# Assessing Sustainable Biosimilar Competition: Current Trends and Impacts of Anti-TNF Biosimilar Competition in Europe

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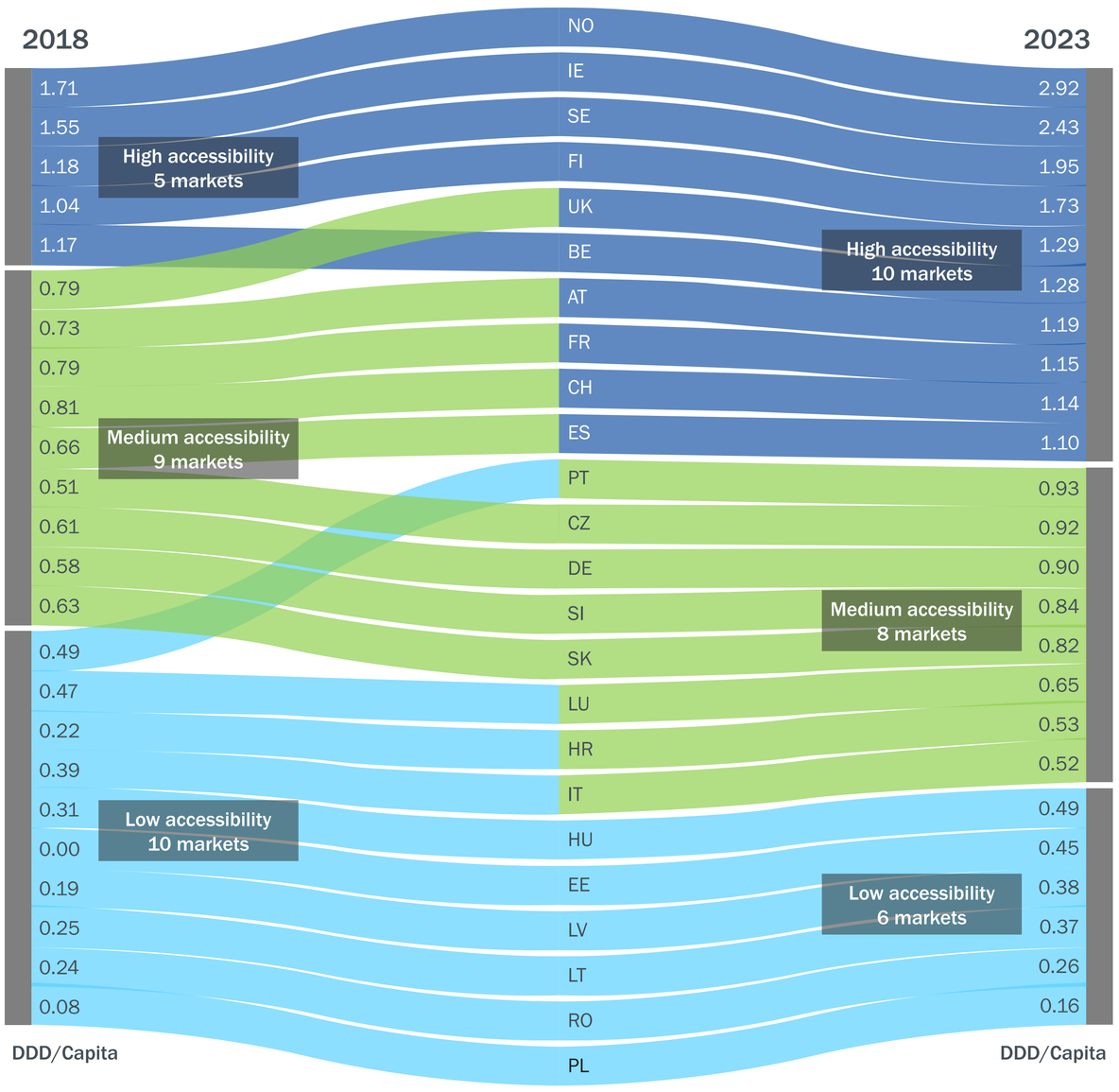
## Objectives

- This study aims to analyze the evolving landscape of anti-TNF biosimilars in Europe from 2018 to 2023 and examine its implications for market competition and sustainability.

## Methods

- A comparative analysis across 24 European countries was conducted based on IQVIA MIDAS® sales data (licensed from IQVIA. Copyright IQVIA. All Rights Reserved).[1]
- Three anti-TNFs: adalimumab, etanercept, and infliximab, were included. Market sustainability was assessed in three dimensions: accessibility, affordability, and availability, using defined daily dose/capita (DDD/capita), biosimilar penetration and number of biosimilar competitors with market share above 3% as a proxy, respectively.

### Figure 1. Accessibility Evaluation By Country 2018 vs. 2023[1,2]




Biogen analysis based on IQVIA MIDAS® Monthly sales (DDD [defined daily dose]) data for the period of January 2018 to December 2023, reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved.

