The Impact of Biosimilar Competition in Europe 2022

Prepared for European Commission (DG SANTE)

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Disclaimer:

This report has been prepared by IQVIA at the request of the European Commission services with initial contributions on defining the KPIs from EFPIA, Medicines for Europe, and EuropaBio.

The observations have been developed solely by IQVIA based on the data and analyses performed. The information and views set out in this report are those of its authors and are not to be attributed to, nor necessarily reflect the views of the European Commission or any of its services.

The European Medicines Agency (EMA) has a central role in setting the rules for biosimilar submissions, approving applications, establishing approved indications and monitoring adverse events, and if necessary, issuing safety warnings. We have, when appropriate, quoted their information and statements.
Agenda

+ Introduction

+ Methodology and the Country & Therapy Area KPIs

+ IQVIA’s 5 Observations in 2022

+ 10.10am – 10.20am: Q&A session
Key observations on price, volume and market share since the arrival of biosimilars in Europe

Sources: IQVIA/IMS Health, The Impact of Biosimilar competition in Europe (2015-2021)
The Impact of Biosimilar Competition in Europe 2022; Prepared for European Commission (DG SANTE) December 2022
Agenda

+ Introduction
+ Methodology and the Country & Therapy Area KPIs
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+ Q&A
9 therapy classes with biosimilar competition are shown

The products are split into 4 categories based on regulatory and protection status

<table>
<thead>
<tr>
<th>Therapy classes</th>
<th>Product categorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Human Growth Hormone (HGH)</td>
<td>• <strong>Biosimilar Medicinal Product</strong>: Product, granted regulatory approval, demonstrating similarity to the Reference Medicinal Product in terms of quality characteristics, biological activity, safety and efficacy.</td>
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<tr>
<td>2. Granulocyte-colony Stimulating Factor (GCSFs)</td>
<td>• <strong>Referenced Medicinal Product</strong>: Original product, granted market exclusivity at the start of its life, exclusivity has now expired, and the product has been categorised as referenced by having a biosimilar with an EMA-approved marketing authorisation available on a European market.</td>
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<tr>
<td>3. Epoetin (EPO)</td>
<td>• <strong>Non-Referenced Medicinal Product</strong>: Original product, granted market exclusivity at the start of its life, exclusivity has now expired*, and the product has never been categorised as a Referenced Medicinal product by receiving EMA-approved marketing authorisation.</td>
</tr>
<tr>
<td>4. Anti-Tumour Necrosis Factor (Anti-TNFs)</td>
<td>• <strong>Non-accessible category</strong>: products within the same ATC4 code as the accessible category products. These are typically second-generation products; this category may include products with different dosing schedules and / or route of administration to those in the accessible category, and have valid protection status</td>
</tr>
<tr>
<td>5. Fertility (Follitropin Alfa)</td>
<td></td>
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<td>6. Insulins</td>
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<tr>
<td>7. Oncology</td>
<td></td>
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<tr>
<td>8. Low-Molecular-Weight Heparin (LMWHs)</td>
<td></td>
</tr>
<tr>
<td>9. Ophthalmology</td>
<td></td>
</tr>
</tbody>
</table>

*The Intellectual Property for biologicals can involve multiple patents and patent timelines for each individual product and therefore it is difficult to give an exact date for patent expiry for biologicals. It should be noted that these results are estimates as determined from IQVIA MIDAS and ARK Patent Intelligence where available. ** ATC definitions: EPO = B3C0 (ERYTHROPOIETIN PRODUCTS); GCSFs = L3A1 (COLONY-STIMULATING FACT); HGH = H4C0 (GROWTH HORMONES); ANTI-TNF = L4B0 (ANTI-TNF PRODUCTS); INSULIN = A10C 1,2,4,5,9; Oncology = L1G0 1,2,3,5,9 (RESTRICTED TO 3 major products with biosimilar competition); LMWHs = B1B2 (FRACTIONATED HEPARINS), Ophthalmology: S1PO (OCULAR ANTINEOVAS)
The report is continually adjusted to reflect new situations

Information for biosimilar stakeholders

Expanded data period
- In 2022, full-year 2022 data plus June MAT 2022 data to remain up to date

Stricter definitions
- Restricting the definition of ‘referenced’ to reflect biosimilar EMA-MA prior to LOE
- Protection status was not explicitly highlighted
- Historic recategorization

Granularity
- View historical status of products
- Delay to biosimilar entry
- Visibility to 2nd, 3rd, 4th...
- 12-year history of the market

Larger scope
- Ophthalmology included in full for the first time
- Oncology has been expanded further from rituximab, bevacizumab, and trastuzumab to include (currently) non-accessible biologics pertuzumab and combinations
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The biologic market is increasingly important

Biologics represent a large portion of current expenditure, making competition critical

