The impact of policy interventions to increase the uptake of biosimilar medicines in Belgium: A nationwide interrupted time series analysis

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Background and objective

- Belgium has experienced a malfunctioning off-patent biologicals market since the entry of the first biosimilar more than a decade ago.
- The Belgian government has implemented a series of measures to increase the uptake of biosimilars in past years.
- No formal evaluation of the impact of these measures has been made yet. This study aimed to investigate the impact of the implemented measures.

Methods

An interrupted time series analysis was performed using an Autoregressive Integrated Moving Average (ARIMA) model. A significance level of 5% was used for all analyses.

Data source:
Volumes were expressed as Defined Daily Doses (DDD) per month/quarter and obtained from the Belgian National Institute for Health and Disability Insurance (NIHDI).

Included molecules:
Etanercept (ambulatory care), filgrastim (hospital), epoetin (hospital)

Results

January 2016

Biosimilar prescribing target, monitoring of hospitals, circular letter to hospitals on tendering

A small **decrease** in quarterly **epoetin** biosimilar uptake of 449,820 DDD (95% CI: -880,113 to -19,527; p=0,05) was observed. For **filgrastim**, 1809,833 DDD (95% CI: 1354,797 to 2264,869; p<0,001) **more** biosimilars were dispensed immediately after the intervention and 151,639 DDD (95% CI: -203,128 to -100,150; p<0,001) **fewer** biosimilars each quarter after the intervention.

December 2018

Information campaign on biosimilars + circular letter to hospitals on correct tendering

The intervention resulted in a larger **increase** in quarterly **epoetin** biosimilar uptake of 2733,692 DDD (95% CI: 1648,648 to 3818,736; p<0,001). An immediate and sustained **increase** of 700,932 DDD (95% CI: 180,536 to 1221,328; p=0,016) in quarterly **filgrastim** biosimilar volume was also observed.

January-June 2019

Pilot financial incentive for biosimilar TNF-alpha inhibitors

After the intervention, 44,504 (95% CI: -61,61 to -14,812; p<0,001) **fewer etanercept** biosimilar DDDs were dispensed monthly than expected in the absence of the intervention.

Figure 1. Monthly etanercept biosimilar volume over time.*

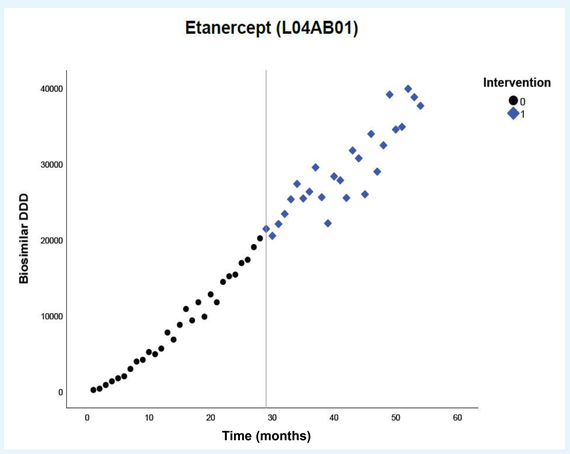


Figure 2. Quarterly filgrastim biosimilar volume over time.*

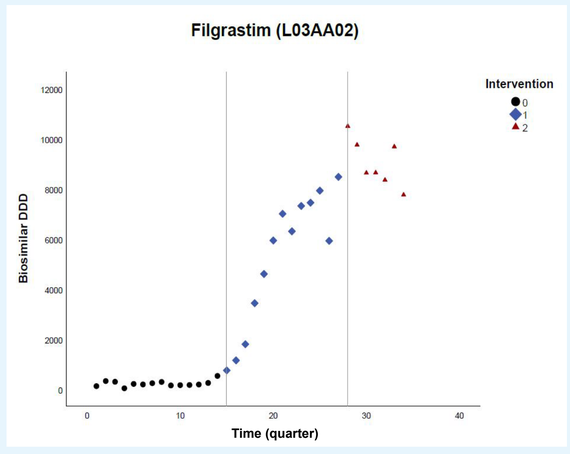
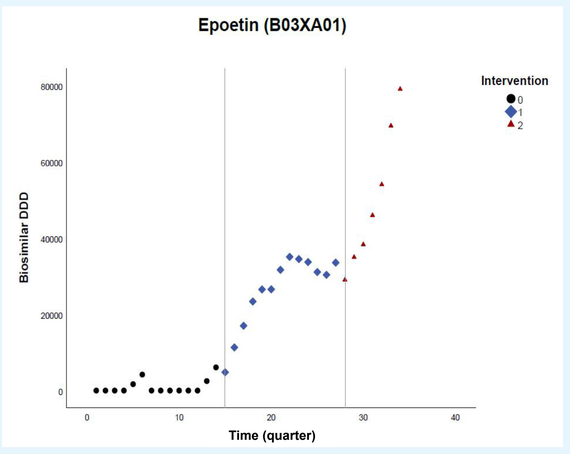


Figure 3. Quarterly epoetin biosimilar volume over time.*



*Vertical lines represent the timing of the implementation of the investigated intervention

Context and interpretation

- All other parameter estimates for the different investigated molecules were not statistically significant at the 5% level of significance.
- Confounding events such as prescribing shifts to other molecules, new biosimilars entering the market, or COVID-19 should be considered when interpreting the results.
- Notwithstanding possible confounders, this analysis illustrates that the measures taken have been insufficient to increase the uptake of biosimilars to date. More is needed to make the Belgian market more competitive and sustainable.

Conclusion

The results of this study suggest that the impact of past policy interventions to increase the uptake of biosimilars has been varied and limited. A holistic policy framework is required to develop a competitive and sustainable off-patent biologicals market in Belgium.

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