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A review of biosimilar utilization across EU4 and UK since the introduction of the first biosimilar

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Background

- The first biosimilar was approved in the European Union (EU) in 2006.
- Since then, many European countries have introduced regulations to incentivize biosimilar uptake to lower spending and facilitate access, but the degree of implementation varies.

Objective(s)

- The aim of this research was to analyze the availability and uptake of biosimilars in the 5 largest European markets (France, Germany, Italy, Spain [EU4] and the United Kingdom [UK]).

Methods

- The availability of biosimilars approved by the European Medicines Agency (EMA) between 2006 and April 2023 was determined by each country individually using national drug databases.
- Biosimilar uptake was assessed via a targeted literature review on PubMed, along with a grey literature search conducted in April 2023.
- Publications were excluded if no uptake numbers or no data from countries of interest were mentioned, or if the publication was a case study or letter.

Results

- The targeted literature search resulted in 241 hits. Of these, 23 hits were included for full-text assessment. Due to the differences in methodology, data collection, timeframe, and molecule in focus, results cannot be uniformly reported.
- Per the EMA database, 18 biosimilar molecules and 75 brands have been approved by the EMA since 2006.[1]
- Availability in the EU4 and UK ranges from 15 biosimilar molecules in Spain to 18 in Germany.[2-7] Most biosimilar brands are available in Germany and least in the UK (**Figure 1**, **Table 1**).
- Uptake rates of biosimilars vs. originators vary between countries, regions, and molecules.
- Germany had the lowest biosimilar uptake in 2021 at around 15%, whereas Italy had an uptake of 43%[8-11] (**Figure 2**).
- Data in the UK is only available for certain molecules, not for the total biosimilar market.
  - In August 2019, biosimilar uptake of adalimumab, etanercept, infliximab, rituximab, and trastuzumab ranged from 74% for adalimumab to 95% for infliximab in England.[12]
  - There is a high degree of variability in biosimilar uptake between National Health Service Trusts, ranging from 0% to 100% uptake for some molecules.[12]

Results (cont.)

