White Paper

The Impact of Biosimilar Competition in Europe

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Introduction

To mark the 10th edition of the 'Impact of Biosimilar Competition in Europe' publication by IQVIA, this report will take a more forward-looking view on the upcoming opportunities and challenges for biosimilar competition in Europe.

Biosimilars remain a critical part of the European healthcare system and are able to balance pharmaceutical spending by generating savings for payers, creating headroom for innovation, and expanding access to biologic therapy for patients. Since the first biosimilar was launched in 2006, biosimilar medicines have become a core component of an effective healthcare system, but latest information on the biosimilar pipeline signals future headwinds that were highlighted in previous reports and remain steadfast.

The report consists of novel observations on market conditions for 2024, and a set of Key Performance Indicators (KPIs) to monitor the impact of biosimilars in 23 European markets. Previous observations remain relevant and have been refined or referenced to align with the report's approach of sharing novel observations on the value of biosimilars, and the impact of competition that biosimilars provide in the European healthcare system.

The KPIs describe the effects on price, volume, and market share following the arrival of biosimilar competition in Europe. The report has been a long-standing source of information on the status of the biosimilars market. The report continues to add and track new therapy areas in order to maintain its relevance. This means that previous definitions are refined to make them representative of the current environment, building on the 2020 (6th) report which permitted the classification of historic dynamics in the market, and allows policymakers, national competent authorities, patient groups, and industry to view the market with greater granularity.

This report has been prepared by IQVIA 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.

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.

IQVIA gratefully acknowledges the contributions of those who have supported the development of this series over the years, notably: Vibhu Tewary, Michael Kleinrock, Urvashi Porwal, Kirstie Scott, Mohit Agarwal, Siobhan Palmer, Mariusz Jedrzejewski and many others.

IQVIA observations

Background

Biologics represent a large share of total EU expenditure

Biologic medicines play a crucial role in modern healthcare, with their ability to target complex and previously untreatable conditions. In 2024 (Q2 MAT), the European Union spent €228 Bn on medicines at list prices, including €95 Bn on biologics, which now comprise 41% of total pharmaceutical spending (Exhibit 1). Even with the effect of biosimilar competition, biologics spending has increased significantly over the past decade at a compound annual growth rate (CAGR) of 10% (2014–2024), outpacing the 4% CAGR for non-biologics.

This growing share of biologic spending is driven by factors such as the launch of new therapies, significant growth in established brands, and the recognition of biologics as advanced treatment options. At the same time, spending faces downward pressures from biosimilar competition, as well as from rebates, discounts, and clawback mechanisms.

Within this landscape, biosimilars currently represent approximately 4% of pharmaceutical spending in the EU (~€10 Bn in 2023). Although this is a relatively small share, their impact is substantial, offering far-reaching benefits for patients, payers, and healthcare systems.

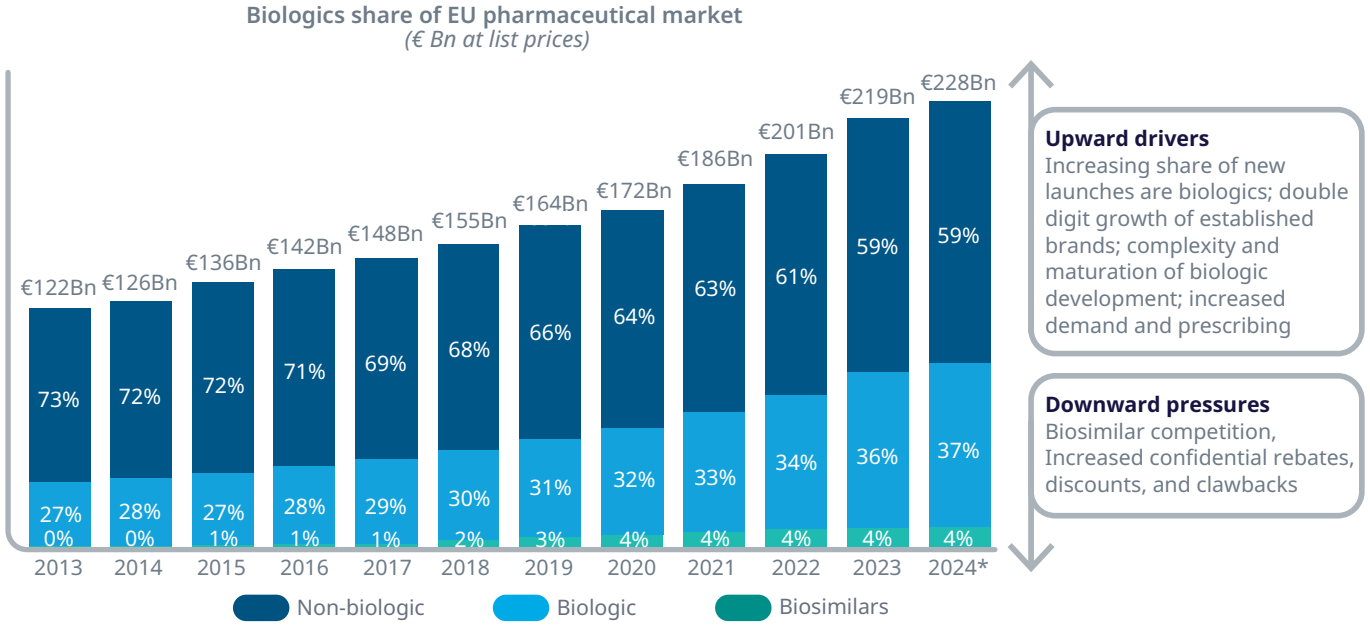
Biologics continue to grow faster than non-biologic medicines

Biologic medicines are an increasingly important therapeutic option in European health systems, due to their efficacy as treatments for complex conditions. Biologic spend continues to outpace small molecules by 3x and the total prescription market, at a rate of 14.7% in the most recent period (Exhibit 2).

Conversely, biosimilar spending has declined over the past few years as the market matures, falling to the same level as the total pharmaceutical market growth rate (8.7%). However, this is to be expected following significant anti-TNF loss of exclusivity opportunities in 2018/2019, causing considerable biosimilar growth during the following years.

Biosimilar molecules are now available in 6 of the top-10 major therapy classes by total EU spending. However, there are two classes that remain entirely

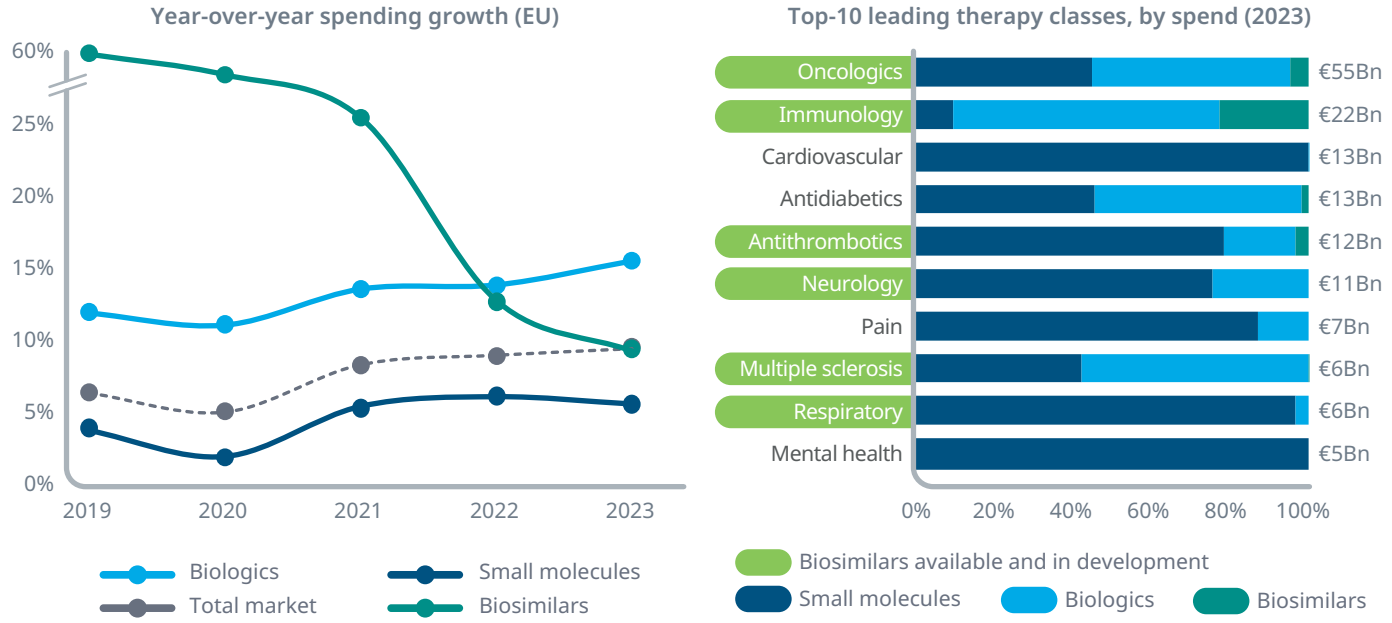
Exhibit 1: The importance of biologics within the EU pharmaceutical market



Source: IQVIA MIDAS, Rx only; Biologic molecules exclude ATC-V (various) and vaccines, LC€ (inflation adjusted). The Impact of Biosimilar Competition in Europe 2023. *Q2 MAT 2024 data.

Notes: Biologic market includes all biologic molecules (excluding biosimilars); and EU country scope (excludes Norway, UK, and Switzerland); Percentages may not total 100% due to rounding.

Exhibit 2: EU spending growth at list price levels by segment and leading therapy areas (2023)



Source: IQVIA MIDAS data (FY 2023), Rx only; Biologic molecules exclude ATC-V (various) and vaccines, LC€ (inflation adjusted); Total biologic growth includes biosimilars.
Notes: EU country scope (excludes Norway, UK, and Switzerland) and differs from country scope in 2023 report (EEA+UK); Therapy areas segmentation follows IQVIA Institute top 20 categorization.

small molecule dominated (cardiovascular, mental health), and availability remains limited to one biosimilar only in multiple sclerosis and respiratory.

Biosimilars represent a small share of spend, but have wider importance

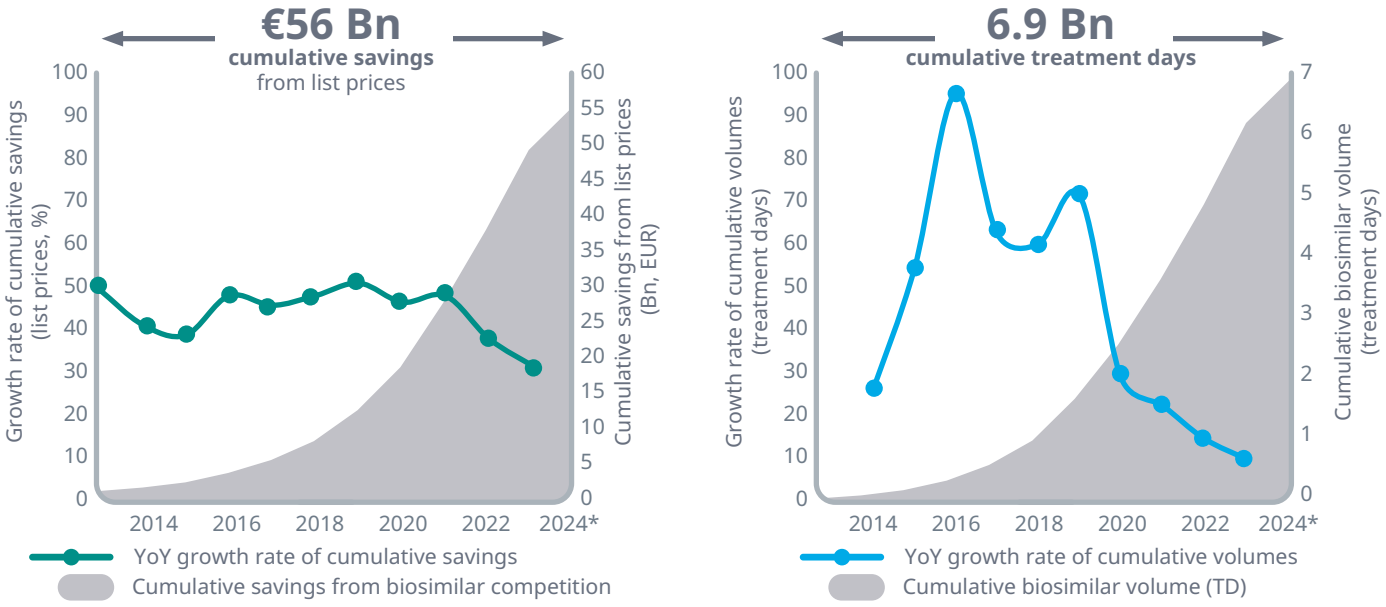
The impact of biosimilar competition is often viewed in terms of the volume of treatment (measured in treatment days). However, the presence of biosimilars cannot be viewed in isolation or without an appreciation of their direct and indirect benefits:

- Biosimilars have a direct impact on the accessible biologics market, providing 12% of the volume of treatment and generating savings from reduced list and net prices of the referenced medicines
- Biosimilars have an indirect impact on the non-referenced market (i.e. newer on-patent biologics), where molecules are superseded in clinical practice by biologic access options provided by biosimilars
- The prospect of biosimilars leads to the development of new generation molecules (non-referenced market), which can improve patient outcomes and increase patient treatment volumes
- Biosimilars have a direct and/or indirect impact on prices through increased biosimilar competition, in order to stay relevant in the treatment landscape

Despite being around since 2006, the past decade has shown the true impact of biosimilar competition in Europe. Using 'pre-biosimilar' prices, it is possible to calculate the list price savings that are generated on 'post-biosimilar' volumes. Whilst the true cost of biologic therapy (originator or biosimilar) remains commercially sensitive, list prices across Europe act as a base-case to estimate savings generated in European markets. As of July 2024, the cumulative savings at list prices from the impact of biosimilar competition in Europe reached €56 Bn (Exhibit 3).

Biologic spend continues to outpace small molecules by 3x and the total prescription market, at a rate of 14.7% in the most recent period.

Exhibit 3: Cumulative savings from list prices and cumulative treatment days from biosimilars (2013–2024*)



*H1 data only

Source: IQVIA MIDAS™ data from 2013 – 2024, using Euros at constant exchange rates;

Notes: Developed using country-level list prices pre- and post-biosimilar entry; Value includes all originator products with approved biosimilars from 2006 – 2024, covering EEA+UK, calculated volume is in treatment days determined by WHO-DDD, and where values are unavailable via Oncology Dynamics Physician Survey (2017) DDD estimates. 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.

In the same amount of time, total patient treatment days provided by biosimilars has reached 6.9 Bn. Whilst treatment volumes are still growing year on year, growth rates have fallen considerably in the past 5 years. Volumes are no longer growing at >50%, as was the case between 2015–2019, and instead are declining towards single digit figures.

Historic insights remain valid but new trends emerge rapidly

Since the creation of this series of reports in 2015, IQVIA has provided observations on the European biosimilar market (Exhibit 4). The themes of these observations have been around savings, prices, access, strategy, and competition, which are the central tenets of a healthy biosimilar ecosystem.

Each year the aim is to provide novel insights on the market, but previous years' insights remain valid and are now referenced for posterity, such as changing originator strategies (2019), the estimates of the net savings as a proportion of healthcare expenditure (2020), the location of emerging biosimilar manufacturers (2021), the growing disparity in access (2022), and the biosimilar void (2023).

In the 10th iteration of the 'Impact of Biosimilar Competition in Europe', IQVIA's observations re-focus on forward-looking themes that will impact the future market, such as pipeline, future savings potential, and commercial success.

The report provides a full-year update on the KPIs within the second segment of the report versus the prior report, while the observations reference IQVIA's most up to date information (Q2 MAT 2024) to track the approaches, successes, and challenges for all stakeholders in this important segment. In 2024, the observations on the impact of biosimilar competition are as follows:

1. **Pipeline**: A record number of biologics are due to lose exclusivity, however the pipeline has gaps
2. **Savings**: Long-term potential savings for European countries may be at risk
3. **Competition**: Competition is increasing, and competitive dynamics are not static
4. **Commercial success**: Success is not guaranteed for all biosimilars
5. **Future indicators**: Leading indicators offer insight into future impact of biosimilar competition

Exhibit 4: IQVIA's historic 5 observations on the biosimilar market (2015–2023)

2015

- Competition drives down price
- The correlation between biosimilars market share and price reduction is weak
- Competition can also influence the originator's behaviours
- Lower prices has the most impact on usage (patient access) in countries with low initial usage
- The product profile differences in classes can explain differences in impact on the KPIs

2016

- Competition drives down price
- The correlation between biosimilars market share and price reduction is weak
- Competition can also influence the originator's behaviours
- Lower prices increase patient access in countries with low initial usage
- The product profile differences in classes can explain differences in impact on the KPIs

2017

- The entrance of biosimilars increases price competition
- In some therapeutic classes, lowering the price of the referenced product can limit the market penetration of the biosimilar
- There is a first to market advantage in biosimilar markets
- Biosimilars have the potential to improve patient access of the total market

2018

- The entrance of biosimilars increases price competition
- Biosimilars have the potential to improve patient access of the total market
- In some countries, biosimilars have completely taken over
- In some TAs, lowering the price of the referenced product can limit biosimilar penetration
- The speed of uptake has increased for some of the more recent biosimilar launches

2019

- Biosimilar competition has a significant potential impact on overall drug spend
- Major products see fast uptake and large price reductions
- Originator manufacturers have changed strategy to stay competitive
- Access is not yet increasing for all molecules and in all countries after biosimilar introduction
- More is needed to create a sustainable market for biosimilar manufacturers

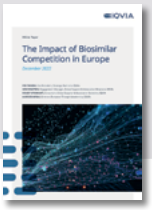
2020

- Biosimilar competition continues to offer opportunities to make healthcare savings
- Some countries are not increasing usage despite price reductions
- The variation of originator response to protection expiry
- Several models can work to support competitive markets
- The real impact of biosimilar competition is just beginning

2021

- COVID-19 has impacted certain segments of the biologic market
- Savings from biosimilar competition at an all-time high
- Development of access to biologic medicines remains challenging
- The competition environment in Europe is changing
- Ensuring preparedness for the future of biosimilar opportunity

2022



- Biologic prescribing has rebounded, but macroeconomic challenges loom
- The savings from biosimilar competition continues to grow
- Access is improving, but a growing disparity is occurring across countries
- Not all originators will see competition
- LOE will triple in the next 5 years versus the previous 5

2023

- Access to current biologics signals access challenges as disparity grows
- Savings growth has fallen from list prices due to the LoE opportunity
- Guaranteed savings do not exist for all classes as the pipeline shows gaps
- Policy changes take time to impact, and are part of a multifactorial environment
- A new era of molecules losing exclusivity show changing dynamics

In the 10th iteration of the 'Impact of Biosimilar Competition in Europe', IQVIA's observations re-focus on forward-looking themes that will impact the future market, such as pipeline, future savings potential, and commercial success.

Observation 1: Pipeline

TWO THIRDS OF BIOLOGICS LOSING EXCLUSIVITY DO NOT HAVE A BIOSIMILAR PIPELINE

In 2023, IQVIA published a report detailing the emergence of a 'biosimilar void' for biologics facing loss of exclusivity (LoE) in the coming years.[1] New pipeline activity analysis shows that a total of 69 biological medicines are anticipated to lose exclusivity in Europe by 2030, a 2-fold increase compared to the previous 7 years. However, despite the record numbers of upcoming biologic LoEs, at present only 29% of molecules have a biosimilar currently in development (Exhibit 5).

In parallel to the increasing number of biologics LoEs, the cumulative forecast value of these products based on annual sales before LoE is also shown to reach ~€28 Bn between 2024 and 2030. This figure represents a 3-fold increase when compared to the cumulative historic value of biologics that faced LoE in the previous 7 years. The assessment is limited to the next 7 years in order to reflect the duration of biosimilar development by manufacturers, which is estimated to be between 5–7 years.