*H2 MAT 2022

Notes: Biologic market includes originator biologics and biosimilars; and EU country scope (excludes UK, Switzerland)
Source: IQVIA MIDAS (Q2 2022), Rx only; Biologic molecules exclude ATC-V (vaccines, and various)
The direct impact of COVID-19 has largely passed

*Indirect impact on access to healthcare, diagnosis, and treatments are being minimised*

Notes: Ophthalmology therapy area excluded due to the impact of new product entries within the class skewing the index
EU savings from the impact of competition have reached >€30Bn

Cost has fallen for multiple years in a row while total volume has increased

Observation 1: COVID-19
Observation 2: Savings
Observation 3: Access
Observation 4: Competition
Observation 5: Future LOE

Savings from the impact of biosimilar competition at list prices

Caveats: This figure is not equivalent to all savings. And is therefore an under-estimate. The data does not include the impact of rebates or discounts, which may have been present prior to the introduction of biosimilars in small quantities, and are highly significant post-biosimilar entry as it is based on publicly available list prices. Source: IQVIA MIDAS™ data from 2006 – 2022, using Euros at constant exchange rates; value includes all originator products with approved biosimilars from 2006 – 2022, covering the full European Economic Area (33 CTYs), calculated volume is in treatment days determined by WHO-DDD, and where values are unavailable via Oncology Dynamics Physician Survey (2017) DDD estimates. Volume is solely biosimilar treatment days.
Access to biologics is increasing in all country, but not evenly

*Countries which high growth start from a low base and are not catching up*

Notes: Calculation is based on the normalized year before biosimilar entry for each molecule in the anti-TNF class, and the treatment days before and since the LOE date in Europe.
Increasing the uptake of biosimilars is not enough to reduce the gap without considering the system

The disparity between countries is increasing

*Normalised to the year of first recorded biosimilar sales in each country, to account for markets that are delayed in using biosimilars after loss of patent protection.

Chart notes: Includes TD for all market segments (Non-accessible, Non-referenced, Referenced, Biosimilars); All countries are ranked based on TD/Capita at +6 years and the top-5 and bottom-5 countries includes in this analysis.

Observation 1: COVID-19
Observation 2: Savings
Observation 3: Access
Observation 4: Competition
Observation 5: Future LOE

Anti-TNFs

114% Increase in access disparity

- High-access countries (NO, IE, SE, BE, DK)
- Low-access countries (IT, BU, HU, RO, PO)

Oncology

50% Increase in access disparity

- High-access countries (BE, FR, AT, CH, FI)
- Low-access countries (SK, CZ, DE, PO, RO)

Insulins

20% Increase in access disparity

- High-access countries (FI, DE, CZ, HU, SE)
- Low-access countries (BU, PO, IT, IE, CH)
High proportions of EU spending expect competitors

Competition within the major molecules is increasingly fierce

Source: IQVIA Institute, The Global Use of Medicines 2022, Outlook to 2026 (January 2022). Notes: * Molecules for which no biosimilar development has been reported in last 3 years; **Withdrawals = pipeline withdrawals or discontinuations

Observation 1: COVID-19
Observation 2: Savings
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Observation 4: Competition
Observation 5: Future LOE
Not all molecules are attractive for competitors to enter

Biologic molecules do not necessarily support a biosimilar in the current system

Biologic LOEs are increasing, and research has already started

The number of molecules is higher, while average value is lower

- 2/3 of historic LOEs received biosimilar competition, due to molecule size and type
- More biologics will be losing protection that historically (+30)
- More biologics molecules have a competitor in development than before (+14)
- Not all future biologics will have competition, historically this has been ~1/3 of all molecules
- Multiple high value biologics losing exclusivity which explains the uptick in 2025
- Biologics with competitors development are already for products losing exclusivity in 2027

Source: IQVIA Patent Intelligence, Pipeline Intelligence, and IQVIA Forecast Link analysis (November 2022); Historic analysis sourced from IQVIA Institute report, Protection expiry and Journey into the Market (2022) Note: The intellectual property for biologicals can involve multiple patents, patent timelines, data exclusivity, and litigation for each individual product and therefore it is difficult to give an exact date for protection expiry for biologicals. It should be noted that these results are estimates as determined from IQVIA MIDAS® and ARK Patent Intelligence where available, and historical products are cross-referenced to public sources.
Availability of recently launched biologics is low

*Biosimilar entry is complex without originator access, and offers payers limited savings if unused*

Source: Based on IQVIA W.A.I.T dataset and IQVIA HTA-Accelerator datasets covering novel active substances (NAS) molecules launched within 2014 – 2020 (November 2022 analysis), including all current EU members, EEA members, and countries considering ascension. Reimbursement defined by availability on a public reimbursement list in a country.
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Thank you!

Contact us for further questions

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