Figure 1. No. of available biosimilar brands and molecules per country

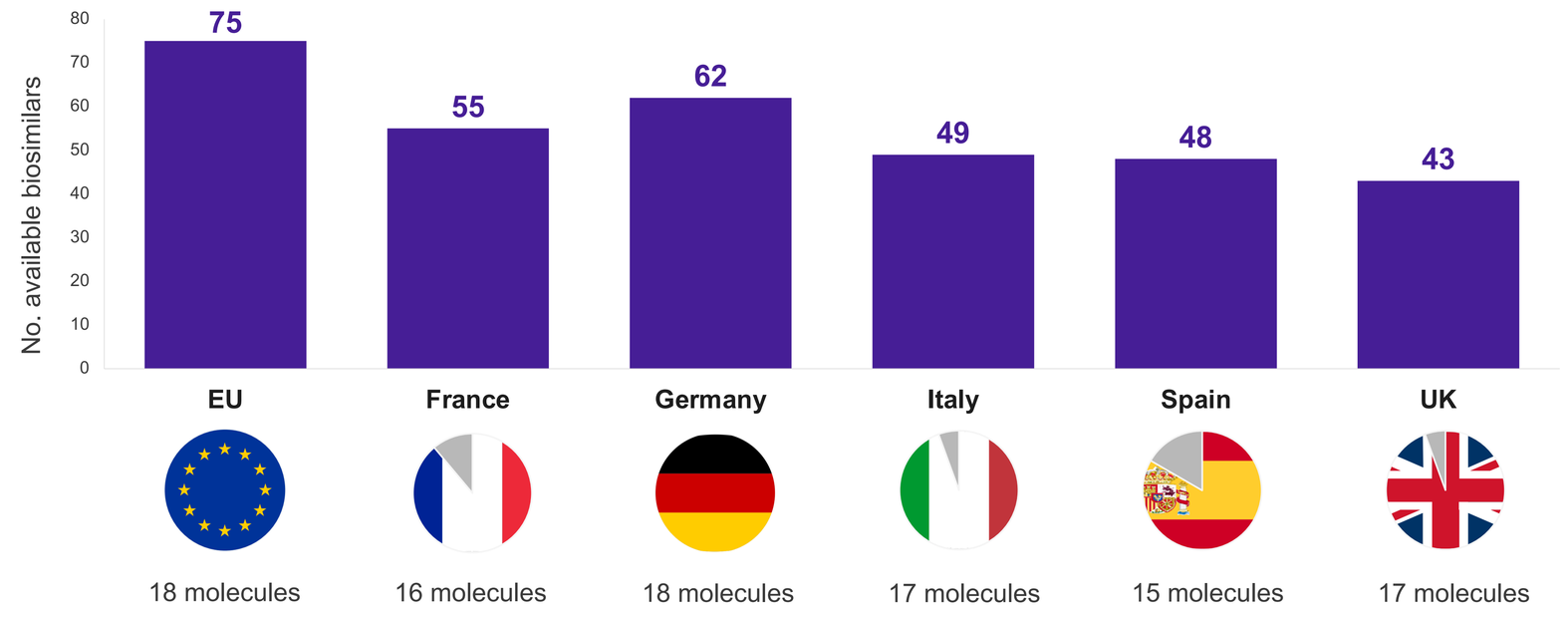

Figure 2. Biosimilar uptake in EU4 in 2021/2022 (share of biosimilar prescribing in biologics prescribing)

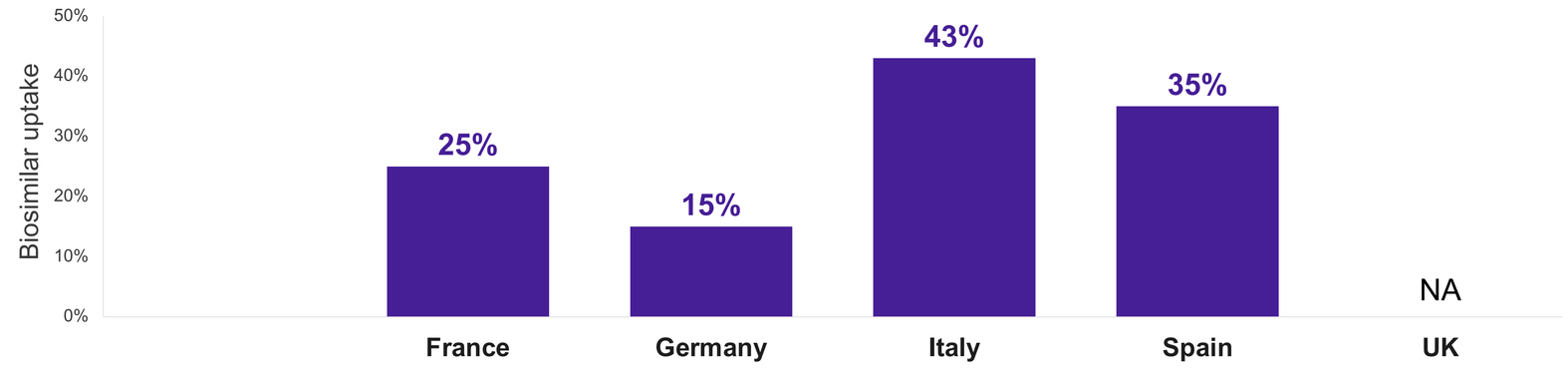

Table 1. Biosimilar molecules and no. of brands per molecule authorized by EMA and available by country

Biosimilar molecule	EU	France	Germany	Italy	Spain	UK
adalimumab	10	8	7	5	6	5
bevacizumab	8	6	7	7	6	5
enoxaparin sodium	1	1	1	1	1	1
epoetin alfa + zeta	5	2	5	2	2	1
etanercept	3	3	3	2	2	2
filgrastim	7	4	4	4	3	3
follitropin alfa	2	2	2	2	2	2
infliximab	4	4	4	4	4	4
insulin aspart	3	1	1	1	0	1
insulin glargine	2	1	2	1	2	2
Insulin human (rDNA)	1	0	1	1	0	1
insulin lispro	1	0	1	1	0	1
pegfilgrastim	8	8	7	4	4	3
ranibizumab	3	1	3	0	2	0
rituximab	5	3	3	3	3	3
somatropin	1	1	1	1	1	1
teriparatide	5	4	4	4	4	3
trastuzumab	6	6	6	6	6	5

Key: EMA – European Medicines Agency; EU – European Union; EU4 – France, Germany, Italy, Spain; NA – not available; No. – number; UK – United Kingdom.

Conclusions

- The EU is a pioneer in biosimilar authorization; however, the degree of uptake at a national and regional level varies significantly in individual European markets, meaning that the full benefits of biosimilars are yet to be realized. To better understand differences in uptake, cross-national studies following the same methodological approach to assess biosimilar uptake are needed.
- Low penetration may be explained by a lack of confidence in biosimilars among physicians and patients and pricing mechanisms that are unfavorable for biosimilar use.
- Biosimilar manufacturers need to thoroughly assess measures in place that may facilitate or impede a successful market entry to maximize the potential for biosimilars in individual European markets.

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