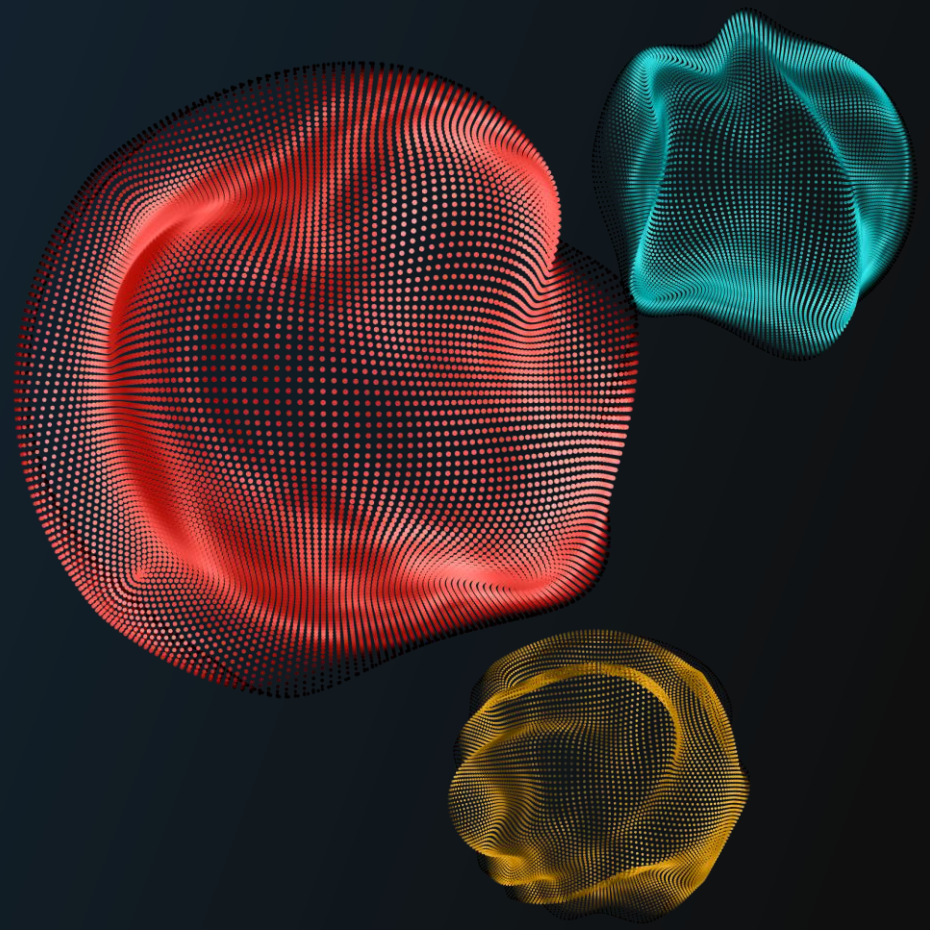

# Assessing the Impact of Access Policies on Biosimilar Pricing: A Comparative Study of Five Major European Markets

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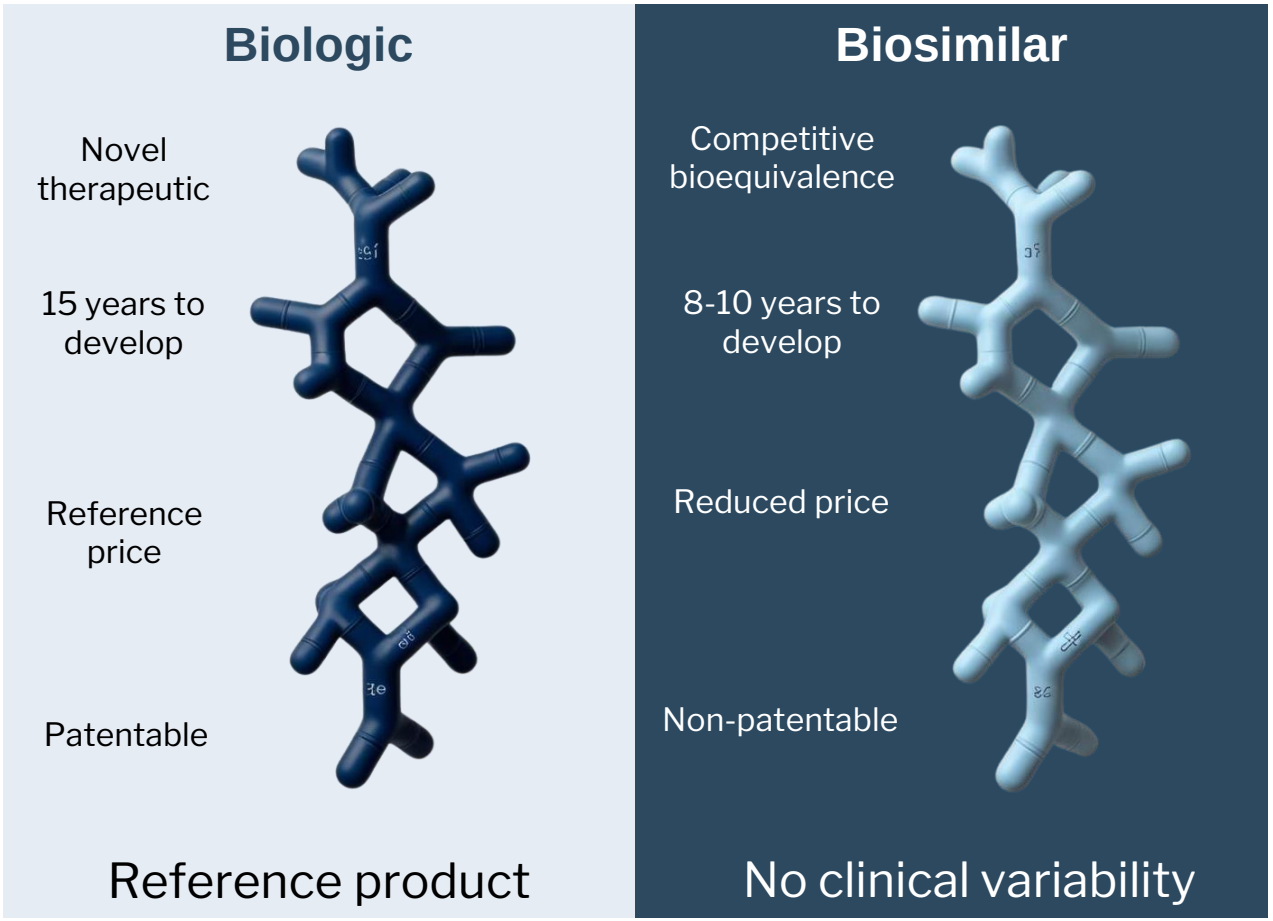
# Biosimilars offer a similar, lower-cost alternative to biologics, increasing patient accessibility

A biosimilar is a **legally approved biological product** that is highly **similar to an already approved biologic**, known as the "reference product," with no clinically meaningful differences in