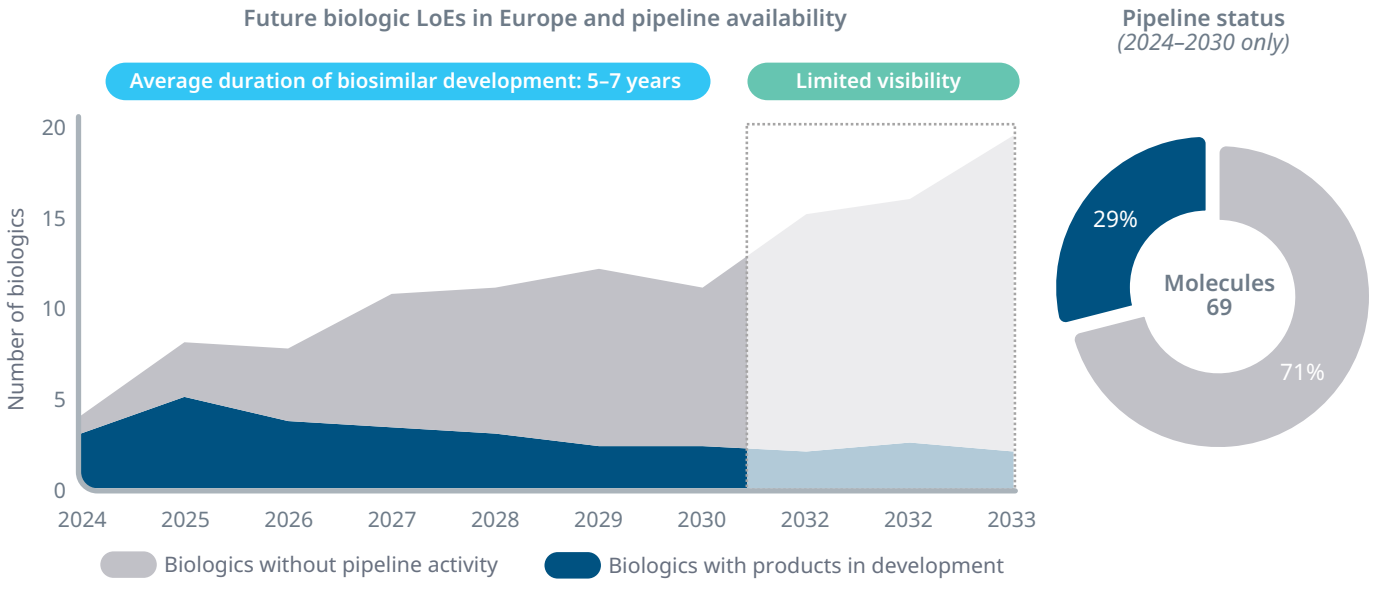
PIPELINE ISSUES ARE DRIVEN BY LOW VALUE BIOLOGICS, WHICH ARE INCREASING IN NUMBER

Previous IQVIA analysis highlighted the challenges for lower sales value biologics (LoE-1 sales <€500 Mn) in attracting biosimilar development, due to limited commercial opportunities, high development costs, and constrained returns on investment.[1]

Of the 69 biologics expected to face LoE by 2030, 74% are anticipated to generate annual sales under €500 Mn in the year before losing exclusivity (Exhibit 6). While the figure aligns with historical trends (72% for the 2017–2023 period), the larger number of low-sales biologics facing exclusivity in the coming year, means that low-sales products for which competition is not expected could cost an estimated ~€2.6 Bn in missed opportunity in the future (a 5-fold increase vs. the 2017–2023 period).

Low-sales biologics represent the majority of products losing exclusivity by 2030, however 8 high-sales (>€1 Bn) biologics with annual peak sales amounting to €25 Bn will also lose exclusivity between 2024 and 2030. This number is double that of high-sales biologics that lost exclusivity between 2017 and 2023.

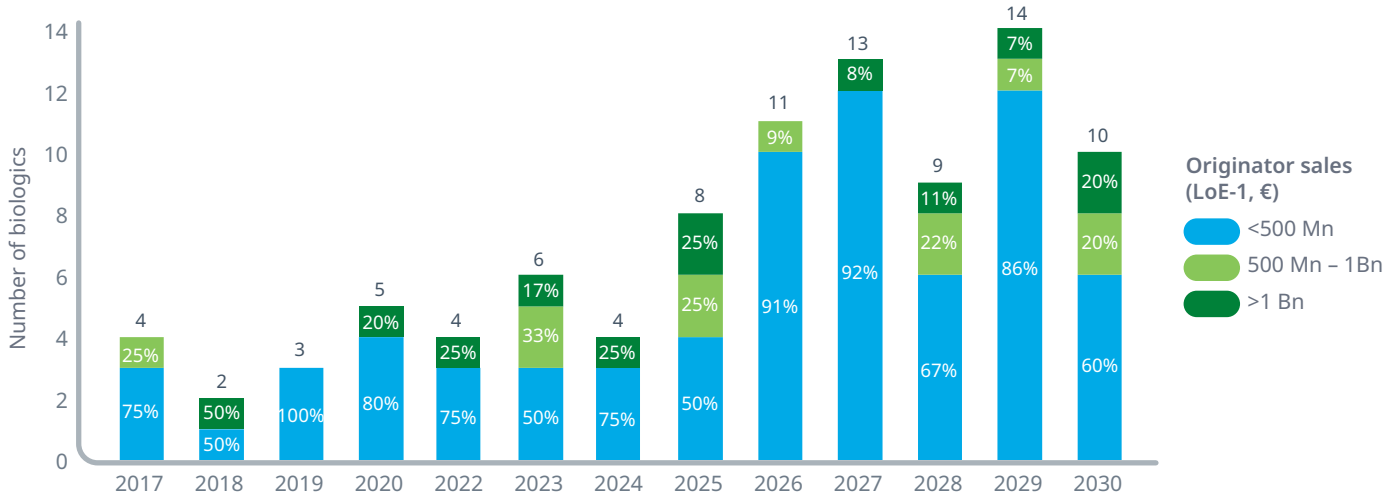
Exhibit 5: Biologics at risk of no, or limited, competition (molecules, 2024–2030)



Source: IQVIA Patent Intelligence (2024); IQVIA analysis of the IQVIA Global Biosimilar Database (Q3 2024).

Notes: Timeframe is limited to 2030 (low pipeline potential >7 years into the future due to the biosimilar development timeline); Global pipeline analysis includes all biosimilars in development from pre-clinical pre-registered; excl. approvals. To reduce uncertainty in pipeline forecast data, data from 2024 onwards is shown as a 3-year rolling average. The IP profile of individual biologics is subject to change as new patents and/or patent extensions become available during a product lifecycle. The data shown in this chart is accurate as of November 2024.

Exhibit 6: Biologic LoE events, by peak originator European sales (LoE-1)

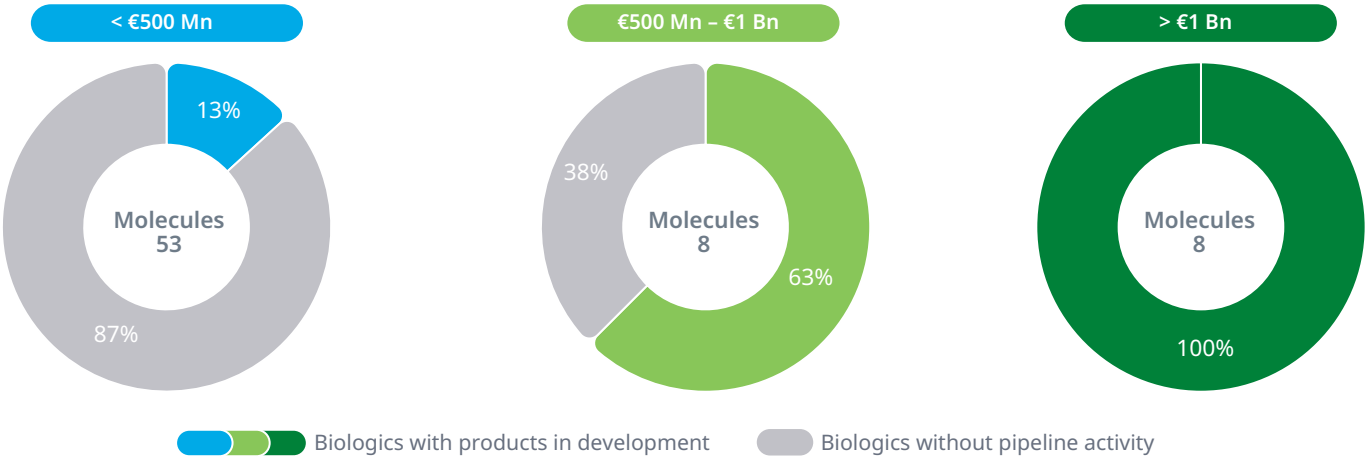


Source: IQVIA MIDAS sales; IQVIA Forecast link; IQVIA Patent Intelligence (2024); IQVIA analysis of the IQVIA Global Biosimilar Database (Q3 2024).

Note: Global pipeline analysis includes all biosimilars in development from pre-clinical pre-registered; excl. approvals; Originator sales (LoE-1) are for Europe only. The IP profile of individual biologics is subject to change as new patents and/or patent extensions become available during a product lifecycle. The data shown in this chart is accurate as of November 2024.

Current data shows that only 13% of the biologics with the lowest commercial value (LoE-1 sales <€500 Mn) have a biosimilar in the pipeline (Exhibit 7). Conversely, pipeline activity remains strong for molecules with higher commercial value. For instance, all biologics with a high sales value (>€1 Bn) have a biosimilar in development, as well as 63% of molecules with medium sales value (€500 Mn-1 Bn). The latter category includes two cell & gene therapies (Yescarta and Spinraza) for which there is currently no clear biosimilar pathway.

Exhibit 7: Forecast Biologic LoEs in Europe (2024–2030) and competitor development, by originator sales value



Source: IQVIA Patent Intelligence (2024); IQVIA analysis of the IQVIA Global Biosimilar Database (Q3 2024).

Notes: Timeframe is limited to 2030 (low pipeline potential >7 years into the future due to the biosimilar development timeline); Global pipeline analysis includes all biosimilars in development from pre-clinical pre-registered; excl. approvals. To reduce uncertainty in pipeline forecast data, data from 2024 onwards is shown as a 3-year rolling average. The IP profile of individual biologics is subject to change as new patents and/or patent extensions become available during a product lifecycle. The data shown in this chart is accurate as of November 2024.

Observation 2: Savings

LONG-TERM LOE OPPORTUNITIES IN EUROPE ARE AT RISK

In the next seven years, there will be a significant rise in biologic LoE events compared to previous years, with 69 biological medicines anticipated to loss protection by 2030. Cumulatively, the LoE opportunity is estimated at €28Bn between 2024–2030, peaking around €11.6Bn between 2029 and 2030 (Exhibit 8).

Biosimilar competition is the key driver behind price reductions, enhanced patient access, and the generation of health system savings post-LoE. Therefore, the status of the biosimilar development pipeline must be taken into consideration when evaluating future LoE opportunity. Without biosimilars in development, potential savings opportunities are at risk of not materialising.

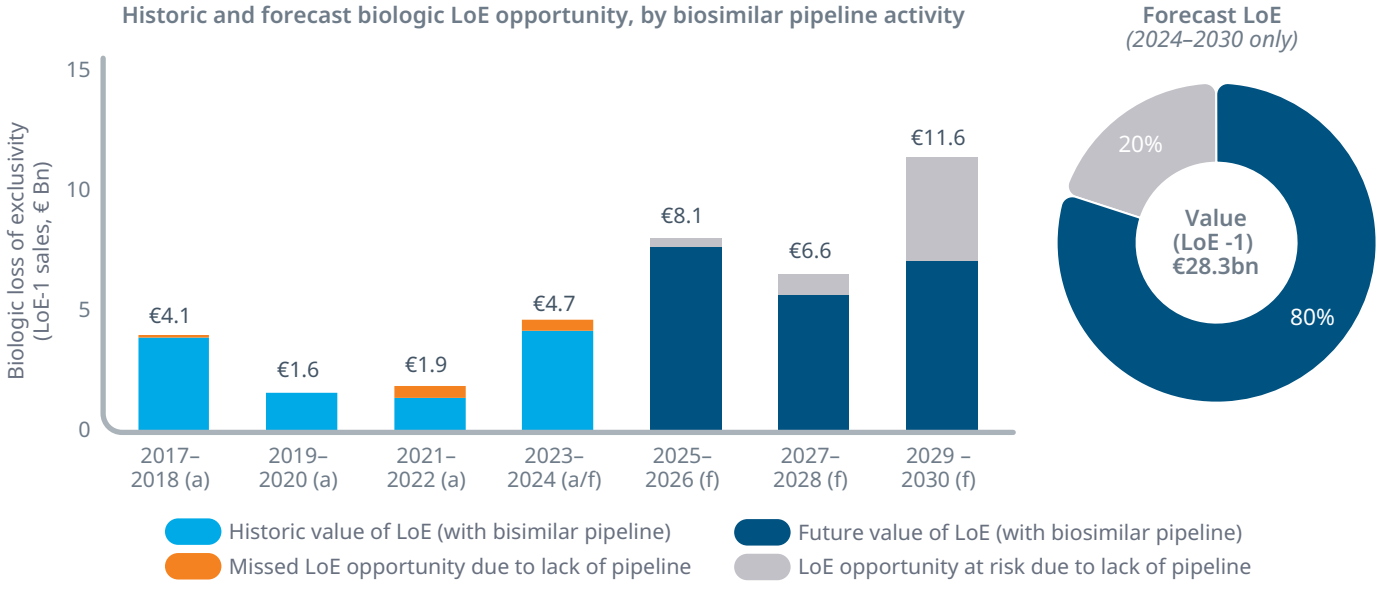
The current analysis suggests that 20% of the forecast LoE opportunity is at risk, due to lack of biosimilars in the pipeline. This increases in the longer-term, with 38% of LoE opportunity at risk for biologics facing exclusivity between 2029 and 2030 amounting to €4.4Bn.

Exhibit 8 shows that short-term savings are more likely to be realised, as over 90% of the LoE opportunity for the period 2025-2028 is linked to high-sales products for which biosimilars entry is expected post LoE.

At the national level, the LoE opportunity is anticipated to vary depending on the initial usage of the originator molecules, forecasted expenditure, and subsequent savings potential.

For instance, in Germany, €1.1 Bn in LoE opportunity may be at risk due to lack of biosimilar pipeline, which represents 19% of the total LoE opportunity (2024-2030) (Exhibit 9). In contrast, the LoE opportunity in Poland is anticipated to be smaller as would be expected due to country size and associated pharmaceutical expenditure. Nonetheless, it is estimated that the missed opportunity for Poland totals €270 Mn, which represents 25% of the overall loss of exclusivity forecast. The higher percentage indicates greater spending on biologics without a biosimilar pipeline in this country.

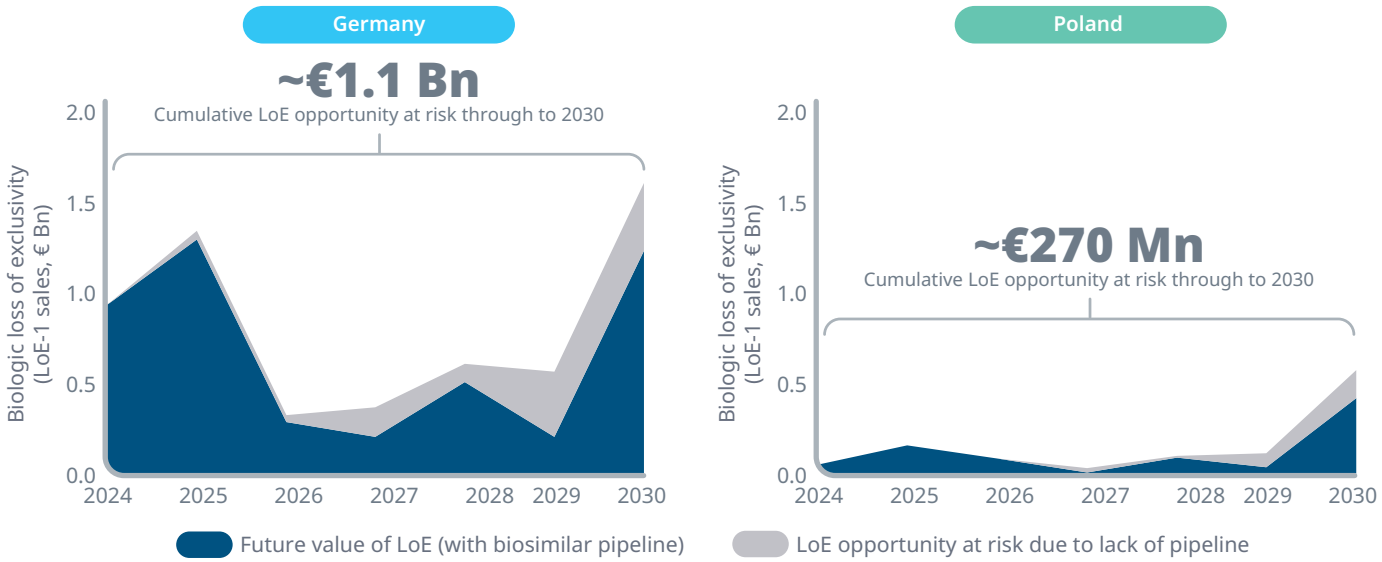
Exhibit 8: Historic and forecast biologic LoE opportunity, by biosimilar pipeline activity



Source: IQVIA MIDAS sales; IQVIA Forecast link; IQVIA Patent Intelligence (2024); IQVIA analysis of the IQVIA Global Biosimilar Database (Q3 2024).

Notes: Global pipeline analysis includes all biosimilars in development from pre-clinical pre-registered; excl. approvals; Originator sales (LoE-1) are for Europe only. The IP profile of individual biologics is subject to change as new patents and/or patent extensions become available during a product lifecycle. The data shown in this chart is accurate as of November 2024.

Exhibit 9: Germany and Poland forecast biologic LoE opportunity, by biosimilar pipeline activity



Source: IQVIA MIDAS sales; IQVIA Forecast link; IQVIA Patent Intelligence (2024): IQVIA Forecast Link (2024).

Notes: LoE opportunity calculated by forecasting peak biologic sales for year LoE-1 in Germany and Poland, and determining risk based on biosimilar pipeline status; The IP profile of individual biologics is subject to change as new patents and/or patent extensions become available during a product lifecycle. The data shown in this chart is accurate as of November 2024.

Observation 3: Competition

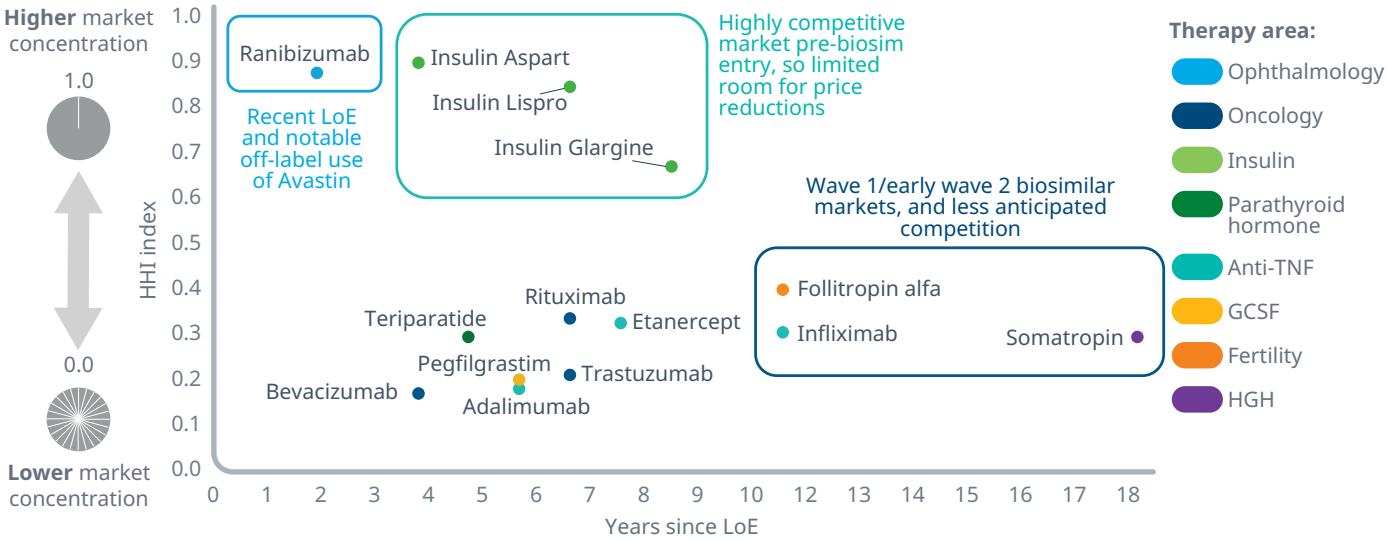
LIMITED CORRELATION BETWEEN TIME SINCE LOE AND MARKET CONCENTRATION

In order to maintain price competition and generate savings for European health systems, several biosimilar competitors must stay active in the market. The market concentration of key molecules with biosimilar competition can be defined using the Herfindahl-Hirschman Index (HHI).[2]

The HHI is calculated by squaring the market share of each product in the market (i.e. originator, biosimilar 1, biosimilar 2, etc.) and summing the resulting numbers, with the index ranging from low market concentration (0.0) to high market concentration (1.0). A low degree of concentration means that the market is closer to a perfect competition scenario, where competing products share the market equally.

Exhibit 10 highlights the varying degrees of biosimilar competition within the European market.

Exhibit 10: European Herfindahl-Hirschman Index and time since LoE



Source: IQVIA MIDAS data (Q2 MAT 2024); EU country scope (excludes Norway, UK, and Switzerland).

Notes: Only considers EMA approved biosimilars (through centralized procedure); >0.8 HHI index considered highly concentrated market; GCSF = Granulocyte-colony stimulating factor; HGH = Human growth hormones.

Market concentration might be expected to correlate with time since LoE, with high concentration at LoE, increasing competition as biosimilars enter, and consolidation as the market matures. Ranibizumab, which recently lost exclusivity, shows little competition, while earlier biosimilar markets (e.g. wave 1 and early wave 2 molecules) exhibit higher concentration compared to molecules that have lost exclusivity less than 10 years ago.

However, market dynamics are nuanced, and therapy area characteristics are also important. For instance, all three insulin molecules exhibit high market concentration (>0.6 HHI) despite sufficient time since LoE. This is partly due to the already competitive insulin market before biosimilar entry, which limited further competition or price reductions. Similarly, whilst limited competition for ranibizumab might be expected, other market dynamics — such as off-label use of oncology medicines (e.g. Avastin) — may also discourage direct biosimilar competition.

