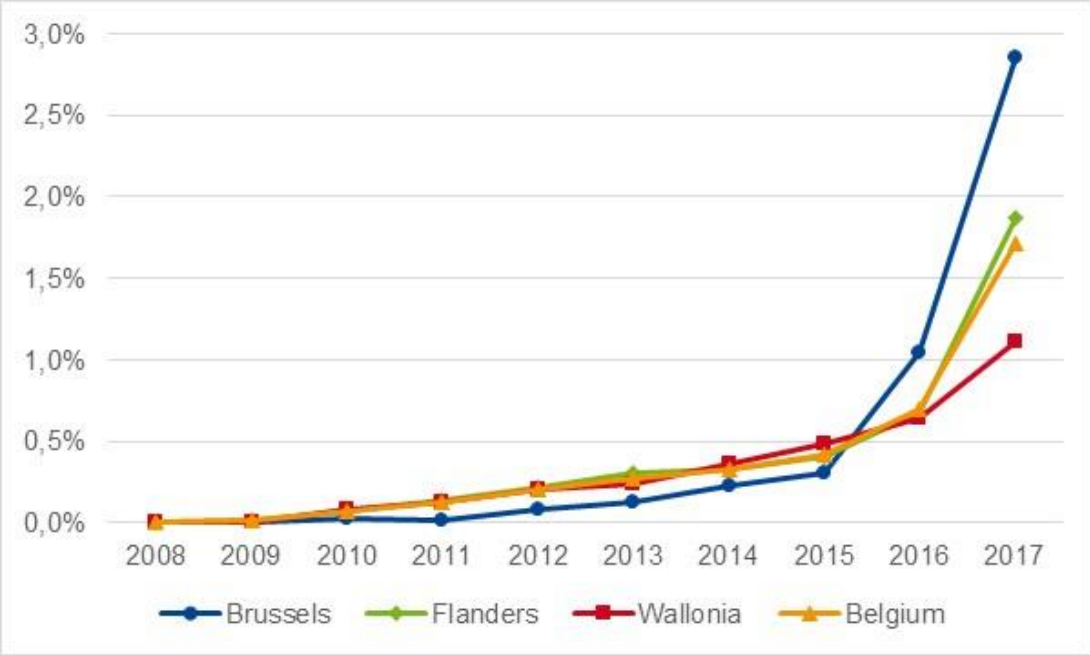
Figure 93 – Biologicals consumption in Belgium (2008-2017) and share of biosimilars



Source: INAMI – RIZIV

Regions have almost the same level of uptake, except for 2017, where Brussels (2.86%) increase is bigger than Flanders (1.87%) and Wallonia (1.11%), cf. Figure 94 (Belgium: 1.71%).

Figure 94 – Proportion of biosimilars share (in DDDs) by region



There are currently 9 biological pharmaceuticals with a biosimilar alternative to the original product. They account in the 2017 INAMI – RIZIV expenditures for an amount of 430 million EUR (Table 61).

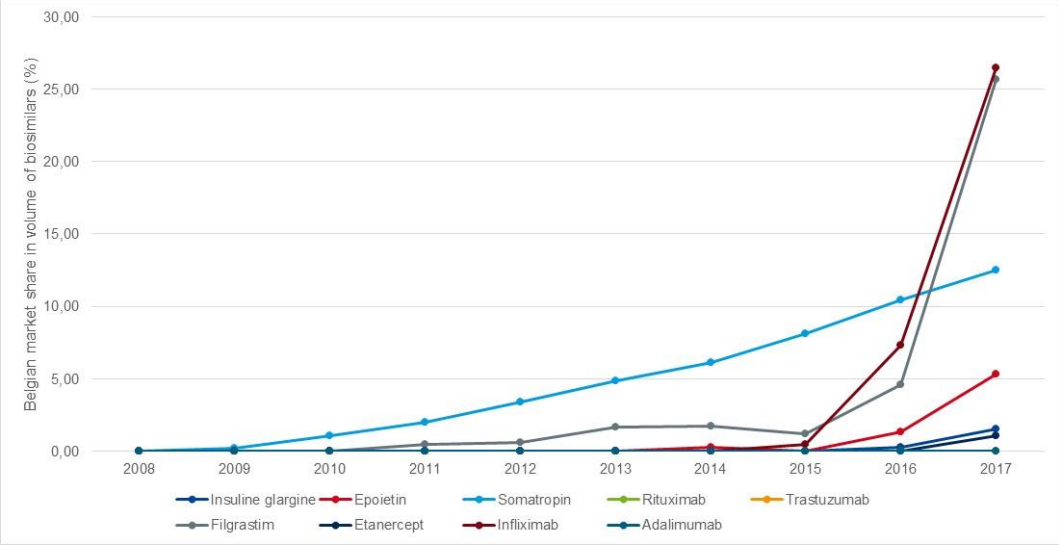
Table 61 – Biologicals with existing biosimilars in Belgium