safety, purity, or potency. Biosimilars are subsequent versions of innovator biologic products, **introduced following the expiration of the reference product's patent and exclusivity periods**.[1,2]




**Sources:** 1. García et al. (2020); 2. Ratih et al. (2021)

# European countries introduced frameworks and policies to encourage biosimilar's adoption

**2006 – 1st biosimilar approved in the EU**

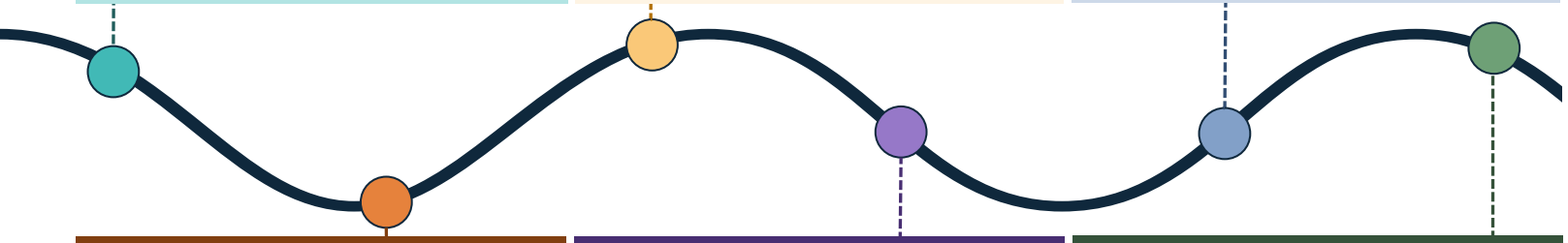
The EMA approved the first biosimilar, somatropin, for growth hormone deficiency and gonadal dysgenesis.[1,2]