Competition levels can also vary significantly between countries due to differences in healthcare systems and biosimilar procurement processes. In Germany, the HHI for infliximab is 0.35, while in Poland, it is 0.51, reflecting different levels of market concentration and competition. Some countries, like Denmark, show very high competition with an HHI of 0.99 for certain products, indicating a market dominated by a single biosimilar (Exhibit 11). These country-specific variations highlight the importance of local healthcare policies and procurement strategies in shaping the competitive landscape.

In the long-term, a highly concentrated market means that only a few companies can participate in a tender. This eventually means poor price competition and comes with all the associated risks of reliance on a single supplier. As such, dynamic competition is key to ensuring long-term benefits from biosimilar competition.

Exhibit 11: Select countries Herfindahl-Hirschman Index

	HOSPITAL								MIXED		INSULIN		
EU4	Infliximab	Follitropin alfa	Etanercept	Rituximab	Trastuzumab	Pegfilgrastim	Bevacizumab	Teriparatide	Adalimumab	Ranibizumab	Insulin Aspart	Insulin Glargine	Insulin Lispro
Germany	0.35	0.40	0.37	0.42	0.21	0.20	0.23	0.41	0.17	0.97	0.97	0.70	0.88
France	0.40	0.37	0.38	0.29	0.40	0.14	0.29	0.32	0.27	0.91	0.89	0.57	1.00
Italy	0.32	0.40	0.39	0.48	0.21	0.40	0.18	0.34	0.22	0.95	0.95	0.78	0.77
Spain	0.40	0.36	0.35	0.36	0.20	0.37	0.30	0.28	0.23	0.71	1.00	0.65	1.00
Other EU													
Netherlands	0.33	1.00	0.53	0.35	0.28	0.82	0.22	1.00	0.27	0.82	0.53	0.58	0.71
Denmark*	0.98	0.52	0.81	0.56	0.94	0.99	0.96	0.82	0.52	1.00	0.90	0.51	1.00
Finland	0.39	0.62	0.40	0.42	0.31	0.38	0.51	0.71	0.18	1.00	0.99	0.94	0.51
Poland	0.51	0.37	0.94	0.55	0.51	0.54	0.63	1.00	0.84	0.65	0.70	0.63	0.61
Slovenia*	0.30	0.59	0.51	0.33	0.42	0.45	0.31	0.60	0.47	1.00	1.00	0.40	1.00

Higher market concentration 1.0 — Lower market concentration 0.0

*Some or all hospital tender contracts allow for more than one winner.

Source: IQVIA MIDAS data (Q2 MAT 2024); Medicines for Europe Market Review 2023 https://www.medicinesforeurope.com/wp-content/uploads/2023/09/Biosimilars-Market-Review-2023-final-06-09-2023.pdf

Notes: Only considers EMA approved biosimilars (through centralized procedure).

EUROPEAN BIOSIMILAR OWNERS REMAIN IN AN INCREASINGLY EXPERIENCED MARKET

Although Europe continues to play a central role in the global biosimilar market, the share of EMA approved biosimilars developed by ex-EU players is on the rise. Historically, biosimilar approvals were led by European companies, but this landscape has evolved significantly over the years as new regions and companies have entered the biosimilar market.

The regional distribution of biosimilar developers shows a strong participation from European manufacturers, but also significant investments from companies headquartered in US, India, and, most recently, South Korea. Between 2022 and 2024, 11% of biosimilars approved by the EMA were developed by companies headquartered in India or South Korea, up from 3% in the previous 3 years.

A key trend is the rise in partnerships, which often involve experienced ex-EU companies that partner with European manufacturers to launch products in Europe. Historically, these partnerships were relatively uncommon, but their prevalence has increased. Between 2006 and 2013, ex-EU partnerships represented 30% of all approvals, but more recently this figure increased to 45% (2014–2024).

Not only has the geographic profile of biosimilar developers evolved, so has the level of launch experience. Exhibit 12 shows that the expertise of commercialising companies in Europe is increasing, with almost two thirds (62%) of recent EMA approvals from marketing authorisation holders that have already launched at least 3 biosimilars in Europe.

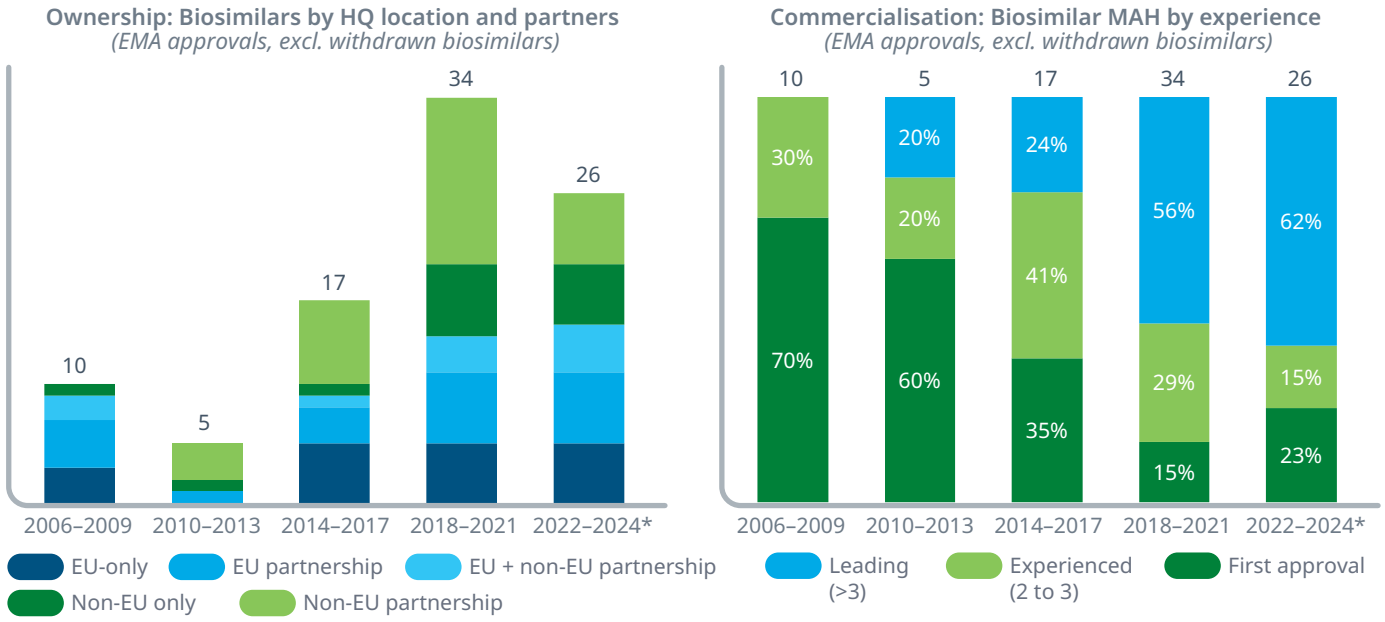
As evidenced by the rise in partnerships, multiple companies can be involved throughout different stages of the biosimilar lifecycle. Therefore, the marketing authorisation holder (MAH) of EMA approval only shows one aspect of the overall process of bringing a biosimilar to market.

MARKET DYNAMICS CAN CHANGE, EVEN WITHIN MATURE MARKETS

In the mature therapy area of human growth hormones (HGH), where biosimilars have maintained a relatively low but consistent market share for the past decade, recent developments illustrate that market dynamics are far from static.

Recent supply chain disruptions to non-referenced HGH products did not impact overall market volumes due to the availability of alternative treatment options,

Exhibit 12: EMA biosimilar approvals by owner HQ location and MAH experience (2006–2024)



*Data for 2024 only includes biosimilars approved between Jan and October 2024.

Source: IQVIA Patent Intelligence (2024); IQVIA Global Biosimilar Database (Q3 2024). EMA, 'EPAR Assessment List' published October 2024.

Notes: Partnerships are defined as R&D, out-licensing or marketing collaborations that involve two or more biosimilar manufacturers. EU only= approval obtained by one EU biosimilar owner only, without any partnership. EU partnership= collaboration between European manufacturers. EU+ non-EU partnership= collaborations between a European manufacturer partners and an non-EU player. Non-EU only= approval obtained by one non-EU biosimilar owner only, without any partnership. Non-EU partnership= collaborations between non-EU manufacturers.

which were available to meet the increased demand (Exhibit 13). Non-originator biologicals of somatropin have maintained a consistent share of the overall human growth hormone market in Europe for over a decade. However, supply chain issues beginning in 2022 for key non-originator products, Norditropin and NutropinAq, led healthcare professionals to switch patients to alternative somatropin products, namely the only EU-approved biosimilar, Onmitrope. Omnitrope's market share by volume (treatment days) has increased from 31% in 2022 to 45% in 2024 (Q2 MAT 2024).

While this shift does not reduce market concentration — reflected in a higher HHI index as a single biosimilar gains market share — the broader benefits of increased biosimilar penetration, such as price reductions and potential health system savings, balance the drawbacks of increased market concentration. This reinforces the need to evaluate market dynamics in combination, and that focusing solely on measures like market concentration or competition in isolation risks overlooking the wider system benefits from biosimilars.

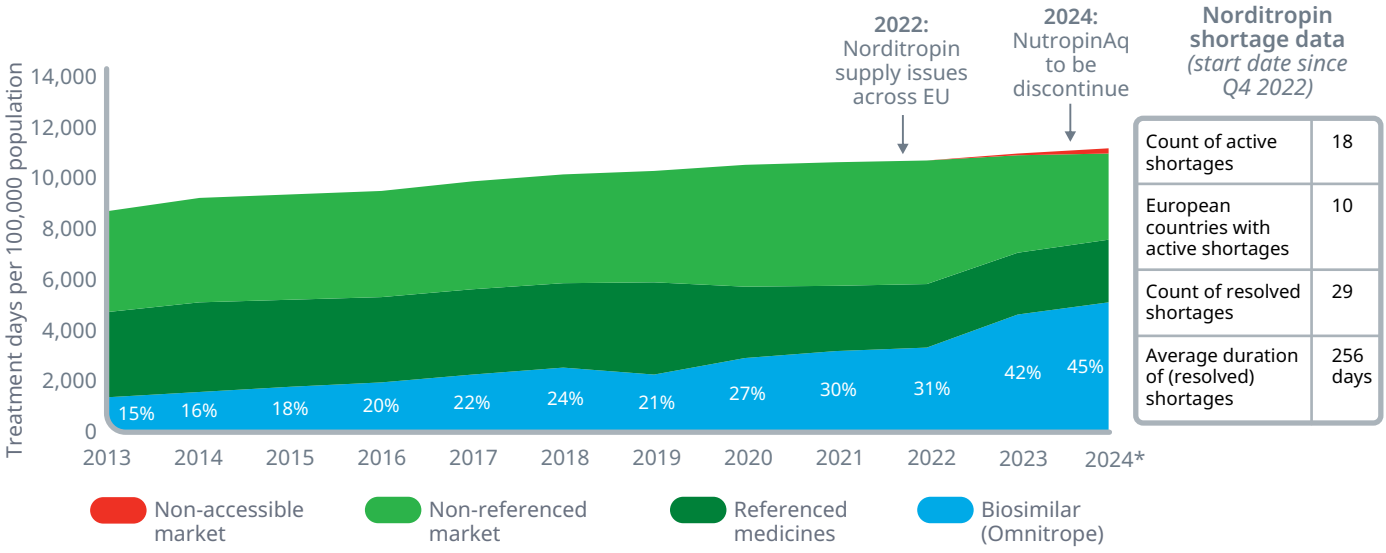
Observation 4: Commercial success

SUCCESS IS NOT GUARANTEED FOR ALL BIOSIMILARS

The commercial success of biosimilars is important for continued investment in their development, and the overall sustainability of the sector. Cumulative global sales at list prices have been used to estimate whether the biosimilars launched in the past 18 years have been commercially successful, as net sales can be reported in earnings reports, but are rare. Cumulative global sales exceeding €300 Mn have been considered as commercially successful, as their revenues have surpassed estimated development costs.[3]

Commercial success is dependent on multiple factors, such as the size of the originator opportunity, number of competitors, cost of developing the biosimilar, location of launch, and ultimately, the price of the product.

Exhibit 13: Human growth hormone (HGH) market development (treatment days) and key supply chain events



Sources: https://www.ema.europa.eu/system/files/documents/shortage/norditropin-oct-2024-shortage-entry-update_en.pdf; https://www.ipsen.com/statement/ipsen-announces-decision-to-permanently-discontinue-distribution-of-nutropinaq-somatropin-cartridges/#:~:text=After%20careful%20consideration%20of%20the,with%20growth%20failure%20due%20to; IQVIA Shortage Transparency Platform data (Accessed October 2024).

Notes: *Q2 MAT 2024. Non-accessible market in 2023: Sogroya (somapacitan), Ngenla (somatrogon), Skytrofa (lonapegsomatropin); Non-referenced market in 2023: Norditropin, Nutropinaq, Saizen, Zomacton (somatropin); Referenced medicines in 2023: Genotropin, Humatrope (somatropin); Biosimilars in 2023: Omnitrope (somatropin).

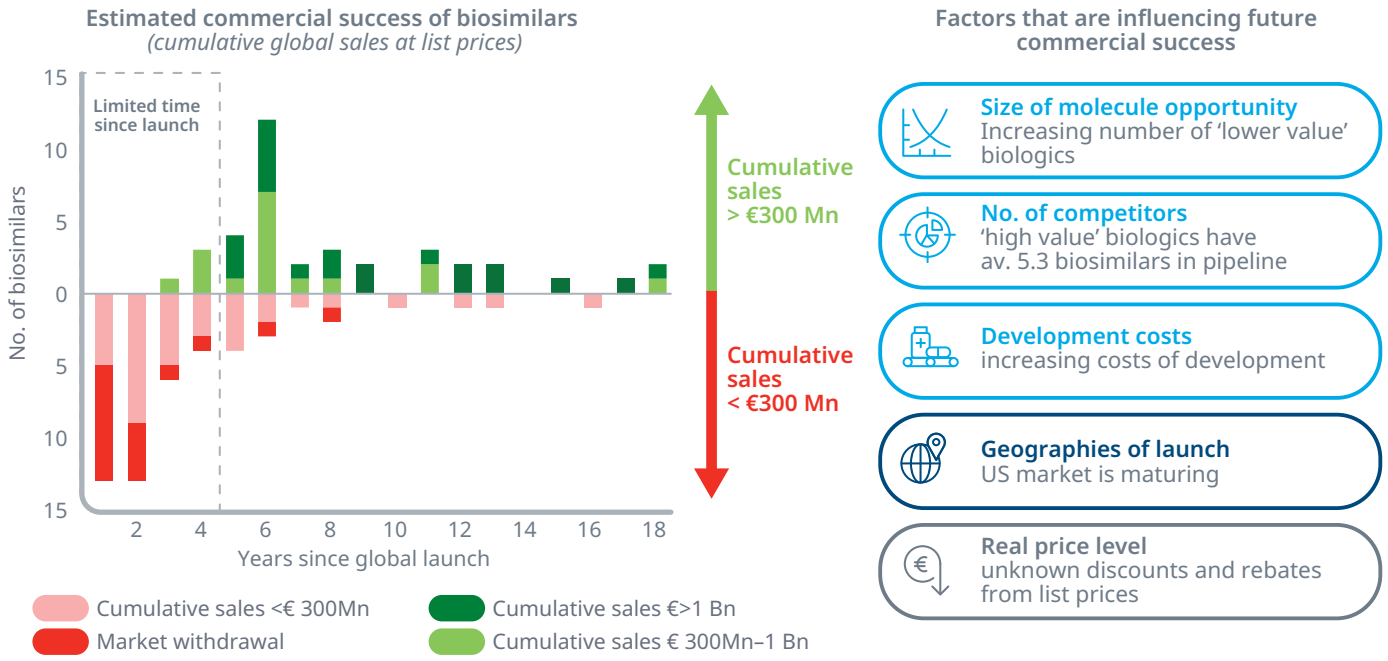
A limitation of this analysis is that development costs for biosimilars will vary and may fall below or exceed €300 Mn. Additionally, global sales are visible at list prices only, as discounts/rebates provided to payers – which are often estimated to exceed 50% of list prices – remain confidential at the product level. Considering these limitations, the analysis provides an estimate for the commercial success of biosimilars.

Less than 5 years since launch does not allow sufficient time for return on investment, therefore analysis focusses on 5+ years since global launch. Historically, the majority of biosimilars have been commercially successful after 5 years of launching (Exhibit 14). A quarter of biosimilars (27%) have cumulative global sales between €300 Mn and 1 Bn, whilst 44% have made over €1 Bn in global sales at list prices. Only 25% have made less than €300 Mn in sales, with a following 4% being withdrawn from the market.

Commercial success is dependent on multiple factors, such as the size of the originator opportunity, number of competitors, cost of developing the biosimilar, location of launch, and ultimately, the price of the product (Exhibit 14). The lack of biosimilars in development for 'lower value' biologics forecast to lose exclusivity by 2030 highlights this clearly. If the molecule opportunity is below that of the estimated development costs, a return on investment for sponsors is unlikely. The increasing number of low value originators with upcoming LoE (Exhibit 6), and the high level of competition in the pipeline for high value molecules (average 5.3 biosimilar per molecule), signal potential future challenges for companies.

For many years, Europe was the only attractive region for biosimilars due to its initial acceptance and uptake. However, biosimilar markets are now maturing in other regions, presenting new opportunities for growth. In the United States, for example, recent biosimilars have achieved high volume shares, reaching more than 60% of the molecule's volume within the first three years.[4] Therefore, the potential for return on investment for biosimilar companies is expanding as these markets continue to develop and mature.

Exhibit 14: Biosimilar commercial success (based on cumulative global sales at list price level) by years since LoE



Source: IQVIA MIDAS Q2 MAT 2024 (at list prices).

Notes: Estimates of biosimilar R&D costs between €150–300Mn; Confidential discounts and rebates range across biosimilars, therefore an approach based on list prices coupled with the higher estimate of the biosimilar R&D costs illustrates the status of commercial success; Market withdrawals calculated from years since EMA marketing authorization, not global launch, as most do not have sales data.

Observation 5: Future indicators

LEADING INDICATORS OFFER INSIGHT INTO THE FUTURE IMPACT OF BIOSIMILAR COMPETITION

Past iterations of the 'Impact of Biosimilar Competition in Europe' report have focused on the current and historic impact of biosimilar competition within the European pharmaceutical market. These 'lagging indicators' have centred around biosimilar uptake, competition, price reductions, system savings, and patient volumes. Such observations have been critical whilst the European biosimilar market has emerged and matured over the last two decades, in order to measure the wide-ranging benefits that biosimilar competition provides to health systems.

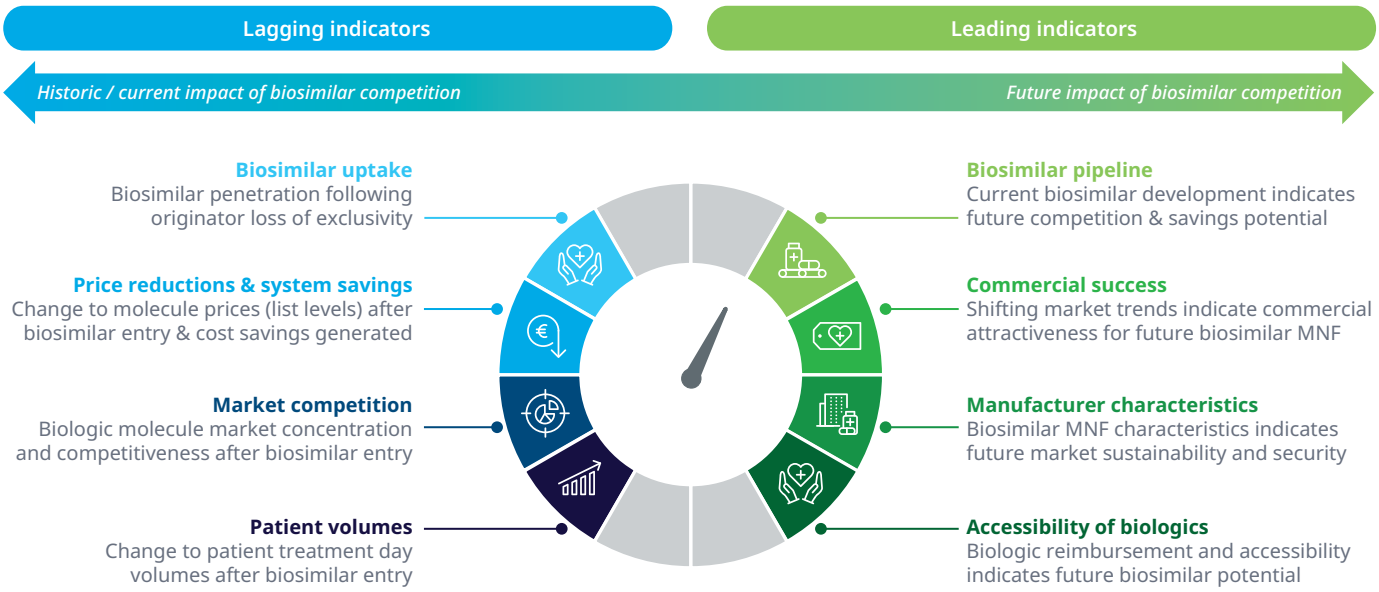
However, the past is not always a predictor of the future, and the current/historic benefits of biosimilar competition are not a guarantee for the coming decades. As such, 'leading indicators' must similarly be considered to help identify and anticipate the future impact of biosimilar competition, and subsequent opportunities and challenges that lie ahead (Exhibit 15).