ATC5	Molecule	INAMI - RIZIV ex-penditures in 2017 (million EUR)	Share of bio-similars in DDDs (2017) (%)
A10AE04	Insuline glargine	28.80	1.52
B03XA01	Erythropoietin	9.64	5.29
H01AC01	Somatropin	20.85	12.48
L01XC02	Rituximab	32.01	0.00
L01XC03	Trastuzumab	62.16	0.00
L03AA02	Filgrastim	3.41	25.69
L04AB01	Etanercept	60.80	1.07
L04AB02	Infliximab	74.65	26.44
L04AB04	Adalimumab	138.38	0.00

Source: INAMI – RIZIV

The biosimilar share is shown for each biological in Figure 95. In 2017, there has been a sharp rise in the proportion of biosimilar for several biologicals exceeding 25% for infliximab and filgrastim.

Figure 95 – Shares of biosimilars for available Belgian biological pharmaceuticals



Source: INAMI – RIZIV

International comparison shows that European countries often have a higher share of biosimilar for anti-TNF's treatments (12/20016 data): Belgium shares (2017 data) are similar to the lowest levels for infliximab (Italy, France) and for etanercept (Spain, Italy, Germany), see Table 62.

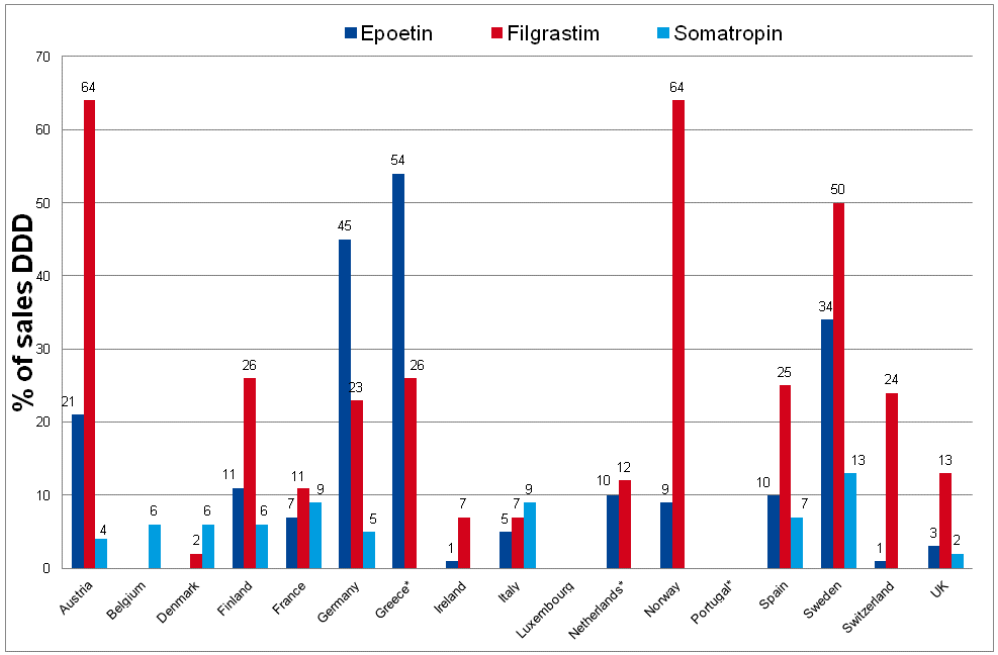
Table 62 – Share of biosimilar for anti-TNF's treatments (in DDD, 12/2016)

Country	infliximab	etanercept
UK	64.1%	31.6%
Italy	24.6%	1.0%
France	27.2%	19.0%
Germany	46.6%	1.0%
Spain	34.8%	0.4%

Source: QuintilesIMS [3]For other biologicals (epoetin, filgrastim and somatropin), Belgium has lower shares of biosimilar than lead European countries (Germany, Sweden, Norway, Austria, Greece), see Figure 96

.

Figure 96 – Percentage of sales in DDD of biosimilars on total market



*Source: IMS data 2nd trimester 2011. *Only retail sector. Second-generation products not included.*

Key points

- **Substitution in biological treatments from orginal drugs to biosimilars has a low uptake in Belgium**
- **Improvements in the share in biosimilars have been sharp the last year (2017), especially concerning infliximab and filgrastim**

References

[1] INAMI R-. 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] QuintilesIMS. The impact of Biosimilar competition in Europe. 2017.