**2012 – Spain advocates biosimilars**

The government issued a decree mandating price cuts for biological reference products upon biosimilars entry.[5]

**2014 – France adopts biosimilars**

France introduced biosimilar substitution to reduce costs and diversify supply.[7]



**2008 – Germany introduces biosimilars**

The Drug Commission of the German Medical Association introduced framework for biosimilars.[3,4]

**2013 – Italy implements biosimilar policies**

AIFA's 2013 position paper introduced Italy's biosimilar framework.[6]

**2017 – The UK introduces biosimilars**

NHS England and Wales introduced framework for biosimilar in 2017 followed by NHS Scotland and Northern Ireland in 2018[8]

- **Variability in biosimilar policies** across European markets **has created uncertainty around their impact on pricing dynamics**
- **Current pricing outcomes are influenced by** multiple factors, including **country-specific prescribing** and **switching guidelines**, as well as **dissimilar pricing regulations**

**Abbreviations:** AIFA: Italian Medicines Agency; EMA: European Medicines Agency; BPCI: Biologics Price Competition and Innovation Act; EU: European Union; FDA: Food and Drug Administration; NHS: National Health System; UK: United Kingdom

**Sources:** 1. Gherghescu and Begoña Delgado-Charro (2020); 2. Olry de Labry (2013); 3. Dieter Ludwig and Dicheva (2017); 4. Arzneimittelkommission der deutschen Ärzteschaft (2008); 5. González et al. (2017); 6. AIFA (2013); 7. Lantrès et al. (2022); 8. Moorkens et al. (2021)

# The objective of the research was to evaluate the biosimilar access policies and their pricing dynamics in five major European markets

Secondary research was conducted to explore the impact of biosimilar policies on the pricing dynamics in EU4 & UK (France, Germany, Italy, Spain, and the United Kingdom)

## 01 | RESEARCH

- **A TLR was conducted, focusing on country-specific policy requirements** (e.g. HTA mandates, tendering procedures), **financial models and switching guidelines.**

## 02 | EXTRACT

- **Launch timelines and pricing data for biosimilars approved between January 2019 and May 2024** across five markets were sourced from NAVLIN, while **biosimilar uptake data** was obtained from the IQVIA report.[1,2]

## 03 | ANALYSE

- **The analysis focused on identifying the impact of national biosimilar policy frameworks on biosimilar pricing dynamics and correlating this with biosimilar uptake.**

**Abbreviations:** EU: European Union; HTA: Health Technology Assessment; TLR: Targeted Literature Review; UK: United Kingdom
**Sources:** 1. NAVLIN Pricing Database (2024); 2. IQVIA, The Impact of Biosimilar Competition in Europe (December 2023)

# All major European markets, except for the UK, implement regulated pricing for biosimilars

## Biosimilar pricing policies across EU4 & UK

| |  |  |  |  |  |
|---|---|---|---|---|---|
| **Regulated Pricing Policies** | | | | | Free Pricing |
| **Criteria to set the prices** | Negotiation | Set % below originator price (40%) | Set % below originator price (20%) and Negotiation | Not beyond a set maximum price | NA |

| | | | | | |
|---|---|---|---|---|---|
| **Tendering system at hospital level** | Retail-level tenders only | National, Regional and Hospital level | Regional and Hospital level | National, Regional and Hospital level | National and Regional level |
| **Agency in charge of tendering system** | NA | Group of hospitals or individual hospitals | National government, Regional government or Group of hospitals | National government, Regional government, Health insurance funds or Group of hospitals | National government |

Yes, policy available  No, policy not available

**Abbreviations:** HTA: Health Technology Assessment; IRP: Internal Reference Pricing; MA: Marketing Authorisation; NA: Not Applicable; NHS: National Healthcare System; UK: United Kingdom