Key 'leading indicators' that shed some light onto the evolution of the biosimilar market in Europe include:

1. **Biosimilar pipeline**: Current biosimilar development indicates future system savings potential
2. **Commercial success**: Current return on investment indicates commercial attractiveness for future MNF
3. **Manufacturer characteristics**: Biosimilar MNF characteristics indicates future market sustainability and security
4. **Availability of originators**: Biologic reimbursement and accessibility indicates future biosimilar potential

These leading indicators have been highlighted in past Impact of Biosimilar Competition in Europe reports as emerging issues for biosimilar sustainability, and will continue to be monitored going forward.

Exhibit 15: Lagging and leading indicators of past and future impact of biosimilar competition



Methodology

'The Impact of Biosimilar Competition' series covers the main therapy areas with biosimilar competition, but it is an incomplete view of the market. With the dynamic development of new patent protected medicines, there is a segment of the biologic market that is not covered (Excluded non-accessible market), which is growing in volume terms. Three molecules represent the majority of this increasing segment, namely denosumab, semaglutide, and dulaglutide (Exhibit 16).

Denosumab is expected to lose exclusivity in major European markets in 2025, and has multiple biosimilars in development, so will be included within future iterations of the report. Semaglutide and dulaglutide's inclusion must be considered differently as IQVIA's definition of a biologic molecule differs from European regulatory definitions. IQVIA's definition of biologicals covers "medicinal products whose active substances are derived from a living organism (such as blood components, allergenics, recombinant therapeutic proteins, etc)", and therefore is not a direct match for products that can be granted a biosimilar in Europe.

The indicators are intended to give a broad overview of the uptake and the implications on price and volume evolution after introduction of biosimilar medicines.

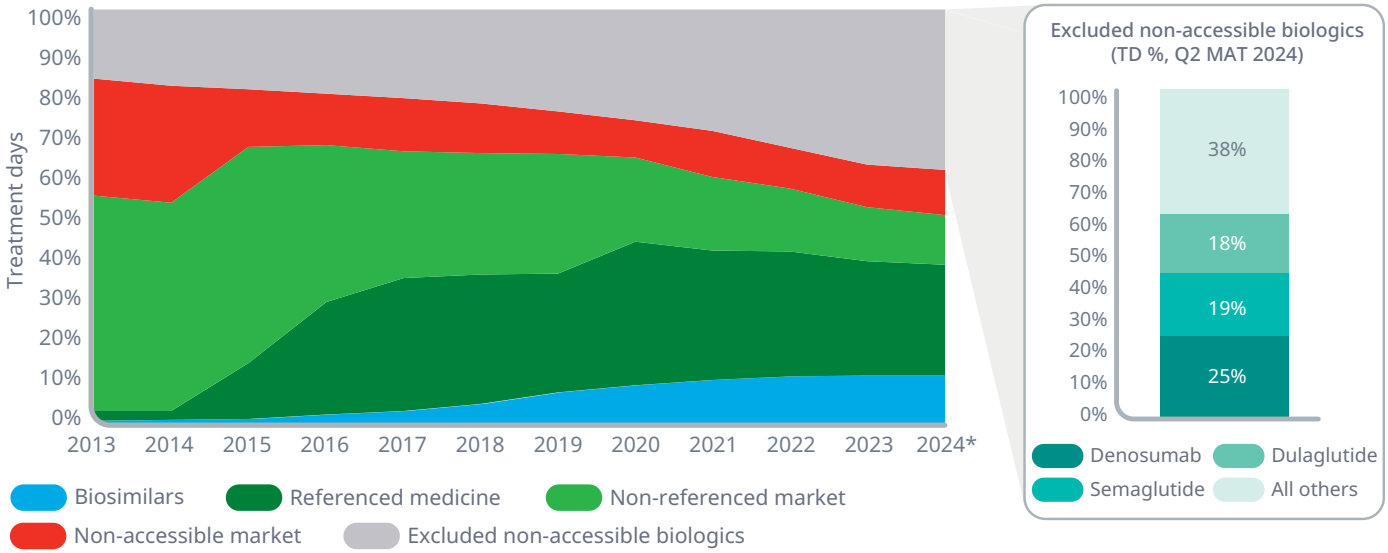
There are differences in perspective between payers, providers, and different types of manufacturers. Focusing on the payer perspective, there are caveats that should be considered when interpreting the results.

Pricing and discounts: the report is based on publicly available list prices. Discounting occurs, especially in contracting with hospitals and in countries using tenders for biological drug procurement, which can lead to larger price fluctuations than is visible through the reported IQVIA data.

Approved indications and efficacy: Not all products in a specific product group in the accessible, non-accessible or total market have the same approved indications and can have differences in efficacy and individual patient outcomes. Biosimilars normally receive the same indications as the referenced products and are expected to have the same safety and efficacy.

Volume estimates: The pack volumes reported are based on IQVIA collected data which may have been unknowingly impacted by issues such as parallel exporting. The volumes have been converted to daily doses using the published World Health Organization (WHO) defined daily doses (DDD), which can introduce bias. Consumption measures are therefore not adjusted

Exhibit 16: Scope of the IQVIA report, 10 key therapy areas with biosimilar competition



*Q2 MAT 2024 data.

Source: IQVIA MIDAS (MAT Q2 2024), Rx only; Biologic molecules exclude ATC-V (various) and vaccines, LC€ (inflation adjusted).

Notes: EU country scope (excludes Norway, UK, and Switzerland); Treatment day (TD) data corrected for biologics within 10 TAs only.

for clinical practice guidelines, patient characteristics, indications for which the molecule is used, or other factors that may result in different volumes utilised on a per patient Treatment Day basis.

Long-term vs. one-off use/hospital-only vs. retail: No distinction is made in this report between biologicals for long-term (repeat use) and one-off use, nor between hospital-only and retail products, although competitive conditions and scope for biosimilar uptake are likely to differ in the various scenarios.

Protection expiry: 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.

OTHER DEFINITIONS FOUND WITHIN THE REPORT INCLUDE:

Launch date: date of first recorded sales of Biosimilar Medicinal Product in the country. Products can be approved in Europe prior to this date but it is not recorded as such.

Price indicators:

- **Price:** the price level used is gross ex-manufacturer price (list price), which values the product at the level that the manufacturer sells out, without considering rebates or discounts.
- **Price evolution:** price per Treatment Day (TD) in 2023 versus year before biosimilar entry.

Volume indicators:

- **Volume:** Volume is measured in Treatment Days (also known as Defined Daily Dose) which is a measure of the average dose prescribed as defined by the WHO.
- **Biosimilar market share:** Number of biosimilar treatment days as a share of (i) biosimilar + referenced product(s) volume, (ii) accessible market volume, and (iii) total market volume.
- **Volume evolution:** Number of Treatment Days in 2023 versus year before biosimilar entry.
- **Volume per capita 2023:** Number of Treatment Days consumed in 2023 normalised by population size (World Bank data).
- **Volume per capita year before biosimilar entrance:** Number of Treatment Days consumed the year before the entrance of biosimilars, normalised by population size.

The following terms are used throughout this segment of the report:

TOTAL MARKET Products within the same ATC code	**ACCESSIBLE MARKET**	**Referenced Medicinal Product:** 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.	
		Non-Referenced Medicinal Product: Original product, granted market exclusivity at the start of its life, exclusivity has now expired, and the product has never been categorised as Referenced Medical product by receiving EMA-approved marketing authorisation.	
		Biosimilar Medicinal Product: Product, granted EMA regulatory approval (via centralized process, unless otherwise specified), demonstrating similarity to the Reference Medicinal Product in terms of quality characteristics, biological activity, safety and efficacy.	
	NON-ACCESSIBLE MARKET	**Non-Accessible Category:** Products within the same ATC4 code as the accessible category products. These are typically second-generation products; this category may include products within different dosing schedules and/or route of administration to those in the accessible category, and have valid protection status.	

Country and therapy area KPIs

Human growth hormone (HGH)

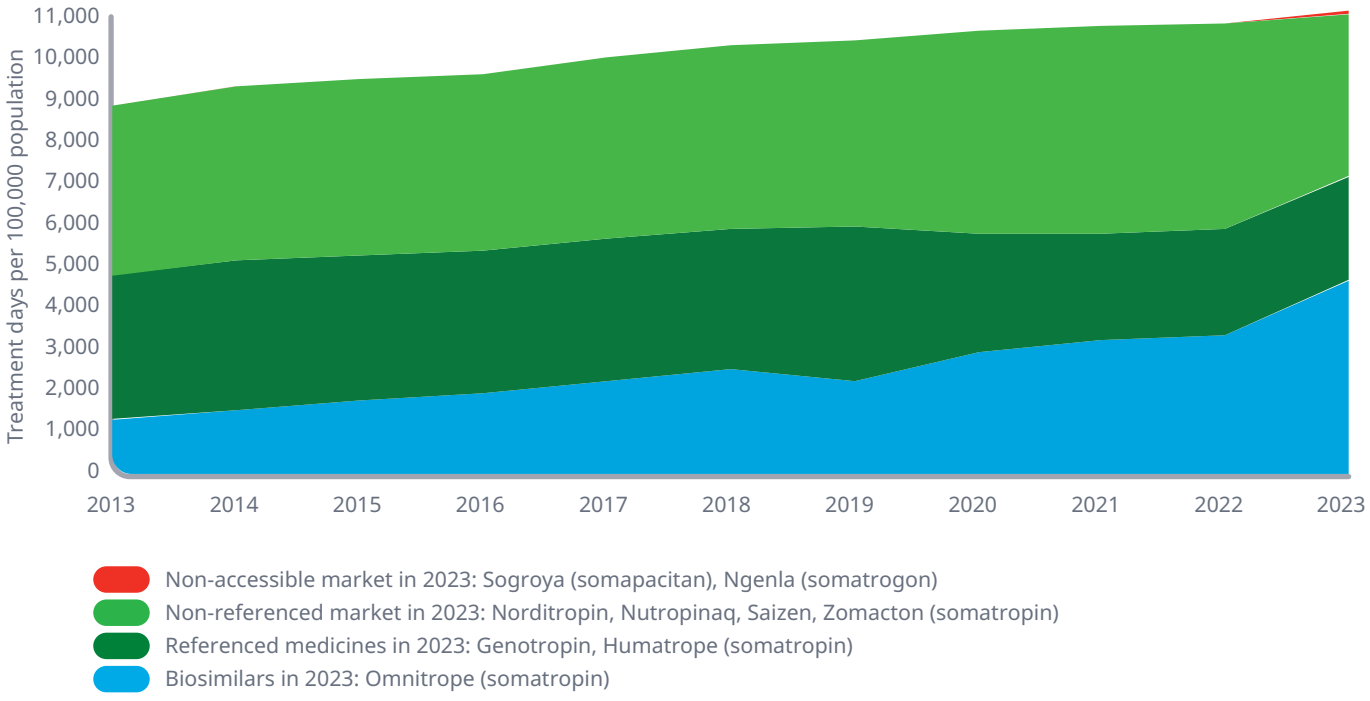
HGH, also known as somatropin, are peptide hormones that stimulates growth, cell reproduction and regeneration in humans. It is used to treat growth disorders in children and growth hormone deficiency in adults.

HGH MARKET DEVELOPMENT

Sogroya (somapacitan) and Ngenla (somatrogon) were included in the 2023 report, along with Skytrofa (lonapegsomatropin) in the 2024 report, and were classified in the 'non-accessible' market. Sogroya, Ngenla, and Skytrofa are long-acting GH therapies recently approved for growth hormone deficiencies, with an aim of prolonging the half-life of the GH molecule. The total market has not increased as Sogroya, Ngenla, and Skytrofa account for <1% of the total HGH market.

In 2023, the sudden uptick in biosimilar volumes has been driven by supply chain disruption and shortages of non-referenced medicines, and patients being switched to alternative therapies (i.e. biosimilars).

HGH market development status



ADDITIONAL INFORMATION ABOUT HGH MEDICINES

Subcutaneous injection is typically used to administer Human Growth Hormone treatment. The dosage of administration should be individualized for each patient, with a weight-based regimen. The duration of treatment, usually a period of several years, will depend on maximum achievable therapeutic benefit.

Fast-acting GH (somatropin) is typically administered daily, whilst long-acting GHs (somapacitan, somatrogon, and lonapegsomatropin) are typically administered weekly.

HGH approved indications

NAMING		CLASSIFICATION											INDICATIONS										DOSING/ ADMINISTRATION	
MOLECULE	PRODUCT	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	PEDIATRIC GROWTH HORMONE DEFICIENCY	ADULT GROWTH HORMONE DEFICIENCY	TURNER SYNDROME	GROWTH FAILURE DUE TO CHRONIC RENAL INSUFFICIENCY (CRI)	SGA - SMALL FOR GESTATIONAL AGE	PWS - PRADER-WILLI SYNDROME	IDIOPATHIC SHORT STATURE	SHOX - SHORT-STATURE HOMEBOX-CONTAINING GENE DEFICIENCY	NOONAN SYNDROME	FREQUENCY	MODE OF ACTION
SOMATROPIN	GENOTROPIN HUMATROPE* OMNITROPE NORDITROPIN NUTROPINAQ SAIZEN ZOMACTON	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	Daily	Fast-acting
SOMAPACITAN	SOGROYA									●	●	●	●	●								Weekly	Long-acting
SOMATROPIN	NGENLA										●	●	●									Weekly	Long-acting
LONAPEGSOMATROPIN	SKYTROFA										●	●	●									Weekly	Long-acting

● Non-accessible market ● Non-referenced market ● Referenced medicines ● Biosimilars

* Note: The biosimilar for Humatrope (Valtropin) has been withdrawn from the market, however Humatrope is still categorized as a referenced medicine.

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries

		AT	BE	BU	CZ	DK	FI	FR	DE	GR*	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD (2023)	Biosimilar vs.Referenced product	51%	42%	46%	26%	99%	76%	60%	60%	0%	31%	0%	72%	73%	96%	99%	60%	66%	0%	23%	57%	60%	61%	63%	65%
	Biosimilar vs.Accessible market	19%	36%	46%	14%	70%	25%	31%	37%	0%	16%	0%	39%	62%	73%	99%	33%	51%	0%	14%	39%	48%	14%	42%	42%
	Biosimilar vs. Total market	19%	36%	46%	13%	70%	25%	31%	36%	0%	16%	0%	39%	62%	73%	99%	33%	51%	0%	13%	39%	47%	14%	41%	42%
PRICE PER TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-27%	-37%	-31%	-37%	-22%	-46%	-38%	-9%	-18%	-37%	-25%	-37%	-66%	-47%	0%	-60%	-34%	-40%	-43%	-28%	-53%	-46%	-25%	-37%
	Biosimilar accessible market	-22%	-39%	-31%	-41%	-25%	-49%	-35%	-5%	-18%	-36%	-24%	-33%	-65%	-43%	-1%	-51%	-47%	-35%	-42%	-28%	-53%	-43%	-19%	-35%
	Total market	-22%	-39%	-31%	-36%	-25%	-49%	-35%	-4%	-18%	-36%	-25%	-33%	-65%	-43%	-1%	-51%	-47%	-35%	-36%	-28%	-53%	-43%	-19%	-34%
VOLUME TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	13%	100%	104%	155%	105%	64%	78%	34%	-69%	5%	74%	85%	150%	160%	185%	55%	264%	61%	108%	135%	0%	31%	93%	93%
	Biosimilar accessible market	77%	38%	100%	94%	-8%	112%	73%	33%	-69%	16%	70%	62%	61%	58%	184%	19%	75%	26%	63%	123%	-14%	98%	86%	69%
	Total market	77%	39%	100%	101%	-8%	113%	75%	34%	-69%	16%	86%	63%	61%	58%	184%	19%	75%	26%	79%	125%	-14%	100%	88%	71%
	TD per capita (2023)	0.06	0.12	0.05	0.16	0.13	0.13	0.17	0.07	0.00	0.06	0.07	0.10	0.13	0.20	0.12	0.05	0.04	0.08	0.10	0.21	0.12	0.12	0.07	0.11
	TD/capita (Yr before BS entrance)	0.04	0.10	0.02	0.08	0.15	0.06	0.10	0.05	0.00	0.05	0.05	0.06	0.09	0.14	0.04	0.04	0.02	0.06	0.06	0.10	0.16	0.07	0.04	0.07
	First recorded sales of biosimilars	2008	2009	2012	2010	2011	2008	2007	2006	2015	2012	2006	2007	2008	2011	2008	2014	2008	2013	2010	2007	2007	2010	2007	2006

* Only retail panel data is available for Greece. There are no HGH biosimilar sales in Greece in 2023 and only very low referenced product sales; hence, zero treatment days per capita but slight changes in price and volume since before biosimilar entry in 2015.

Note: 'EU' represents the total sales in European Union countries included in the table (i.e. excluding NO, CH, UK), and the subsequent indicators associated.

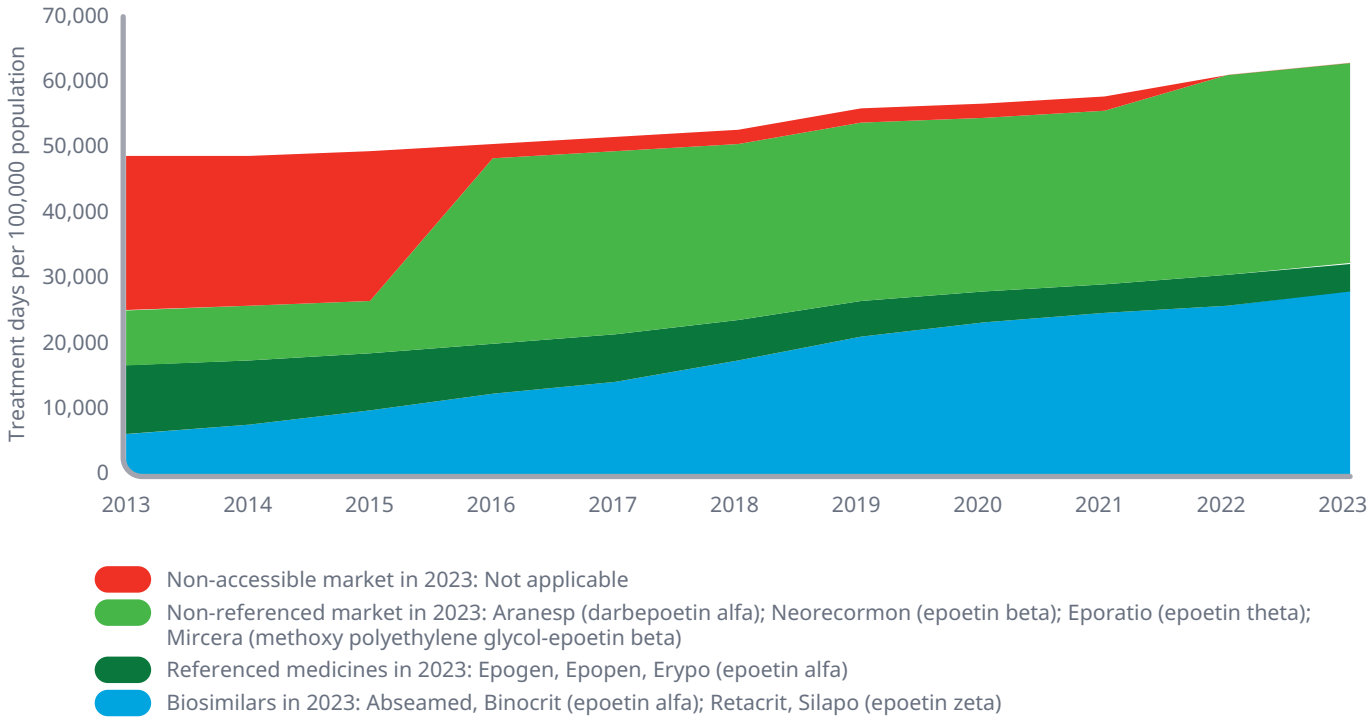
Epoetin (EPO)

EPO is a form of human erythropoietin produced by recombinant technology, with the same amino acid sequence and mechanism of action as endogenous erythropoietin. Its major functions are to promote the differentiation and development of red blood cells and to initiate the production of haemoglobin, the molecule within red blood cells that transports oxygen.

EPO MARKET DEVELOPMENT

According to IQVIA MIDAS and ARK Patent Intelligence insights, protection expired for Mircera (methoxy polyethylene glycol-epoetin beta) in 2022. The figure below reflects this shift from the molecule from a non-accessible product, to one that is now open to biosimilar competition but is yet to be referenced.