High accessibility: DDD/capita ≥1; Medium accessibility: DDD/capita ≥0.5–<1; Low accessibility: DDD/capita <0.5

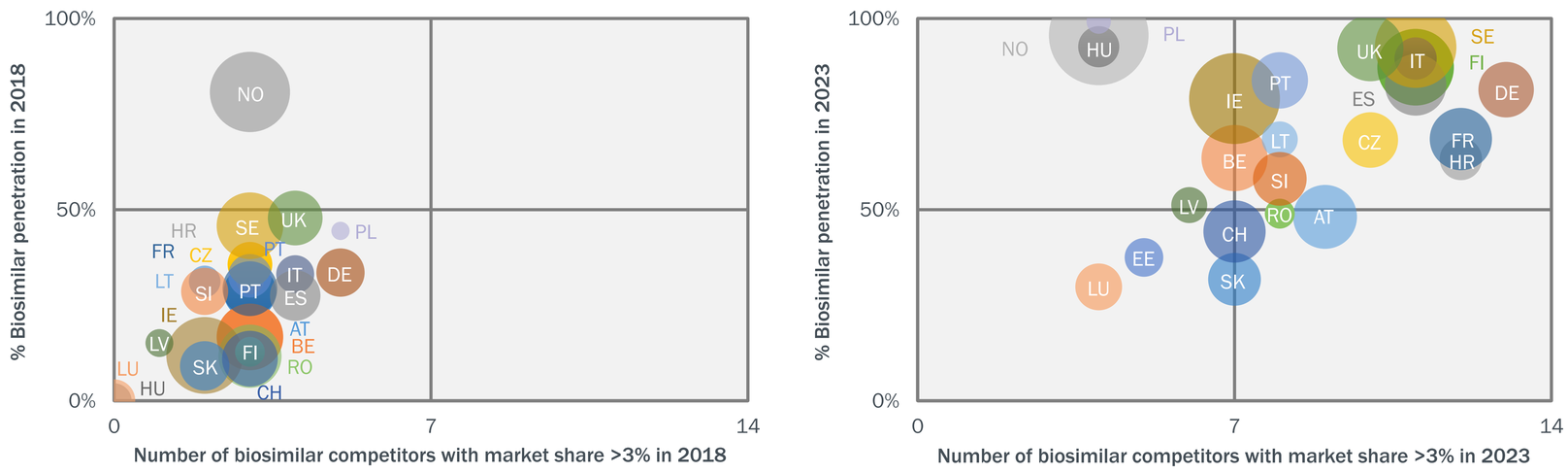
*AT, Austria; BE, Belgium; CH, Switzerland; CZ, Czech Republic; DDD, defined daily dose; DE, Germany; ES, Spain; IE, Ireland; FI, Finland; FR, France; HR, Croatia; EE, Estonia; HU, Hungary; IT, Italy; LT, Lithuania; LU, Luxembourg; LV, Latvia; NO, Norway; PL, Poland; PT, Portugal; RO, Romania; SE, Sweden; SI, Slovenia; SK, Slovakia; UK, United Kingdom*

### Table 1. Summary Accessibility Evaluation 2018 vs. 2023[1,2]

| | Population weighted avg. DDD/capita 2018 | Population weighted avg. DDD/capita 2023 | Absolute change of DDD/capita from 2018 to 2023 | % change from 2018 to 2023 |
|---|---|---|---|---|
| 5 HA that have not changed status | 1.28 | 1.92 | 0.64 | 50% |
| 6 LA that have not changed status | 0.16 | 0.25 | 0.09 | 56% |
| 5 MA that have moved to HA | 0.76 | 1.19 | 0.43 | 57% |
| 4 LA that have moved to MA | 0.40 | 0.58 | 0.18 | 45% |

High accessibility: DDD/capita ≥1; Medium accessibility: DDD/capita ≥0.5–<1; Low accessibility: DDD/capita <0.5 *DDD, defined daily dose; HA, high accessibility; LA, low accessibility; MA, medium accessibility*

### Figure 2. Accessibility, Affordability and Availability by Country 2018 vs. 2023[1,2]




Biogen analysis based on IQVIA MIDAS® Monthly sales (DDD [defined daily dose]) for the period of January 2018 to December 2023, reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved.

When evaluating availability of biosimilar competitors, only brands with market share >3% is considered to eliminate products that are not actively competing in the market. Bubble size represents the absolute value of DDD/capita.