**Source:** 1. Market review- European Biosimilar Medicine Markets 2023; 2. Craddy (2022)

# Germany and the UK offer higher financial incentives to encourage the adoption of biosimilars

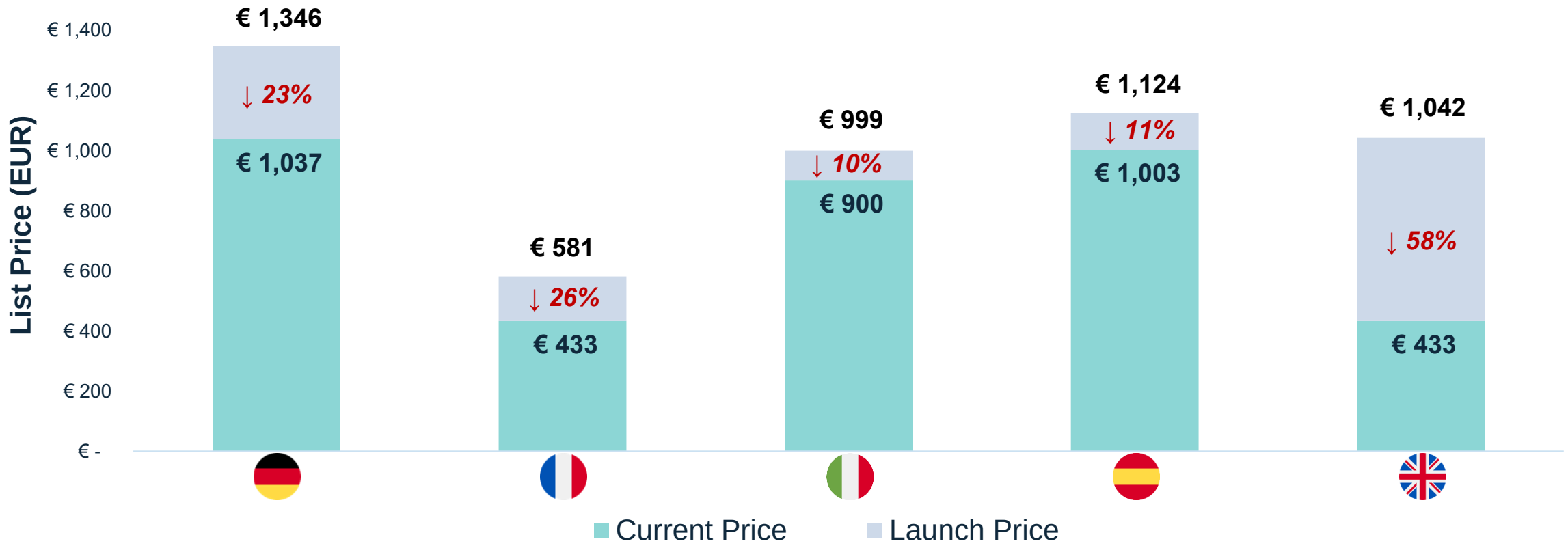
## Adoption of financial incentives for biosimilar uptake across EU4 & UK

| |  |  |  |  |  |
|---|---|---|---|---|---|
| **Financial incentives (inc. gain-share agreements)** | ✓ | ✓ | | | ✓ |
| **Financial penalties** | ✓ | | | | |
| **Prescription target or quotas** | ✓ | | ✓ (Regional level) | ✓ (Regional level) | ✓ |

**Note:** Physician incentives, prescribing guidelines and recommendations and INN prescription are provided by all scope markets
**Abbreviations:** EU: European Union; UK: United Kingdom
**Sources:** 1. Machado et al. (2024); 2. Schmidt et al. (2023); 3. Simoens et al. (2024)