EPO market development



EPO approved indications

NAMING		CLASSIFICATION											INDICATIONS					DOSING/ ADMINISTRATION	
MOLECULE	PRODUCT	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	ANEMIA FOR CHEMOTHERAPY PATIENTS	ANEMIA FOR PATIENTS WITH CKD*	PREVENTING ANEMIA IN PREMATURE BABIES	ANEMIA IN ADULTS WITH MDS	REDUCTION OF ALLOGENIC TRANSFUSION EXPOSURE IN ORTHAPEDIC SURGERY	PATIENT TYPE** (ADULT OR PEDIATRIC)	FREQUENCY
DARBEPOETIN ALFA	ARANESP	●	●	●	●	●	●	●	●	●	●	●	●	●			●	Both	3 x per week
EPOETIN ALFA	ABSEAMED BINOCRIT EPOGEN EPOPEN ERYPO	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●		● ● ● ●	● ● ● ● ●	Both	3 x per week
EPOETIN BETA	NEORECORMON	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	Both	3 x per week
EPOETIN DELTA	DYNEPO***	●											●	●	●			Both	3 x per week
EPOETIN THETA	EPORATIO	●	●	●	●	●	●	●	●	●	●	●	●	●				Adult	3 x per week
EPOETIN ZETA	RETACRIT SILAPO	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●				Both	3 x per week
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA	MIRCERA	●	●	●	●	●	●	●	●	●	●	●		●				Adult	Every 2 weeks

● Non-accessible market ● Non-referenced market ● Referenced medicines ● Biosimilars

* Anaemia for patients with Chronic kidney disease.

** Subcutaneous injection is typically used for chemotherapy patients. Intravenous injection is typically used for patients with kidney problems and for patients who are going to donate their own blood.

*** Dynepo has been discontinued.

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries

		AT	BE	BU	CZ	DK*	FI	FR	DE	GR**	HU	IE*	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD 2023	Biosimilar vs.Referenced product	80%	21%	100%	97%		100%	80%	92%	95%	100%		93%	28%	100%	100%	99%	100%	100%	80%	98%	98%	26%	21%	90%
	Biosimilar vs.Accessible market	22%	7%	59%	31%	0%	16%	29%	60%	93%	53%	0%	82%	1%	6%	32%	27%	48%	57%	18%	58%	19%	1%	5%	49%
	Biosimilar vs. Total market	22%	7%	59%	31%	0%	16%	29%	60%	93%	53%	0%	82%	1%	6%	32%	27%	48%	57%	18%	58%	19%	1%	5%	49%
PRICE PER TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-48%	-26%	-19%	-58%	-100%	-58%	-41%	-60%	-59%	-87%	-100%	-25%	-55%	-50%	-73%	-82%	-59%	-65%	-55%	-78%	-41%	-55%	-18%	-45%
	Biosimilar accessible market	-52%	-15%	-27%	-51%	-39%	-46%	-47%	-58%	-59%	-65%	-40%	-23%	-48%	-34%	-50%	-76%	-50%	-62%	-56%	-57%	-48%	-48%	-20%	-44%
	Total market	-48%	-26%	-36%	-50%	-36%	-43%	-45%	-57%	-59%	-59%	-36%	-20%	-49%	-31%	-46%	-74%	-49%	-61%	-56%	-55%	-47%	-46%	-18%	-43%
VOLUME TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	19%	54%	147%	482%	-100%	2709%	94%	169%	585%	153%	-100%	283%	-78%	90%	18524%	318%	126%	437%	-14%	114%	21%	-59%	174%	165%
	Biosimilar accessible market	89%	242%	113%	398%	124%	323%	140%	98%	314%	111%	59%	147%	112%	476%	1099%	275%	-46%	150%	77%	74%	114%	216%	214%	124%
	Total market	-2%	25%	63%	256%	-1%	45%	24%	21%	174%	-7%	-7%	58%	-9%	37%	666%	22%	-53%	32%	22%	5%	18%	30%	80%	27%
	TD per capita (2023)	0.87	0.63	0.43	0.32	0.47	0.48	1.09	0.46	0.06	0.34	0.43	1.34	0.46	0.27	0.22	0.53	0.14	0.59	0.62	0.70	0.52	0.41	0.41	0.67
	TD/capita (Yr before BS entrance)	0.98	0.53	0.23	0.09	0.50	0.35	0.94	0.39	0.02	0.35	0.55	0.85	0.55	0.23	0.03	0.43	0.28	0.45	0.54	0.70	0.51	0.37	0.25	0.54
	First recorded sales of biosimilars	2008	2014	2011	2011	2012	2008	2009	2007	2008	2009	2008	2008	2009	2008	2009	2010	2009	2010	2009	2009	2008	2009	2009	2007

* Denmark and Ireland have no biosimilar or referenced medicine sales in 2023, hence the blank cells. There are non-referenced product sales and therefore is an accessible market. ** Only retail panel data is available for Greece.

Note: Volume evolution of Epoetins is considerable for certain countries, due to low sales volumes for epoetin alfa originators before biosimilar entry, and increased volumes from biosimilars since LoE; 'EU' represents the total sales in European Union countries included in the table (i.e. excluding NO, CH, UK), and the subsequent indicators associated.

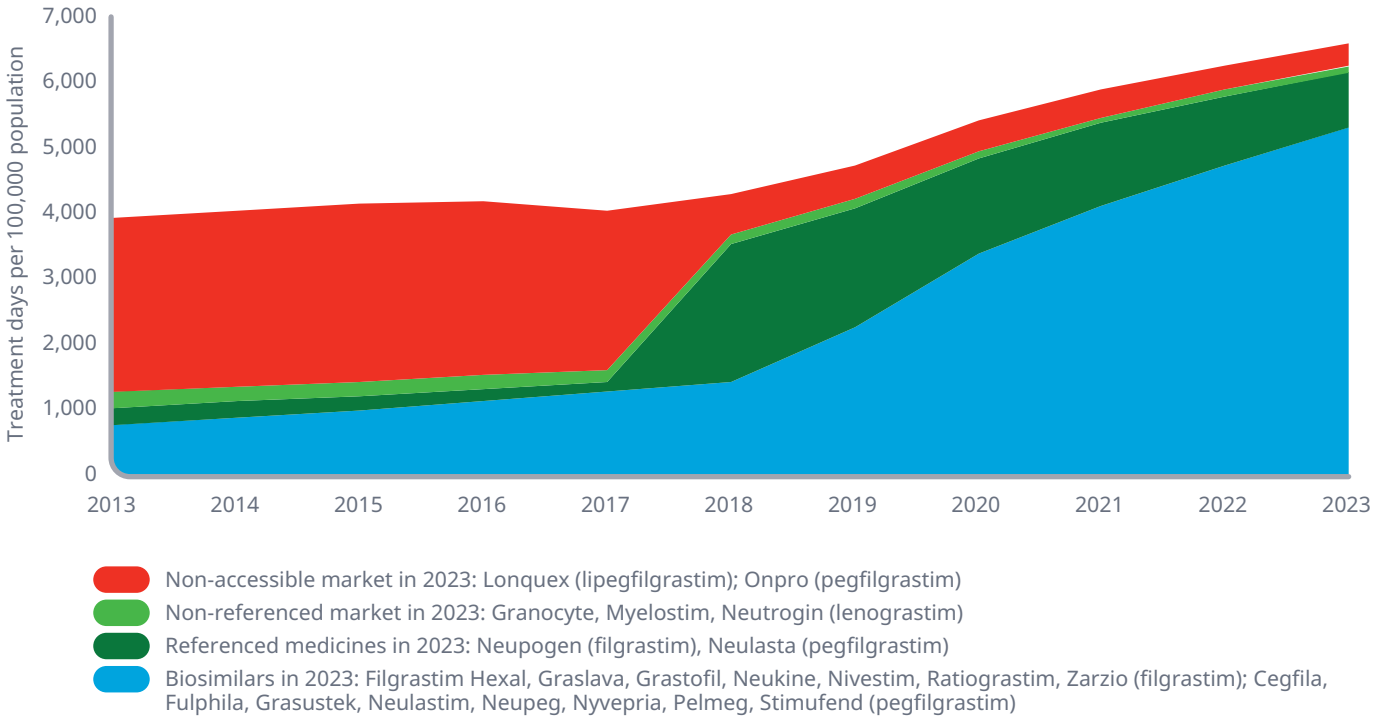
Granulocyte-colony stimulating factor (GCSF)

G-CSF is a glycoprotein that stimulates the bone marrow to produce granulocytes and stem cells and release them into the bloodstream. G-CSF is used prophylactically with certain cancer patients accelerate recovery from neutropenia after chemotherapy, allowing higher-intensity treatment regimens.

GCSF MARKET DEVELOPMENT

According to IQVIA MIDAS and ARK Patent Intelligence insights protection expired in 2018 for a significant molecule in this class, Neulasta (pegfilgrastim). The figure below reflects this shift from the molecule as a non-accessible product with protection, to one that is now open to biosimilar competition and has been referenced within the same year by a significant number of biosimilars.

GCSF market development



ADDITIONAL INFORMATION ABOUT GCSF MEDICINES

Subcutaneous injection typically used to administer G-CSF daily for 5-7 days, starting 72 hrs after completion of chemotherapy or bone marrow transplantation, with the exception of pegfilgrastim and lipegfilgrastim which are long-acting G-CSF and therefore administered once only at least 24 hrs after completion of each chemotherapy cycle.

GSCF approved indications

NAMING		CLASSIFICATION											INDICATIONS					
WMOLECULE	PRODUCT	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	CYTOTOXIC CHEMOTERAPY ASSOCIATED WITH FEBRILE INDUCED NEUTROPENIA	NEUTROPENIA INDUCED BY ACUTE MYELOID LEUKEMIA	BONE MARROW TRANSPLANTATION FOR NON MYELOID MALIGNANCY INDUCED NEUTROPENIA	MOBILISATION OF PERIPHERAL BLOOD PROGENITOR CELLS (PBPCS)	SEVERE CHRONIC NEUTROPENIA (SCN) WITH DIAGNOIS OF CONGENITAL, CYCLIC, OR IDIOPATHIC NEUTROPENIA	NEUTROPENIA PREVENTION AND TREATMENT IN PATIENTS WITH HIV
FILGRASTIM	GRANULOKINE GRASALVA GRASTOFIL NEUKINE NEUPOGEN NIVESTIM RATIOGRASTIM ZARZIO FILGRASTIM HEXAL	● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●	● ● ●	● ● ●	● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●
LENOGRASTIM	GRANOCYTE MYELOSTIM NEUTROGIN	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●		● ● ●	● ● ●		
LIPEGFILGRASTIM	LONQUEX	●	●	●	●	●	●	●	●	●	●	●	●					
PEGFILGRASTIM	NEULASTA ONPRO NEULASTIM NEUPEG PELMEG FULPHILA CEGFILA GRASUSTEK NYVEPRIA STIMUFEND	●	●	●	●	●	● ● ● ● ● ●	● ● ● ● ● ●	● ● ● ● ● ●	● ● ● ● ● ●	● ● ● ● ● ●	● ● ● ● ● ●	● ● ● ● ● ● ● ● ● ●					

● Non-accessible market ● Non-referenced market ● Referenced medicines ● Biosimilars

Notes: Tevagrastim = Grasalva in IQVIA MIDAS; Accofil = Neukine in IQVIA MIDAS; Ziextenzo = Neulastim in IQVIA MIDAS; Pelgraz (EMA name approved in 2018) = Neupeg in IQVIA MIDAS.

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries

		AT	BE	BU	CZ	DK	FI	FR	DE	GR*	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD (2023)	Biosimilar vs.Referenced product	65%	70%	79%	100%	100%	93%	88%	68%	99%	100%	33%	91%	97%	99%	100%	100%	96%	100%	43%	90%	99%	70%	90%	86%
	Biosimilar vs.Accessible market	65%	70%	79%	100%	100%	93%	85%	67%	99%	100%	33%	91%	97%	99%	100%	99%	96%	100%	43%	90%	99%	70%	88%	85%
	Biosimilar vs. Total market	56%	47%	50%	92%	100%	89%	84%	60%	97%	100%	30%	85%	97%	99%	100%	99%	96%	89%	40%	90%	98%	70%	88%	80%
PRICE PER TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-80%	-70%	-88%	-89%	-67%	-84%	-77%	-74%	-74%	-89%	-74%	-59%	-72%	-62%	-92%	-98%	-76%	-91%	-90%	-53%	-77%	-61%	-25%	-75%
	Biosimilar accessible market	-80%	-70%	-88%	-89%	-67%	-84%	-76%	-73%	-74%	-89%	-74%	-59%	-72%	-62%	-92%	-98%	-76%	-91%	-90%	-53%	-77%	-61%	-24%	-74%
	Total market	-67%	-56%	-84%	-85%	-43%	-74%	-60%	-62%	-59%	-86%	-49%	-40%	-52%	-37%	-91%	-93%	-76%	-85%	-84%	-43%	-68%	-36%	-10%	-64%
VOLUME TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	934%	1244%	4825%	2832%	1105%	1271%	2435%	926%	5369%	761%	1079%	520%	1456%	3039%	1187%	842%	2430%	3813%	1431%	120%	959%	602%	698%	1003%
	Biosimilar accessible market	934%	1245%	4825%	2832%	1107%	1271%	2525%	945%	5370%	761%	1089%	523%	1456%	3039%	1187%	844%	2430%	3813%	1431%	121%	960%	602%	714%	1018%
	Total market	145%	150%	4737%	1098%	93%	104%	131%	167%	-24%	99%	101%	29%	24%	240%	434%	8%	2294%	1289%	394%	-26%	170%	105%	169%	128%
	TD per capita (2023)	0.13	0.11	0.09	0.05	0.08	0.11	0.12	0.06	0.02	0.07	0.10	0.04	0.04	0.09	0.09	0.04	0.08	0.12	0.09	0.03	0.06	0.05	0.04	0.07
	TD/capita (Yr before BS entrance)	0.06	0.05	0.00	0.00	0.04	0.06	0.05	0.02	0.02	0.03	0.06	0.03	0.03	0.03	0.02	0.03	0.00	0.01	0.02	0.04	0.02	0.03	0.02	0.03
	First Recorded sales of Biosimilars	2009	2011	2009	2010	2009	2009	2009	2008	2009	2009	2009	2009	2009	2009	2009	2010	2009	2009	2009	2009	2009	2009	2008	2008

* Only retail panel data is available for Greece.

Note: Volume evolution of GCSF therapy area is considerable, due to very low sales volumes before biosimilar entry (from filgrastim and pegfilgrastim originators), and considerable uptake of pegfilgrastim biosimilars since LoE; 'EU' represents the total sales in European Union countries included in the table (i.e. excluding NO, CH, UK), and the subsequent indicators associated.

Anti-tumour necrosis factor (Anti-TNF)

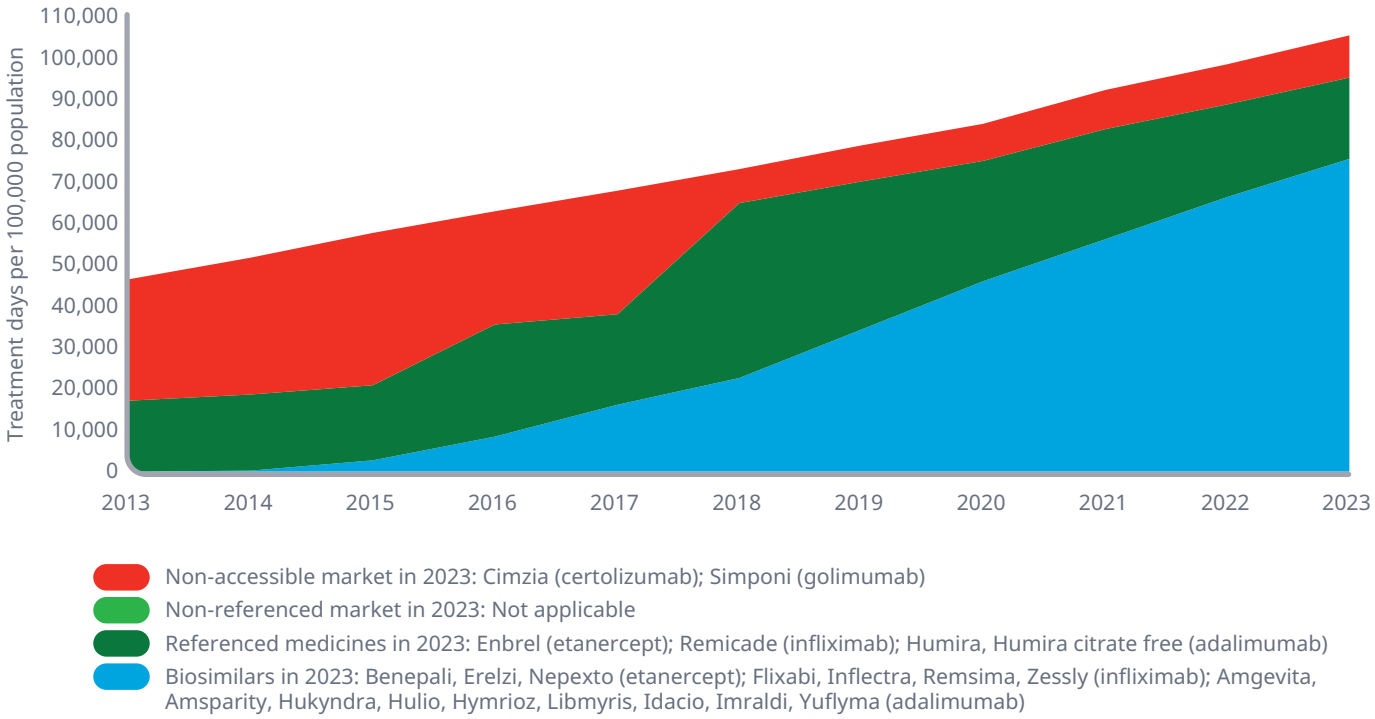
Anti-TNF drugs are a class of drugs that are used to treat inflammatory conditions such as Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, Juvenile Arthritis, Crohn's Disease, Ulcerative Colitis, Psoriasis and Hidradinitis Suppurativa. These drugs are able to reduce inflammation and stop disease progression.

TNF is a chemical produced by the immune system that causes inflammation in the body. In healthy individuals, excess TNF in the blood is blocked naturally, but in those who have conditions like RA, higher levels of TNF in the blood lead to more inflammation, joint destruction and persistent symptoms. Anti-TNF agents can alter the disease's effect on the body by controlling inflammation in joints, gastrointestinal tract and skin.

ANTI-TNF MARKET DEVELOPMENT

In 2016, Humira Citrate free was launched as an improved formulation to the original adalimumab molecule. This product has been categorised as non-accessible up until biosimilar entry in 2018.

Anti-TNF market development



ADDITIONAL INFORMATION ABOUT ANTI-TNF MEDICINES

In this section we report insights from biosimilars on the market in Europe for three anti-TNF molecules: infliximab, etanercept and adalimumab. The EU approved the first infliximab biosimilars in September 2013, the first etanercept biosimilar in January 2016 and the first adalimumab biosimilar in March 2017. The EMA has also approved several rituximab biosimilars, however these have been considered separately in the Oncology section of the report. The market shares and price/volume evolution figures refer to the total Anti-TNF market, therefore, include all products within each category. This means, for example, in markets where only infliximab biosimilars have launched, the "biosimilar versus referenced product" market share will still represent the biosimilar market share of all the biosimilars and referenced products on the market.

Anti-TNF approved indications

NAMING		CLASSIFICATION											INDICATIONS										DOSING	
MOLECULE	PRODUCT	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	RA	JIA	PSA	AS	AS WITHOUT RADIOGRAPHIC EVIDENCE	CD (ADULT/PEDIATRIC)	UC (ADULT/PEDIATRIC)	PSO (ADULT/ PEDIATRIC)	HS	UV (ADULT/PAEDIATRIC)	FREQUENCY	ROUTE (SUBQ/ IV)	CITRATE FREE (Y/N)
ADALIMUMAB	HUMIRA HUMIRA (citrate free) AMGEVITA HULIO HYRIMOZ IMRALDI IDACIO AMSPARITY YUFLYMA LIBMYRIS HUKYNDRA	●	●	●	● ●	● ● ●	● ● ● ● ● ●	● ● ● ● ● ●	● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ●	Every 2 weeks	SC SC SC SC SC SC SC SC SC SC SC	N Y Y Y N N N Y Y Y Y
CERTOLIZUMAB PEGOL	CIMZIA	●	●	●	●	●	●	●	●	●	●	●	●		●	●				●			Monthly	SC	n/a
ETANERCEPT	ENBREL BENEPALI ERELZI NEPEXTO	●	●	●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●				● ● ● ●			Once or twice weekly	SC SC SC SC	n/a n/a n/a n/a
GOLIMUMAB	SIMPONI	●	●	●	●	●	●	●	●	●	●	●	●		●	●			●				Monthly	SC	n/a
INFLIXIMAB	REMICADE* REMSIMA INFLECTRA FLIXABI ZESSLY	● ●	● ●	● ●	● ● ●	● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ● ● ●		● ● ● ● ●	● ● ● ● ●		● ● ● ● ●	● ● ● ● ●	● ● ● ● ●			Every 8 weeks	IV BOTH IV IV IV	n/a n/a n/a n/a n/a

● Non-accessible market ● Non-referenced market ● Referenced medicines ● Biosimilars

* Protection expired earlier in some markets, resulting in the appearance of biosimilars prior to the formal EU protection expiry.