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## Results

- From 2018 to 2023, the number of countries with high accessibility (DDD/capita≥1) has doubled. Five countries moved from medium (0.5≤DDD/capita<1) to high accessibility with an average absolute increase of 0.43 DDD/capita (**Figure 1, Table 1**). Among these 5 countries, Austria shows high accessibility, despite the low biosimilar penetration with an absolute increase of only 20% (**Table 2**).
- In 2018, there were 10 markets with low accessibility (DDD/capita<0.5). By 2023, six of them, all located in Eastern Europe, remained in the same status, experiencing an average absolute increase of only 0.09 DDD/capita (**Figure 1, Table 1**), despite significant increase in biosimilar penetration in some markets, (**Table 2**).
- Between 2018 and 2023, availability of anti-TNF biosimilars increased in most markets, indicating that healthy levels of competition were sustained (**Figure 2, Table 2**). Norway and Poland exhibited the smallest increase or even decrease in availability across all markets, with +1 and -1 biosimilar respectively. By contrast, in Romania, although the number of biosimilar competitors doubled, marginal increase was noted in accessibility and biosimilar penetration (**Figure 1, Table 2**).

### Table 2. Affordability and Availability By Country Evaluation 2018 vs. 2023[1]

| | 2018 | | 2023 | | CHANGE IN NUMBER OF BIOSIMILAR BRANDS WITH MS >3% 2018 VS 2023 |
|---|---|---|---|---|---|
| | MS% of Biosimilars | Number of Biosimilars With MS>3% | MS% of Biosimilars | Number of Biosimilars With MS>3% | |
| NORWAY | 81% | 3 | 96% | 4 | 1 |
| IRELAND | 12% | 2 | 79% | 7 | 5 |
| SWEDEN | 46% | 3 | 93% | 11 | 8 |
| FINLAND | 12% | 3 | 87% | 11 | 8 |
| UK | 48% | 4 | 92% | 10 | 6 |
| BELGIUM | 17% | 3 | 63% | 7 | 4 |
| AUSTRIA | 28% | 3 | 48% | 9 | 6 |
| FRANCE | 29% | 3 | 68% | 12 | 9 |
| SWITZERLAND | 11% | 3 | 44% | 7 | 4 |
| SPAIN | 28% | 4 | 83% | 11 | 7 |
| PORTUGAL | 33% | 3 | 84% | 8 | 5 |
| CZECH REP. | 36% | 3 | 68% | 10 | 7 |
| GERMANY | 34% | 5 | 81% | 13 | 8 |
| SLOVENIA | 29% | 2 | 58% | 8 | 6 |
| SLOVAKIA | 9% | 2 | 32% | 7 | 5 |
| LUXEMBOURG | 0% | 0 | 30% | 4 | 4 |
| CROATIA | 31% | 3 | 63% | 12 | 9 |
| ITALY | 33% | 4 | 90% | 11 | 7 |
| HUNGARY | 0% | 0 | 93% | 4 | 4 |
| ESTONIA | 17% | 1 | 37% | 5 | 4 |
| LATVIA | 15% | 1 | 51% | 6 | 5 |
| LITHUANIA | 31% | 2 | 68% | 8 | 6 |
| ROMANIA | 13% | 3 | 49% | 8 | 5 |
| POLAND | 44% | 5 | 99% | 4 | -1 |

Biogen analysis based on IQVIA MIDAS® Monthly sales (DDD [daily defined dose]) market share data for the period of January 2018 to December 2023, reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved.

*MS, market share*

## Conclusions

- Notwithstanding the increasing biosimilar penetration in Europe, access to anti-TNF treatment grows at a different pace, likely due to country-specific barriers to access, different healthcare settings, and ineffective biosimilar policies. In those European countries that have resource constraints – such as some of the Central Eastern European countries – improving population's health gain by lifting existing barriers to patient access thanks to the availability of more affordable biologic medicines should be reflected in the local biosimilar policies.
- To guarantee a healthy level of competition and maximize the economic and patient benefits of having multiple affordable alternatives, it is crucial that payors, policy makers and procurement authorities work together to drive positive policy change and implement procurement and market policies balancing accessibility, affordability, and availability to ensure long-term sustainability.

Data sources: 1. Based on internal analysis by Biogen using data from the following source: IQVIA MIDAS® Monthly sales (DDD [daily defined dose]) data for the countries listed below*; Data period: January 2018 to December 2023; Market definition: « *Etanercept, Adalimumab and Infliximab* » Metrics: number of products/brands per molecule and country, biosimilars market share in total molecule by country based on the total number of DDD; in each case reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved.

**Countries include Austria, Belgium, Switzerland, Czech Republic, Germany, Spain, Ireland, Finland, France, Croatia, Estonia, Hungary, Italy, Lithuania, Luxembourg, Latvia, Norway, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia, United Kingdom;* 2. World population. The World Bank. Retrieved May 14, 2024, from https://data.worldbank.org/indicator/SP.POP.TOTL

Disclosures of interest: Grieco S and Bodin M are employees of Biogen and may hold stock in Biogen. Xin Q is a former employee of Biogen.