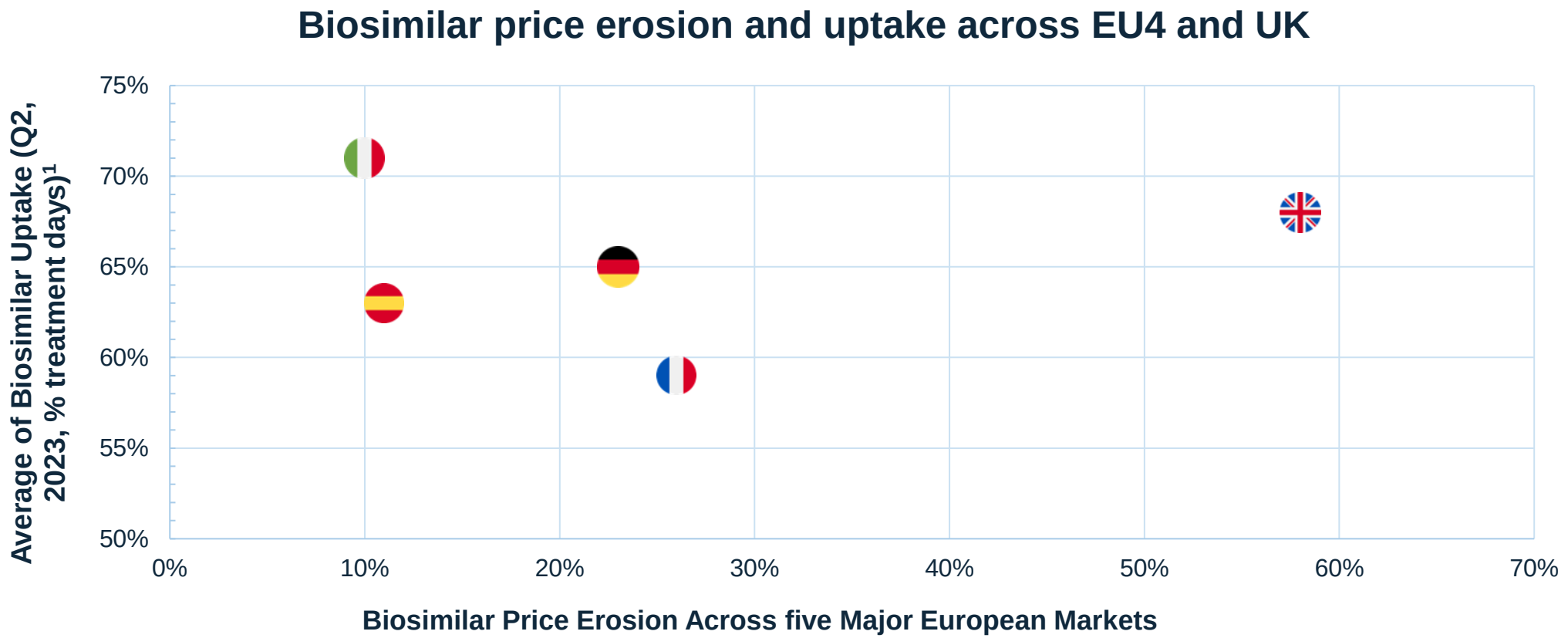
# Biosimilars had the highest price erosion from the list price in the UK (~60%), followed by reductions in France and Germany (~25%)

## Biosimilar Price Erosion Across five Major European Markets[1]




**Note:** The analysis excludes net price calculations (due to confidential discounts), which are more relevant in Italy and Spain; therefore, the results should be interpreted with caution.
**Abbreviations:** NHS: National Healthcare System; UK: United Kingdom
**Sources:** 1. NAVLIN Pricing Database (2024)

# When correlating biosimilar uptake with price erosion, the UK strikes an ideal balance - high price reductions yet high uptake




**Note:** We took the percentage of uptake for each biosimilar and took the average for each market
**Abbreviations:** NHS: National Healthcare System; UK: United Kingdom
**Sources:** 1. IQVIA, The Impact of Biosimilar Competition in Europe (December 2023)

# Striking a balance between regulated pricing policies and biosimilar uptake is the key for health biosimilar market

- Lower cost of biosimilars does not automatically increase the uptake. France, with its stringent price-setting criteria, has the lowest biosimilar uptake among the five markets analysed

- In contrast, the UK achieves similar pricing to France, while maintaining higher uptake. This is driven by centralised tenders at national level and NHS switching policies

- As biosimilar markets mature, pricing policies should be periodically reviewed to avoid mechanisms that cause excessive price erosion or decrease the adoption

**Abbreviations:** NHS: National Healthcare System; UK: United Kingdom

# Thank you

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