Notes: RA = rheumatoid arthritis, JIA = Juvenile idiopathic arthritis; PsA = Psoriatic arthritis; AS = Ankylosing spondylitis; CD = Crohn's disease; UC = ulcerative colitis; PPs = plaque psoriasis; HS = Hidradenitis Suppurativa; UV = Uveitis.

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries

		AT	BE	BU*	CZ	DK	FI	FR	DE	GR**	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD (2023)	Biosimilar vs.Referenced product	48%	62%	20%	66%	98%	86%	66%	80%	72%	93%	80%	89%	78%	96%	99%	84%	48%	30%	57%	82%	93%	42%	92%	77%
	Biosimilar vs.Accessible market	48%	62%	20%	66%	98%	86%	66%	80%	72%	93%	80%	89%	78%	96%	99%	84%	48%	30%	57%	82%	93%	42%	92%	77%
	Biosimilar vs. Total market	40%	56%	17%	60%	91%	73%	58%	71%	62%	83%	73%	77%	74%	92%	81%	79%	44%	28%	52%	75%	89%	34%	86%	69%
PRICE PER TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-48%	-24%	-39%		1%		-34%	-2%	-43%	-8%	-11%	34%	-21%		-73%	-63%	-10%	-43%	-55%	-13%	-56%	-1%	30%	-17%
	Biosimilar accessible market	-48%	-24%	-39%		1%		-34%	-2%	-43%	-8%	-11%	34%	-21%		-73%	-63%	-10%	-43%	-55%	-13%	-56%	-1%	30%	-17%
	Total market	-50%	-41%	-49%	-47%	-31%	-53%	-50%	-43%	-39%	-32%	-37%	-18%	-44%	-17%	-76%	-74%	-40%	-55%	-63%	-36%	-68%	-27%	-8%	-44%
VOLUME TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	1003%	207%	>1MN%		378%		308%	466%	168%	327%	977%	364%	345%		1674%	675%	203%	222%	417%	416%	495%	218%	624%	422%
	Biosimilar accessible market	1003%	207%	>1MN%		378%		308%	466%	168%	327%	977%	364%	345%		1674%	675%	203%	222%	417%	416%	495%	218%	624%	422%
	Total market	790%	51%	422%	298%	115%	188%	100%	97%	91%	68%	201%	60%	81%	195%	354%	237%	35%	76%	99%	115%	133%	77%	125%	109%
	TD per capita (2023)	1.41	1.36	0.58	0.92	1.88	1.81	1.21	0.95	0.01	0.55	2.65	0.59	1.71	3.00	0.20	0.97	0.28	0.87	0.91	1.18	2.04	1.38	1.32	0.96
	TD/capita (Yr before BS entrance)	0.17	0.95	0.10	0.24	0.92	0.65	0.62	0.50	0.01	0.32	1.00	0.36	1.00	1.12	0.04	0.29	0.20	0.49	0.47	0.57	0.95	0.84	0.62	0.47
	First recorded sales of biosimilars	2015	2015	2014	2013	2015	2013	2015	2015	2019	2014	2014	2015	2015	2013	2014	2014	2014	2014	2015	2015	2015	2016	2015	2013

* The significant volume increase in Bulgaria is due to no sales of Remicade prior to biosimilar entry in 2014. ** Only retail panel data is available for Greece.

Note: Volume evolution of Anti-TNF therapy area is considerable, due to low volumes of accessible products before biosimilar entry (only infliximab originator), compared to volumes of the accessible market in 2023 (infliximab, etanercept, and adalimumab molecules); Gaps in price and volume per TD are due to there being no 'Non-referenced' or 'Referenced' products in the year before biosimilar entry; 'EU' represents the total sales in European Union countries included in the table (i.e. excluding NO, CH, UK), and the subsequent indicators associated.

Fertility (follitropin alfa)

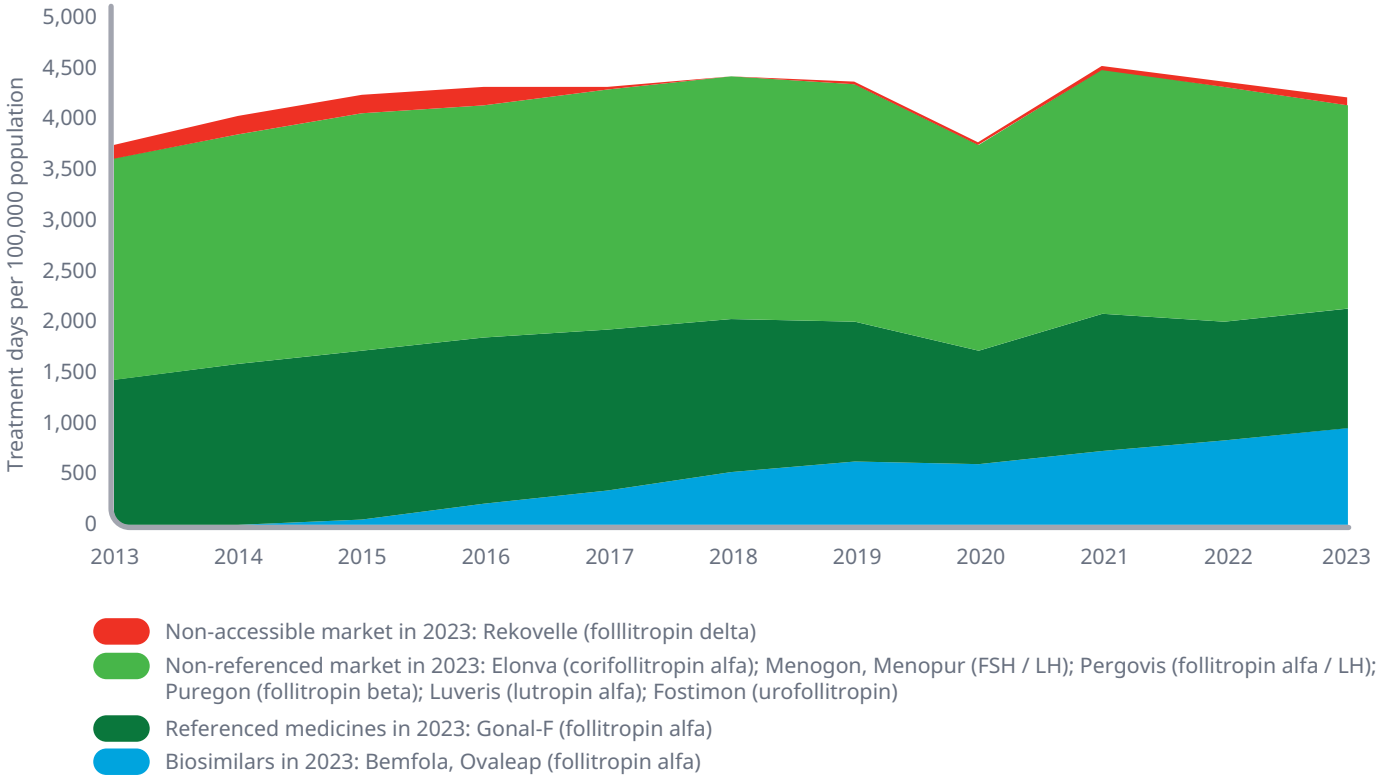
Gonadotropin preparations are drugs that mimic the physiological effects of gonadotropins, used therapeutically primarily as fertility medication for ovarian hyperstimulation and reversal of an ovulation. For the purpose of this report, only Follicle-Stimulating Hormones (FSH) and Luteinizing Hormone (LH) preparations were considered.

FERTILITY MARKET DEVELOPMENT

A significant decline in treatment volume in 2020 is not a trend break in reporting, but the impact of the COVID-19 pandemic on prescriptions in this area and is therefore an accurate assessment of the market dynamics. The market has since recovered to pre-pandemic levels in 2021, however has been declining slightly since.

According to IQVIA MIDAS and ARK Patent intelligence insights, Elonva (corifollitropin alfa) has lost protection and is classified as 'non-referenced' from 2020 onwards.

Fertility market development



Fertility approved indications

NAMING		CLASSIFICATION											INDICATIONS					DOSING/ ADMINISTRATION	
MOLECULE	PRODUCT	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	INFERTILITY	HYPOGONADISM	ANOVULATION	OVULATION INDUCTION	REPRODUCTIVE TECHNIQUES, ASSISTED	ROUTE (SUBQ/IV/ IM)	FREQUENCY
CORIFOLLITROPIN ALFA	ELONVA	●	●	●	●	●	●	●	●	●	●	●	●					SC	Patient specific
FOLLICLE-STIMULATING HORMONE / LUTEINISING HORMONE	MENOGON MENOPUR	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●		●		● ●	SC/IM	Daily Daily
FOLLITROPIN ALFA	GONAL-F BEMFOLA OVALEAP	● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ●	● ●		● ●	All All All	Daily Daily Daily
FOLLITROPIN ALFA/ LUTEINISING HORMONE	PERGOVERIS	●	●	●	●	●	●	●	●	●	●	●	●					All	Daily
FOLLITROPIN BETA	PUREGON	●	●	●	●	●	●	●	●	●	●	●	●	●				SC	Patient specific
FOLLITROPIN DELTA	REKOVELLE	●	●	●	●	●	●	●	●	●	●	●	●			●	●	SC	Daily
LUTROPIN ALFA	LUVERIS	●	●	●	●	●	●	●	●	●	●	●	●			●		All	Daily
UROFOLLITROPIN	FOSTIMON	●	●	●	●	●	●	●	●	●	●	●	●			●		IM	Daily

● Non-accessible market ● Non-referenced market ● Referenced medicines ● Biosimilars

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries

		AT	BE	BU	CZ	DK	FI	FR	DE	GR*	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD (2023)	Biosimilar vs.Referenced product	41%	53%	0%	52%	39%	24%	51%	54%	35%	95%	2%	45%	0%	19%	57%	51%	9%	74%	28%	59%	25%	28%	40%	46%
	Biosimilar vs.Accessible market	12%	17%	0%	23%	17%	16%	29%	25%	19%	54%	1%	19%	0%	12%	23%	23%	5%	49%	22%	30%	14%	10%	26%	24%
	Biosimilar vs. Total market	12%	17%	0%	22%	17%	16%	29%	25%	19%	51%	1%	18%	0%	11%	22%	23%	5%	48%	22%	30%	14%	10%	26%	23%
PRICE PER TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-33%	-6%	-21%	-24%	-27%	-34%	-35%	-12%	-29%	-24%	-39%	-11%	-16%	-4%	-1%	-27%	-15%	-22%	-29%	-26%	-19%	-23%	15%	-24%
	Biosimilar accessible market	-11%	12%	19%	1%	-2%	13%	-16%	19%	16%	12%	8%	7%	-5%	40%	-9%	8%	20%	37%	-7%	4%	-14%	-11%	20%	0%
	Total market	-9%	3%	3%	3%	-7%	7%	-17%	17%	12%	22%	10%	5%	1%	40%	2%	3%	20%	36%	-11%	-1%	-13%	-11%	21%	-2%
VOLUME TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	220%	72%	285%	27%	61%	126%	52%	25%	166%	52%	87%	-24%	18%	158%	103%	125%	152%	134%	115%	50%	99%	33%	29%	36%
	Biosimilar accessible market	29%	38%	-46%	41%	33%	-6%	16%	0%	52%	29%	63%	-9%	-14%	27%	43%	71%	79%	-15%	4%	7%	34%	0%	-18%	12%
	Total market	31%	39%	-46%	44%	27%	-9%	14%	-6%	50%	27%	66%	-11%	-12%	29%	46%	68%	81%	-13%	4%	-1%	36%	1%	-18%	9%
	TD per capita (2023)	0.01	0.05	0.00	0.06	0.09	0.03	0.08	0.03	0.03	0.06	0.10	0.05	0.05	0.06	0.02	0.04	0.02	0.02	0.05	0.06	0.08	0.05	0.01	0.05
	TD/capita (Yr before BS entrance)	0.01	0.04	0.01	0.05	0.07	0.03	0.07	0.03	0.02	0.05	0.07	0.06	0.06	0.05	0.01	0.02	0.01	0.02	0.05	0.06	0.06	0.05	0.01	0.04
	First recorded sales of biosimilars	2014	2015	2016	2015	2014	2014	2015	2014	2016	2015	2016	2015	2016	2014	2015	2015	2017	2016	2015	2015	2014	2018	2015	2014

* Only retail panel data is available for Greece.

Note: 'EU' represents the total sales in European Union countries included in the table (i.e. excluding NO, CH, UK), and the subsequent indicators associated.

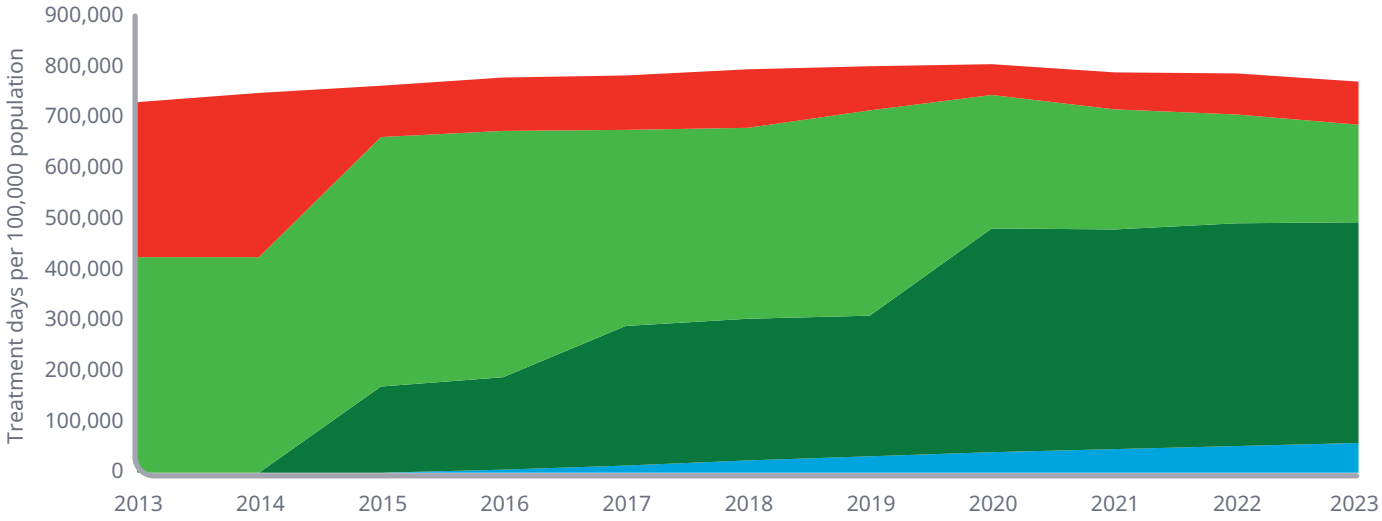
Insulins

Recombinant human insulin is a form of insulin made from recombinant DNA that is identical to human insulin; used to treat diabetics who are allergic to preparations made from beef or pork insulin.

INSULIN MARKET DEVELOPMENT

According to IQVIA MIDAS and ARK Patent intelligence insights, Apidra (insulin glulisine) has lost protection and is classified as 'non-referenced' from 2019 onwards.

Insulin market development



- Non-accessible market in 2023: Ryzodeg (insulin aspart / insulin degludec); Tresiba (insulin degludec); Xultophy (insulin degludec / liraglutide); Toujeo (insulin glargine); Soliqua (insulin glargine / lixisenatide)
- Non-referenced market in 2023: Novomix (insulin aspart / proatmine); Levemir (insulin detemir); Apidra (insulin glulisine); Actrapid, Humulin, Protaphane (insulin human); Humalog/Liprolog Mix (insulin lispro / insulin lispro protamine)
- Referenced medicines in 2023: Novorapid (insulin aspart), Lantus (insulin glargine); Humalog / Liprolog (insulin lispro)
- Biosimilars in 2023: Insulin aspart SNFI, Kirsty (insulin aspart); Truvelog Mix 30 (insulin aspart / protamine); Abasaglar, Semglee (insulin glargine); Ademlog / insulin lispro SNFI (insulin lispro)

ADDITIONAL INFORMATION ABOUT INSULIN MEDICINES

Insulin preparations differ mainly by their kinetic/pharmacodynamic profiles. They are usually classified as rapid- (faster acting than soluble human insulin), short- (e.g. soluble human insulin), intermediate- (NPH /Neutral Protamine Hagedorn insulin, e.g. human isophane insulin), and long-acting preparations (insulins with action profiles significantly longer than NPH insulin). They are used alone or as free mixtures or premixed preparations of rapid/short-acting insulin and intermediate/long-acting (biphasic) insulin in various proportions.

Regular insulin is a short-acting insulin and is generally injected subcutaneously (SubQ) 2–5 times daily within 30–60 minutes before a meal. In conventional regimen the total daily insulin dose is administered as a mixture of rapid/short-acting and intermediate-acting insulins in 1–2 injections. In intensive regimen the total daily dose is administered as 3 or more injections or by continuous subcutaneous infusion to cover basal and pre-meal bolus insulin requirements.

Insulin approved indications

NAMING		CLASSIFICATION											INDICATIONS	DOSING/ADMINISTRATION	
MOLECULE	PRODUCT	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	DIABETES MELLITUS	FREQUENCY	MODE OF ACTION
INSULIN ASPART	NOVORAPID INSULIN ASPART SANOFI KIRSTY	●	●	●	●	●	●	●	● ●	● ● ●	● ● ●	● ● ●	● ● ●	before every meal	Fast-acting
INSULIN ASPART#INSULIN ASPART PROTAMINE	NOVOMIX TRUVELOG MIX 30	●	●	●	●	●	●	●	●	●	● ●	● ●	● ●	before every meal	Fast-acting
INSULIN ASPART#INSULIN DEGLUDEC	RYZODEG	●	●	●	●	●	●	●	●	●	●	●	●	daily	Fast-acting
INSULIN DEGLUDEC	TRESIBA	●	●	●	●	●	●	●	●	●	●	●	●	daily	Long-acting
INSULIN DEGLUDEC / LIRAGLUTIDE	XULTOPHY		●	●	●	●	●	●	●	●	●	●	●	daily	Long-acting
INSULIN DETEMIR	LEVEMIR	●	●	●	●	●	●	●	●	●	●	●	●	twice a day	Long-acting
INSULIN GLARGINE	LANTUS TOUJEO ABASAGLAR SEMGLEE	●	●	● ● ●	● ● ●	● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	daily daily daily daily	Long-acting Long-acting Long-acting Long-acting
INSULIN GLARGINE / LIXISENATIDE	SOLIQUA					●	●	●	●	●	●	●	●	daily	Long-acting
INSULIN GLULISINE	APIDRA	●	●	●	●	●	●	●	●	●	●	●	●	before every meal	Fast-acting
INSULIN HUMAN*	ACTRAPID HUMULIN PROTAPHANE	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	before every meal once/twice a day once/twice a day	Short-acting Short-acting Intermediate-acting
INSULIN LISPRO	HUMALOG/LIPROLOG ADEMLOG/ INSULIN LISPRO SANOFI	●	●	●	●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	before every meal before every meal	Fast-acting Fast-acting
INSULIN LISPRO#INSULIN LISPRO PROTAMINE	HUMALOG /LIPROLOG MIX	●	●	●	●	●	●	●	●	●	●	●	●	determined by physician	Fast-acting

● Non-accessible market ● Non-referenced market ● Referenced medicines ● Biosimilars

* Only the top 3 products by sales are shown in the table

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries

		AT	BE	BU*	CZ	DK	FI	FR	DE	GR**	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD (2023)	Biosimilar vs.Referenced product	8%	1%	3%	4%	20%	5%	16%	9%	10%	2%	0%	10%	32%	11%	23%	15%	5%	17%	5%	14%	28%	0%	5%	13%
	Biosimilar vs.Accessible market	5%	1%	1%	3%	18%	4%	14%	6%	8%	1%	0%	9%	26%	8%	11%	9%	3%	9%	2%	11%	21%	0%	3%	10%
	Biosimilar vs. Total market	5%	1%	1%	2%	14%	4%	12%	6%	6%	1%	0%	8%	22%	7%	10%	8%	3%	8%	2%	10%	20%	0%	3%	8%
PRICE PER TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-34%	-38%					-40%		-24%		-40%	-32%				-29%	-16%		-48%					-25%
	Biosimilar accessible market	-1%	-11%		26%	-25%	0%	-22%	25%	-5%	33%	-17%	-11%	3%	32%	8%	1%	15%	22%	-17%	19%	17%	0%	13%	5%
	Total market	1%	-6%		30%	-24%	-23%	-11%	10%	25%	71%	-12%	25%	-9%	50%	3%	3%	34%	39%	10%	-10%	3%	3%	-1%	5%
VOLUME TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	434%	236%					157%		113%		284%	163%				144%	163%		330%					545%
	Biosimilar accessible market	-7%	7%		40%	64%	154%	23%	18%	-4%	4%	38%	-2%	84%	28%	12%	8%	22%	43%	-13%	145%	61%	80%	114%	28%
	Total market	-6%	8%		26%	4%	-5%	21%	-11%	7%	-7%	30%	-6%	-5%	14%	-4%	8%	34%	4%	-6%	1%	0%	8%	23%	2%
	TD per capita (2023)	4.96	6.90	6.30	9.42	6.60	10.82	7.36	9.96	7.66	8.76	5.56	5.48	8.53	7.47	6.62	5.79	7.10	6.78	7.79	6.90	9.27	4.68	8.39	7.56
	TD/capita (Yr before BS entrance)	5.50	6.69		7.72	6.70	11.62	6.25	11.74	6.89	9.12	4.79	5.65	9.54	7.02	6.66	5.45	5.11	6.51	8.55	7.10	10.07	4.68	7.23	7.55
	First recorded sales of biosimilars	2017	2016	2015	2015	2015	2015	2016	2015	2016	2015	2016	2016	2015	2015	2015	2016	2016	2015	2016	2015	2015	2015	2015	2015

* Data the year before biosimilar entry in Bulgaria is not available, hence data gaps. ** Only retail panel data is available for Greece.

Note: Gaps in price and volume per TD are due to there being no 'Non-referenced' or 'Referenced' products in the year before biosimilar entry; 'EU' represents the total sales in European Union countries included in the table (i.e. excluding NO, CH, UK), and the subsequent indicators associated.

Oncology

Monoclonal Antibody Antineoplastic agents use monoclonal antibodies (mAb) to bind monospecifically to certain cells or proteins to treat cancer. The objective is that this treatment will stimulate the patient's immune system to attack those cells.

Mabthera is a medicine used to treat several blood cancers and inflammatory conditions, including follicular lymphoma and diffuse large B cell non-Hodgkin's lymphoma (two types of non-Hodgkin's lymphoma) and Chronic Lymphocytic Leukaemia (CLL). It is also used to treat severe RA and other inflammatory conditions. Considering that the primary indications used for Mabthera and rituximab biosimilars are in Oncology, and since IQVIA sales and treatment day volume cannot be split by indication, rituximab market dynamics are only considered in this separate Oncology section, within the Monoclonal Antibody Antineoplastic class.

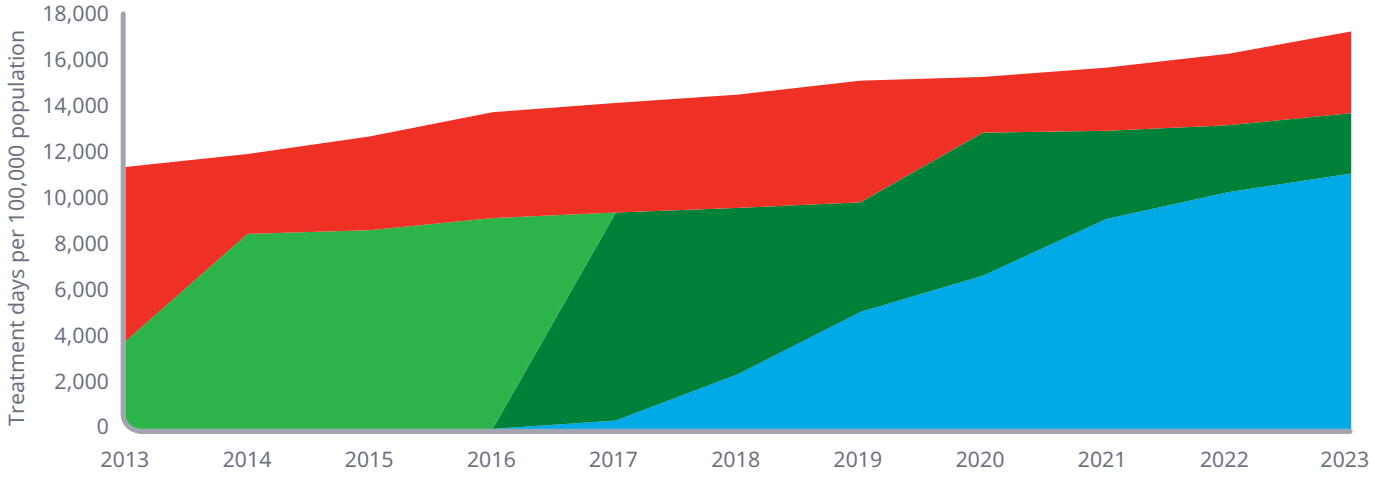
In this market the non-accessible products are classified by identifying products which have a similar mechanism of action, and are used for similar indications to rituximab. There are both IV and SC forms of Mabthera available, but because the biosimilar is only available in IV form, Mabthera IV is classified as the referenced product, and Mabthera SC is classified as a non-referenced product.

WHO DDD's are not available for all products in this class, so rituximab DDD's were calculated using IQVIA Oncology Dynamics data (MAT Dec 2017), accounting for the dosing and length of the treatment cycle in EU5. For other products in the class, the DDD's were calculated using EMA dosing information.

ONCOLOGY MARKET DEVELOPMENT

Perjeta (pertuzumab) and Phesgo (pertuzumab/trastuzumab) have been included since the 2022 report and classified within the 'non-accessible' market. This means that the total market is ~10–15% bigger than in the 2021 report, therefore caution should be taken when comparing between reports for this therapy area.

Oncology market development



Non-accessible market in 2023: Kadcyla (trastuzumab emtansine), Enhertu (trastuzumab deruxtecan); Perjeta (pertuzumab); Phesgo (pertuzumab / trastuzumab)

Non-referenced market in 2023: Not applicable

Referenced medicines in 2023: Mabthera (rituximab), Herceptin (trastuzumab), Avastin (bevacizumab)

Biosimilars in 2023: Mvasi, Zirabev, Aybintio, Abevmy, Alymsys, Onbevzi, Oyavas, Vegzelma (bevacizumab); Rixathon, Truxima, Blitzima, Ruxience (rituximab); Herzuma, Kanjinti, Ogivri, Ontruzant, Hertraz, Trazimera, Zercepac, Herwenda (trastuzumab)

Oncology approved indications

NAMING		CLASSIFICATION											INDICATIONS									DOSING	
MOLECULE	PRODUCT	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	FL, DLBC (NON-GL)	CLL	MC	BC	METASTATIC GC	RCC	NSCLC	EOC	PPC	ROUTE (SUBQ/IV)	FREQUENCY
BEVACIZUMAB	AVASTIN MVASI ZIRABEV AYBINTIO EQUIDACENT ABEVMY ALYMSYS ONBEVZI OYAVAS VEGZELMA	●	●	●	●	●	●	●	●	●	●	●			●	●		●	●	●	●	IV IV IV IV IV IV IV IV IV IV	2 – 3 week cycles (indication/ combination dependant)
RITUXIMAB*	MABTHERA RIXATHON TRUXIMA BLITZIMA RITEMVIA RUXIENCE	●	●	●	●	●	●	●	●	●	●	●	●	●								SC/IV IV IV IV IV IV	3 week cycles
TRASTUZUMAB**	HERCEPTIN HERZUMA KANJINTI ONTRUZANT HERTRAZ TRAZIMERA ZERCEPAC HERWENDA	●	●	●	●	●	●	●	●	●	●	●				●	●					SC/IV IV IV IV IV IV IV IV	3 week cycles
TRASTUZUMAB EMTANSINE	KADCYLA	●	●	●	●	●	●	●	●	●	●	●				●						IV	3 week cycles
TRASTUZUMAB DERUXTECAN	ENHERTU								●	●	●	●				●						IV	3 week cycles
PERTUZUMAB	PERJETA	●	●	●	●	●	●	●	●	●	●	●				●						IV	3 week cycles
ERTUZUMAB-#TRASTUZUMAB	PHESGO								●	●	●	●				●						SC	3 week cycles

● Non-accessible market ● Non-referenced market ● Referenced medicines ● Biosimilars

* Indicated for non-oncology indications such as rheumatoid arthritis, Granulomatosis with polyangiitis and microscopic polyangiitis, Pemphigus vulgaris;
** Eleftha has been excluded as it is not approved via EMA biosimilars pathway;
Equidacent was withdrawn on 2021/10; Ritemvia was withdrawn on 2021/06
FL = follicular lymphoma, DLBC = Diffuse large B-cell lymphoma, MC = metastatic carcinoma, GC = gastic cancer, RCC = renal cell carcinoma, NSCLC = non-small cell lung cancer, EOC = epithelial ovarian cancer, PPC = Primary peritoneal cancer.

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries

		AT	BE	BU	CZ	DK	FI	FR	DE	GR*	HU	IE	IT	NL	NO	PL	PT	RO**	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD (2023)	Biosimilar vs.Referenced product	92%	56%	55%	59%	96%	79%	80%	90%	0%	87%	60%	88%	94%	96%	65%	70%		78%	63%	87%	91%	52%	66%	83%
	Biosimilar vs.Accessible market	92%	56%	55%	59%	96%	79%	80%	90%	0%	87%	60%	88%	94%	96%	65%	70%		78%	63%	87%	91%	52%	66%	83%
	Biosimilar vs. Total market	72%	43%	43%	47%	83%	67%	67%	70%	0%	75%	49%	68%	78%	79%	47%	55%		65%	46%	70%	77%	39%	46%	67%
PRICE PER TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-1%	-25%	-43%	-34%		-19%				-24%					-66%			-46%	-49%		-6%	-23%		-26%
	Biosimilar accessible market	-1%	-25%	-43%	-34%	-14%	-19%	-47%	-35%		-24%	-31%	-14%	-30%	15%	-66%	-57%		-46%	-49%	-30%	-6%	-23%	0%	-33%
	Total market	15%	-20%	-21%	-7%	-1%	-3%	-21%	-16%		-16%	-16%	5%	-23%	30%	-19%	-25%		-22%	-17%	-11%	16%	-3%	47%	-12%
VOLUME TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	66%	50%	127%	26%		51%				91%					13%			79%	-4%		17%	25%		608%
	Biosimilar accessible market	66%	50%	127%	26%	35%	51%	140%	50%		91%	33%	18%	46%	82%	13%	92%		79%	-4%	66%	17%	25%	-18%	63%
	Total market	17%	25%	58%	11%	6%	26%	69%	11%		24%	18%	1%	25%	70%	29%	82%		22%	3%	47%	7%	12%	2%	30%
	TD per capita (2023)	0.21	0.20	0.19	0.12	0.17	0.20	0.29	0.20	0.00	0.15	0.18	0.15	0.17	0.22	0.09	0.17		0.13	0.13	0.19	0.15	0.20	0.12	0.18
	TD/capita (Yr before BS entrance)	0.19	0.17	0.11	0.11	0.17	0.16	0.17	0.18		0.12	0.17	0.15	0.14	0.13	0.07	0.09		0.11	0.12	0.14	0.15	0.18	0.12	0.14
	First recorded sales of biosimilars	2018	2018	2018	2018	2017	2018	2017	2017		2018	2017	2017	2017	2017	2018	2017	2018	2018	2018	2017	2018	2018	2017	2017

* Only retail panel data is available for Greece. ** Sales data for key oncology medicines is incomplete in Romania, and hence data gaps.

Note: Gaps in price and volume per TD are due to there being no 'Non-referenced' or 'Referenced' products in the year before biosimilar entry; 'EU' represents the total sales in European Union countries included in the table (i.e. excluding NO, CH, UK), and the subsequent indicators associated.

Low-molecular-weight heparin (LMWH)

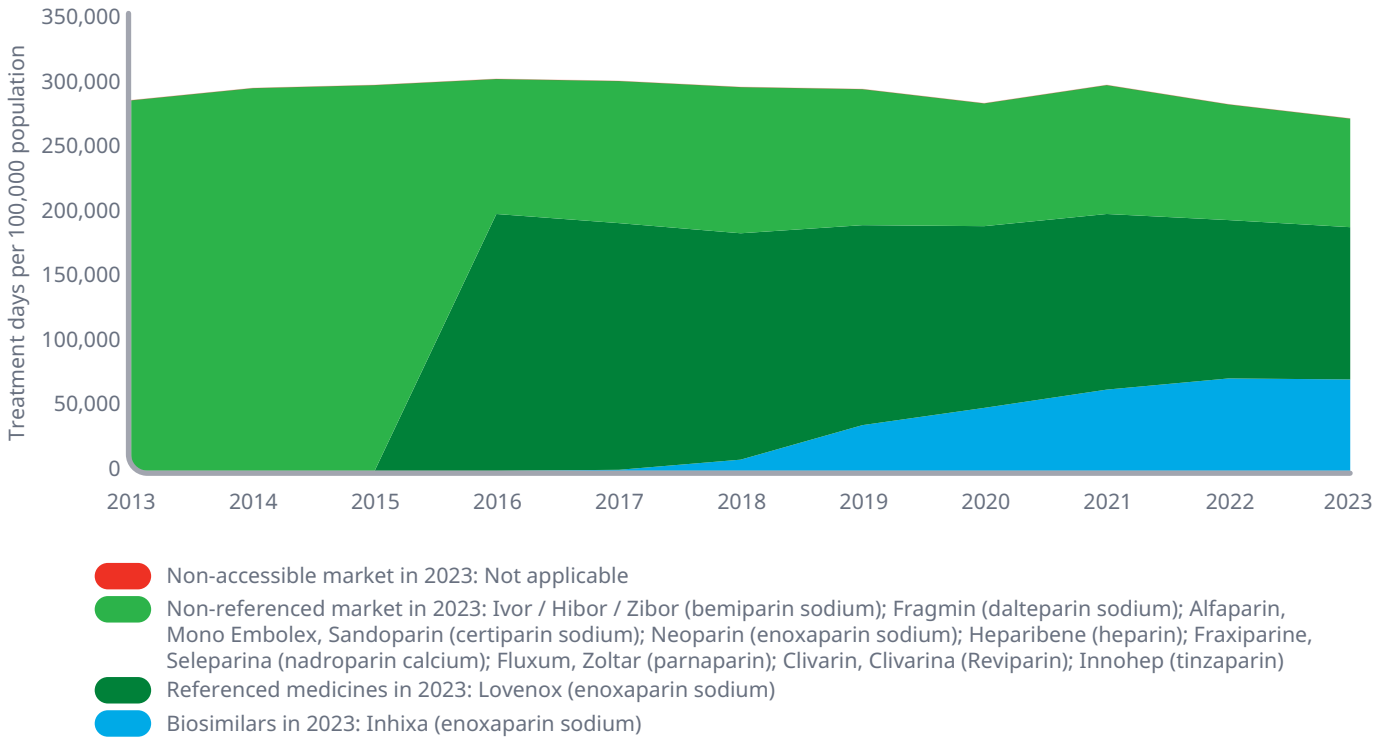
Low-Molecular-Weight Heparin (LMWH) is a class of anticoagulant medications. They are used in the prevention of blood clots, treatment of venous thromboembolism (deep vein thrombosis and pulmonary embolism) and in the treatment of myocardial infarction. LMWH is obtained by fractionation of polymeric heparin. Many LMWH products are on the market, each similar in structure but created using different initial chemical procedures e.g. Enoxaparin is created using alkaline beta-eliminative cleavage of the benzyl ester of heparin.

Two enoxaparin sodium biosimilars (Inhixa and Thorinane) were authorised by the EMA (via centralized procedure) in 09/2016, however Thorinane is now withdrawn meaning that Inhixa is the only remaining centrally authorised biosimilar. However, the biosimilar segment for Enoxaparin Sodium also includes biosimilars approved at a national level, i.e. Enoxaparin Becat (also known in some EU countries as Losmina, Enoxaparin Rovi, Crusia and Arovi). According to the EMA Biosimilars information guide: *"Nearly all biosimilars approved for use in the EU have been approved centrally, as they use biotechnology for their production. Some biosimilars may be approved at national level, such as some low-molecular weight heparins derived from porcine intestinal mucosa."*

LMWH MARKET DEVELOPMENT

Products for molecules in this class (bemiparin sodium, certoparin sodium, dalteparin sodium, heparin, nadroparin calcium, parnaparin, reviparin and tinzaparin) are classified as 'non-referenced' products since 2021 report, according to the definition outlined on page 16 to reflect that they are not protected according to IQVIA MIDAS and ARK Patent intelligence.

LMWH market development



LMWH approved indications

NAMING		CLASSIFICATION											INDICATIONS			
MOLECULE	PRODUCT	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	DEEP VEIN THROMBOSIS TREATMENT AND PROPHYLAXIS	PULMONARY EMBOLISM	ATRIAL THROMBUS	BRIDGING THERAPY PRIOR TO STARTING WARFARIN
BEMIPARIN SODIUM	IVOR/HIBOR/ZIBOR	●	●	●	●	●	●	●	●	●	●	●	●	●		
CERTOPARIN SODIUM	ALFAPARIN MONO EMBOLEX SANDOPARIN	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●		
DALTEPARIN SODIUM	FRAGMIN	●	●	●	●	●	●	●	●	●	●	●	●			
ENOXAPARIN SODIUM	LOVENOX NEOPARIN INHIXA	●	●	●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●			● ● ●
HEPARIN	HEPARIBENE	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
NADROPARIN CALCIUM	FRAXIPARINE SELEPARINA	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●		
PARNAPARIN	FLUXUM ZOLTAR	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●		
REVIPARIN	CLIVARIN CLIVARINA	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●		
TINZAPARIN	INNOHEP	●	●	●	●	●	●	●	●	●	●	●	●	●		●

● Non-accessible market ● Non-referenced market ● Referenced medicines ● Biosimilars

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries

		AT	BE	BU	CZ	DK	FI	FR	DE	GR*	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD (2023)	Biosimilar vs.Referenced product	60%	3%	0%	18%	100%	98%	12%	27%	0%	0%	0%	81%	0%	0%	0%	53%	0%	0%	0%	52%	0%	3%	67%	35%
	Biosimilar vs.Accessible market	49%	2%	0%	13%	0%	57%	9%	18%	0%	0%	0%	76%	0%	0%	0%	51%	0%	0%	0%	41%	0%	2%	38%	25%
	Biosimilar vs. Total market	49%	2%	0%	13%	0%	57%	9%	18%	0%	0%	0%	76%	0%	0%	0%	51%	0%	0%	0%	41%	0%	2%	38%	25%
PRICE PER TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-17%	-2%		3%	-19%	-30%	-11%	8%				-7%	-1%		20%	-19%				-24%	-1%	-23%	-1%	-7%
	Biosimilar accessible market	-15%	2%		4%	18%	-14%	-8%	8%				-8%	-3%		15%	-19%				-16%	17%	-18%	-1%	-4%
	Total market	-15%	2%		4%	18%	-14%	-8%	8%				-8%	-3%		15%	-19%				-16%	17%	-18%	-1%	-4%
VOLUME TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-25%	-9%		60%	-100%	-35%	8%	-37%				5%	-100%		67%	-1%				11%	-7%	5%	19%	8%
	Biosimilar accessible market	-25%	-7%		1%	-31%	-16%	-4%	-28%				-12%	-15%		1%	-3%				4%	-14%	-2%	-1%	1%
	Total market	-25%	-7%		1%	-31%	-16%	-4%	-28%				-12%	-15%		1%	-3%				4%	-14%	-2%	-1%	1%
	TD per capita (2023)	3.69	2.68	1.09	3.68	0.92	2.07	2.55	2.94	2.79	4.84	1.65	3.23	0.91	1.58	3.65	1.79	1.63	5.03	2.52	3.45	1.59	1.98	1.97	2.84
	TD/capita (Yr before BS entrance)	5.08	2.96		3.72	1.36	2.50	2.70	4.20				3.55	1.10		3.51	1.88				3.43	1.90	2.09	2.07	2.85
	First recorded sales of biosimilars	2018	2021		2020	2019	2020	2018	2017				2017	2021		2019	2019				2018	2020	2020	2017	2017

* Only retail panel data is available for Greece.

Note: Gaps in price and volume per TD are due to there being no biosimilar sales yet recorded in that country; 'EU' represents the total sales in European Union countries included in the table (i.e. excluding NO, CH, UK), and the subsequent indicators associated.

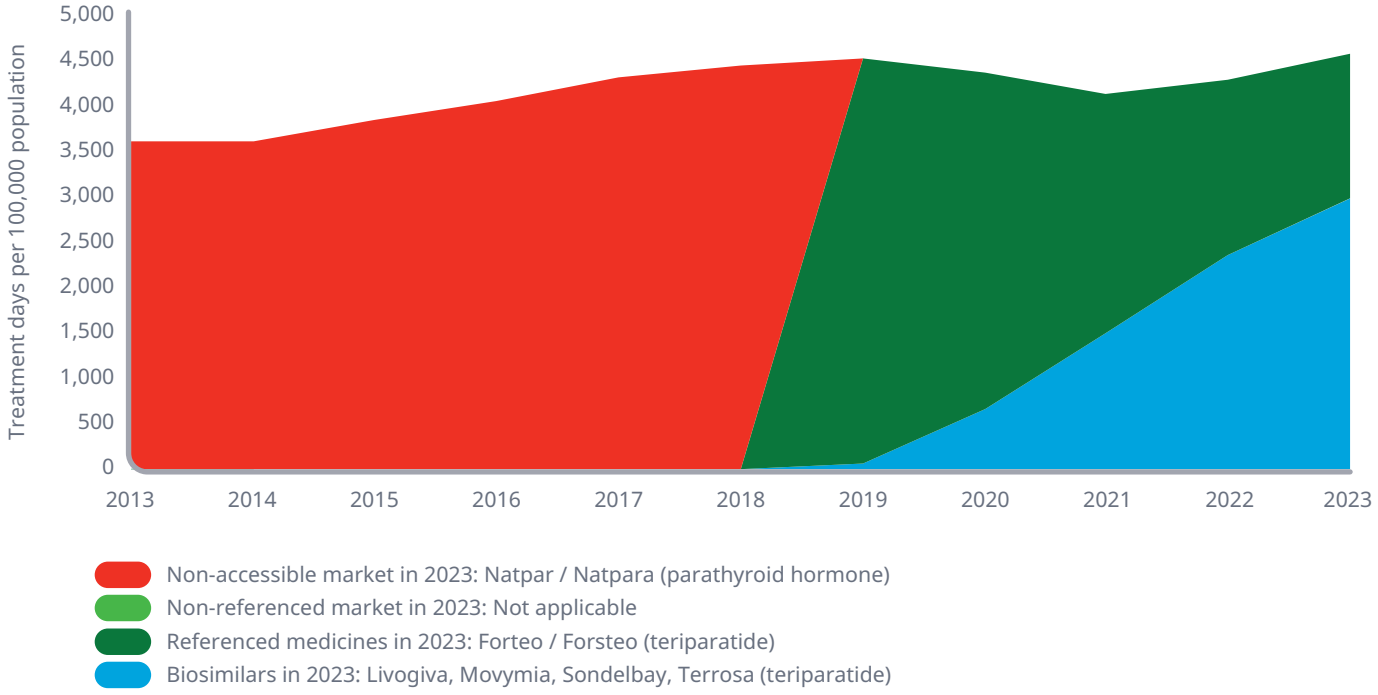
Parathyroid hormones

Parathyroid hormone is an analog of human parathyroid hormone (PTH) used to treat hypocalcemia caused by hypoparathyroidism. Teriparatide is a synthetic form of parathyroid hormone (PTH) used in the treatment of some forms of osteoporosis.

PARATHYROID HORMONES MARKET DEVELOPMENT

Natpar/Natpara and Preotact (parathyroid hormone) have been included since the 2022 report for completeness and classified within the 'non-accessible' market. The total market size has not increased as Natpar / Natpara accounts for <1% market, and Preotact has been withdrawn.

PTH market development



PTH approved indications

NAMING		CLASSIFICATION											INDICATIONS	
MOLECULE	PRODUCT	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	OSTEOPEROSIS (IN POST MENOPAUSAL WMOEN AND MEN AT INCREASED RISK OF FRACTURE)	HYPOPARATHYROIDISM
TERIPARATIDE*	FORTEO MOVYMIA TERROSA LIVOGIVA SONDELBAY KAULIV	●	●	●	●	● ● ●	● ● ●	● ● ●	● ● ● ●	● ● ●	● ● ● ● ●	● ● ● ● ● ●	● ● ● ● ● ●	
PARATHYROID HORMONE	PREOTACT* NATPAR/NATPARA	●	●			●	●	●	●	●	●	●	●	●

● Non-accessible market ● Non-referenced market ● Referenced medicines ● Biosimilars

* Preotact was withdrawn on 2014/05.

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries

		AT	BE	BU	CZ	DK	FI	FR	DE	GR*	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD (2023)	Biosimilar vs.Referenced product	80%	0%	100%	52%	66%	14%	50%	50%	1%	96%	29%	83%	100%	89%	0%	8%	82%	100%	78%	62%	74%	20%	94%	64%
	Biosimilar vs.Accessible market	80%	0%	100%	52%	66%	14%	50%	50%	1%	96%	29%	83%	100%	89%	0%	8%	82%	100%	78%	62%	74%	20%	94%	64%
	Biosimilar vs. Total market	80%	0%	100%	52%	66%	14%	50%	50%	1%	96%	29%	83%	100%	89%	0%	8%	82%	100%	78%	62%	74%	20%	94%	63%
PRICE PER TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product			-71%			-34%			-11%				-31%	-40%		-22%	-48%							-28%
	Biosimilar accessible market			-71%			-34%			-11%				-31%	-40%		-22%	-48%							-28%
	Total market	-59%		-71%	-47%	-53%	-4%	-36%	52%	-11%	-34%	-36%	-44%	-31%	-10%		-22%	-46%	-51%	-52%	-42%	-20%	-12%	1%	-15%
VOLUME TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product			191%			-35%			-89%				-60%	56%		-26%	97%							840%
	Biosimilar accessible market			191%			-35%			-89%				-60%	56%		-26%	97%							840%
	Total market	77%		191%	31%	-36%	-35%	33%	21%	-89%	77%	11%	-32%	-60%	56%		-26%	97%	-4%	91%	18%	-3%	-19%	45%	-11%
	TD per capita (2023)	0.10	0.00	0.01	0.02	0.05	0.01	0.07	0.02	0.01	0.06	0.08	0.06	0.01	0.08	0.00	0.01	0.04	0.02	0.05	0.15	0.01	0.06	0.02	0.05
	TD/capita (Yr before BS entrance)	0.06		0.00	0.01	0.07	0.02	0.05	0.02	0.09	0.03	0.08	0.08	0.04	0.06		0.02	0.02	0.02	0.03	0.13	0.02	0.07	0.02	0.05
	First recorded sales of biosimilars	2019		2021	2019	2019	2020	2019	2019	2022	2019	2019	2019	2020	2020		2020	2020	2019	2019	2019	2019	2019	2019	2019

* Only retail panel data is available for Greece.

Note: Gaps in price and volume per TD are due to there being no 'Non-referenced' or 'Referenced' products in the year before biosimilar entry; 'EU' represents the total sales in European Union countries included in the table (i.e. excluding NO, CH, UK), and the subsequent indicators associated.

Ophthalmology

In addition to their primary use in Oncology, Monoclonal Antibodies (mAbs) have excellent therapeutic applications in ophthalmology by binding to certain cells or proteins that treat ocular inflammatory diseases. The objective is that this treatment will stimulate the patient's immune system to attack those cells. Considering the overlap in molecular targets (e.g., VEGF), mAbs approved for oncology indications are sometimes used off-label for ophthalmology indications. However, this report focuses only on mAbs specifically approved for ophthalmology indications.

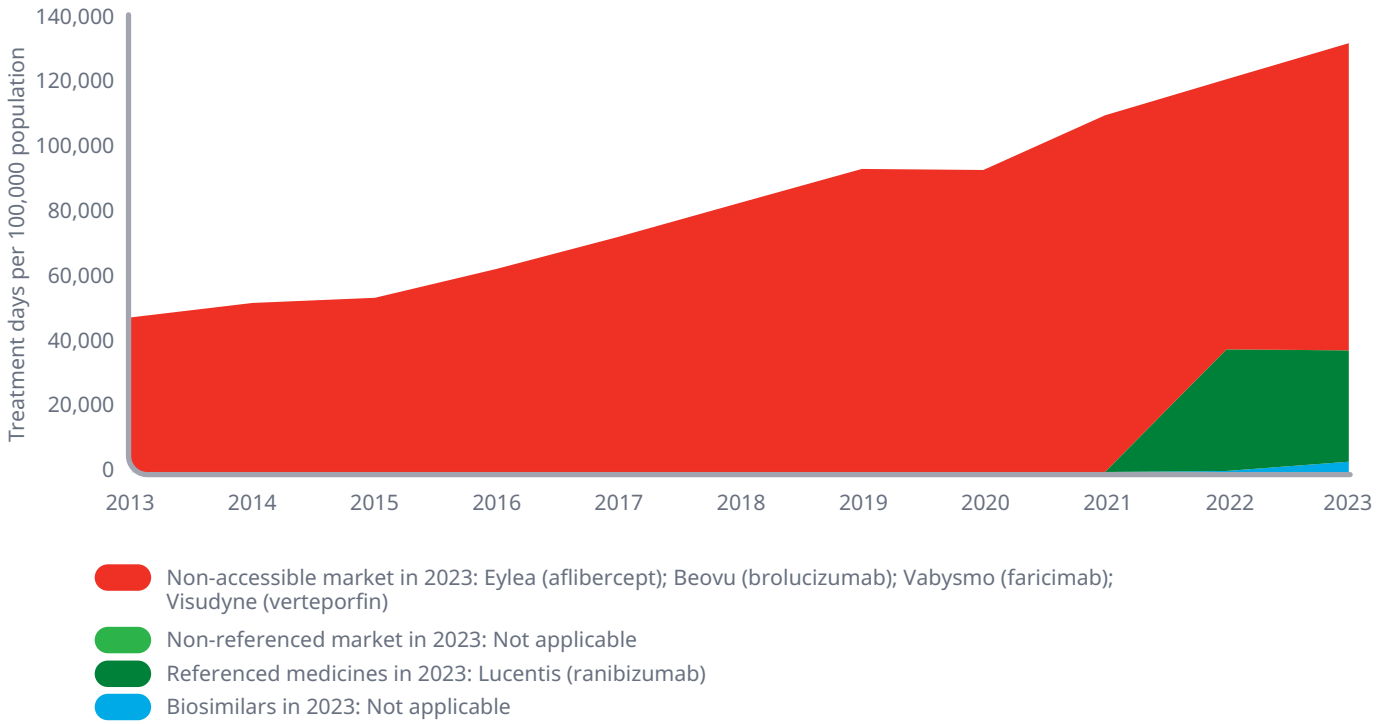
Eylea (aflibercept) and Lucentis (ranibizumab) are anti-VEGF agents used to treat several ocular inflammatory conditions, including wet age-related macular degeneration (AMD), macular edema, and diabetic retinopathy. They work by preventing the growth of abnormal blood vessels in the eye caused by the VEGF protein. Avastin (bevacizumab) is another anti-VEGF agent that is also used to treat inflammatory ocular diseases. However, considering that the primary indications used for bevacizumab biosimilars are in Oncology, and since IQVIA sales and treatment day volume cannot be split by indication, bevacizumab market dynamics are only considered in this separate Oncology section, and not in the Ophthalmology section.

WHO DDD's are not available for products in this class, so the DDD's were calculated using EMA dosing information.

OPHTHALMOLOGY MARKET DEVELOPMENT

According to IQVIA MIDAS and ARK Patent intelligence, Lucentis (ranibizumab) lost protection in 2022 and therefore has been classified as a 'referenced medicine' from 2022 onwards.

Ophthalmology market development



Ophthalmology approved indications

NAMING		CLASSIFICATION											INDICATIONS								DOSING	
MOLECULE	PRODUCT	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	NEOVASCULAR (WET) AGE-RELATED MACULAR DEGENERATION (AMD)	VISUAL IMPAIRMENT DUE TO MACULAR OEDEMA SECONDARY TO RETINAL VEIN OCCLUSION (BRANCH RVO OR CENTRAL RVO)	VISUAL IMPAIRMENT DUE TO DIABETIC MACULAR OEDEMA (DME)	VISUAL IMPAIRMENT DUE TO MYOPIC CHOROIDAL NEOVASCULARISATION (MYOPIC CNV)	PROLIFERATIVE DIABETIC RETINOPATHY (PDR)	RETINOPATHY OF PREMATURITY (ROP) WITH ZONE I (STAGE 1+, 2+, 3 OR 3+), ZONE II (STAGE 3+) OR AP-ROP (AGGRESSIVE POSTERIOR ROP) DISEASE	EXUDATIVE (WET) AGE-RELATED MACULAR DEGENERATION (AMD) WITH PREDOMINANTLY CLASSIC SUBFOVEAL CHOROIDAL NEOVASCULARISATION (CNV)	SUBFOVEAL CHOROIDAL NEOVASCULARISATION SECONDARY TO PATHOLOGICAL MYOPIA	ROUTE	FREQUENCY
AFLIBERCEPT	EYLEA YESAFILI	●	●	●	●	●	●	●	●	●	●	● ●	● ●	●	● ●	● ●					Intravitreal Intravitreal	Every 8 wks Every 8 wks
BROLUCIZUMAB	BEOVU								●	●	●	●	●		●						Intravitreal	Every 8 wks
FARICIMAB	VABYSMO										●	●	●		●						Intravitreal	Every 4 wks
PEGAPTANIB	MACUGEN												●								Intravitreal	Every 6 wks
RANIBIZUMAB	LUCENTIS BYOOVIZ RANIVISIO* XIMLUCI	●	●	●	●	●	●	●	●	●	● ● ● ●	● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	●			Intravitreal	Every 4 wks
VERTEPORFIN	VISUDYNE	●	●	●	●	●	●	●	●	●	●	●							●	●	UV + light activation	Every 12 wks

● Non-accessible market ● Non-referenced market ● Referenced medicines ● Biosimilars

* RANVISIO (ranibizumab) is approved in UK by MHRA under the name ONGAVIA (ranibizumab), and therefore captured within dataset

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries

		AT	BE	BU	CZ	DK	FI	FR	DE	GR*	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD (2023)	Biosimilar vs.Referenced product	0%	0%	0%	42%	0%	0%	1%	1%	0%	27%	0%	0%	2%	11%	5%	10%	0%	4%	0%	7%	0%	1%	69%	3%
	Biosimilar vs.Accessible market	0%	0%	0%	42%	0%	0%	1%	1%	0%	27%	0%	0%	2%	11%	5%	10%	0%	4%	0%	7%	0%	1%	69%	3%
	Biosimilar vs. Total market	0%	0%	0%	11%	0%	0%	1%	0%	0%	8%	0%	0%	0%	0%	1%	3%	0%	1%	0%	2%	0%	0%	11%	1%
PRICE PER TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product				-38%			-22%	-1%		-8%			0%	-1%	-8%	-8%		-18%		-10%		-15%		-15%
	Biosimilar accessible market				-38%			-22%	-1%		-8%			0%	-1%	-8%	-8%		-18%		-10%		-15%		-15%
	Total market				-24%			-11%	-4%		-4%			-2%	-1%	3%	-4%		-10%		-5%		5%	10%	-8%
VOLUME TD (2023/YR BEFORE BS ENTRY)	Biosimilar and Referenced product				18%			2%	-8%		272%			-8%	-30%	-20%	-18%		-34%		-6%		-23%		16%
	Biosimilar accessible market				18%			2%	-8%		272%			-8%	-30%	-20%	-18%		-34%		-6%		-23%		16%
	Total market				33%			9%	11%		49%			10%	23%	15%	15%		13%		18%		-6%	7%	44%
	TD per capita (2023)	0.55	1.88	0.41	1.25	2.50	1.05	2.36	1.38	0.01	0.24	0.93	0.61	1.50	0.93	0.47	0.60	0.44	1.30	1.49	1.44	1.56	1.86	1.63	1.23
	TD/capita (Yr before BS entrance)				0.97			2.17	1.25		0.16			1.37	0.76	0.40	0.53		1.15		1.24		2.00	1.56	0.86
	First recorded sales of biosimilars				2023			2023	2023		2023			2023	2023	2023	2023		2023		2023		2023	2022	2022

* Only retail panel data is available for Greece.

Note: Gaps in price and volume per TD are due to there being no 'Non-referenced' or 'Referenced' products in the year before biosimilar entry, or because there is not yet biosimilar entry; 'EU' represents the total sales in European Union countries included in the table (i.e. excluding NO, CH, UK), and the subsequent indicators associated.

Appendix

EMA list of approved Biosimilars (October 2024)

Table 1: EMA list of approved biosimilars; Source: EMA website, data accessed October 2024
(https://www.ema.europa.eu/en/medicines/download-medicine-data#european-public-assessment-reports-(epar)-section)

MEDICINE NAME	INTERNATIONAL NON-PROPRIETARY NAME (INN)/COMMON NAME	THERAPEUTIC AREA	MARKETING AUTHORISATION DATE	MARKETING AUTHORISATION HOLDER/COMPANY NAME
OMNITROPE	somatropin	Turner Syndrome;Prader-Willi Syndrome;Dwarfism, Pituitary	12/04/2006	Sandoz GmbH
EPOETIN ALFA HEXAL	epoetin alfa	Anemia;Kidney Failure, Chronic;Blood Transfusion, Autologous;Myelodysplastic Syndromes	27/08/2007	Hexal AG
ABSEAMED	epoetin alfa	Anemia;Kidney Failure, Chronic;Blood Transfusion, Autologous;Myelodysplastic Syndromes	27/08/2007	Medice Arzneimittel Pütter GmbH Co. KG
BINOCRIT	epoetin alfa	Anemia;Kidney Failure, Chronic;Blood Transfusion, Autologous;Myelodysplastic Syndromes	28/08/2007	Sandoz GmbH
RETACRIT	epoetin zeta	Anemia;Blood Transfusion, Autologous;Kidney Failure, Chronic;Cancer	18/12/2007	Pfizer Europe MA EEIG
SILAPO	epoetin zeta	Anemia;Blood Transfusion, Autologous;Cancer;Kidney Failure, Chronic	18/12/2007	Stada Arzneimittel AG
TEVAGRASTIM	filgrastim	Neutropenia;Hematopoietic Stem Cell Transplantation;Cancer	15/09/2008	Teva GmbH
RATIOGRASTIM	filgrastim	Neutropenia;Hematopoietic Stem Cell Transplantation;Cancer	15/09/2008	Ratiopharm GmbH
FILGRASTIM HEXAL	filgrastim	Neutropenia;Hematopoietic Stem Cell Transplantation;Cancer	06/02/2009	Hexal AG
ZARZIO	filgrastim	Neutropenia;Hematopoietic Stem Cell Transplantation;Cancer	06/02/2009	Sandoz GmbH
NIVESTIM	filgrastim	Neutropenia;Hematopoietic Stem Cell Transplantation;Cancer	07/06/2010	Pfizer Europe MA EEIG
INFLECTRA	infliximab	Arthritis, Psoriatic;Spondylitis, Ankylosing;Colitis, Ulcerative;Psoriasis;Crohn Disease;Arthritis, Rheumatoid	10/09/2013	Pfizer Europe MA EEIG
REMSIMA	infliximab	Arthritis, Psoriatic;Spondylitis, Ankylosing;Colitis, Ulcerative;Psoriasis;Crohn Disease;Arthritis, Rheumatoid	10/09/2013	Celltrion Healthcare Hungary Kft.
OVALEAP	follitropin alfa	Anovulation	27/09/2013	Theramex Ireland Limited
GRASTOFIL	filgrastim	Neutropenia	17/10/2013	Accord Healthcare S.L.U.
BEMFOLA	follitropin alfa	Anovulation	26/03/2014	Gedeon Richter Plc.
ABASAGLAR (PREVIOUSLY ABASRIA)	insulin glargine	Diabetes Mellitus	09/09/2014	Eli Lilly Nederland B.V.
ACCOFIL	filgrastim	Neutropenia	17/09/2014	Accord Healthcare S.L.U.
BENEPALI	etanercept	Arthritis, Psoriatic;Arthritis, Rheumatoid;Psoriasis	13/01/2016	Samsung Bioepis NL B.V.
FLIXABI	infliximab	Arthritis, Psoriatic;Spondylitis, Ankylosing;Colitis, Ulcerative;Arthritis, Rheumatoid;Crohn Disease;Psoriasis	26/05/2016	Samsung Bioepis NL B.V.
INHIXA	enoxaparin sodium	Venous Thromboembolism	15/09/2016	Techdow Pharma Netherlands B.V.
TERROSA	teriparatide	Osteoporosis	04/01/2017	Gedeon Richter Plc.
MOVYMIA	teriparatide	Osteoporosis	11/01/2017	STADA Arzneimittel AG
TRUXIMA	rituximab	Lymphoma, Non-Hodgkin;Arthritis, Rheumatoid; Wegener Granulomatosis;Leukemia, Lymphocytic, Chronic, B-Cell;Microscopic Polyangiitis	17/02/2017	Celltrion Healthcare Hungary Kft.
AMGEVITA	adalimumab	Arthritis, Psoriatic;Colitis, Ulcerative;Arthritis, Juvenile Rheumatoid;Spondylitis, Ankylosing; Psoriasis;Crohn Disease;Arthritis, Rheumatoid	21/03/2017	Amgen Europe B.V.

MEDICINE NAME	INTERNATIONAL NON-PROPRIETARY NAME (INN)/COMMON NAME	THERAPEUTIC AREA	MARKETING AUTHORISATION DATE	MARKETING AUTHORISATION HOLDER/COMPANY NAME
RIXATHON	rituximab	Lymphoma, Non-Hodgkin;Arthritis, Rheumatoid;Leukemia, Lymphocytic, Chronic, B-Cell;Wegener Granulomatosis;Microscopic Polyangiitis;Pemphigus	15/06/2017	Sandoz GmbH
RIXIMYO	rituximab	Lymphoma, Non-Hodgkin;Arthritis, Rheumatoid; Microscopic Polyangiitis;Wegener Granulomatosis	15/06/2017	Sandoz GmbH
ERELZI	etanercept	Arthritis, Psoriatic;Psoriasis;Arthritis, Juvenile Rheumatoid;Arthritis, Rheumatoid;Spondylitis, Ankylosing	23/06/2017	Sandoz GmbH
BLITZIMA	rituximab	Lymphoma, Non-Hodgkin;Leukemia, Lymphocytic, Chronic, B-Cell	13/07/2017	Celltrion Healthcare Hungary Kft.
INSULIN LISPRO SANOFI	insulin lispro	Diabetes Mellitus	19/07/2017	Sanofi Winthrop Industrie
IMRALDI	adalimumab	Spondylitis, Ankylosing;Arthritis, Rheumatoid;Uveitis;Colitis, Ulcerative;Psoriasis;Arthritis, Psoriatic;Crohn Disease;Hidradenitis Suppurativa;Arthritis	24/08/2017	Samsung Bioepis NL B.V.
ONTRUZANT	trastuzumab	Stomach Neoplasms;Breast Neoplasms	15/11/2017	Samsung Bioepis NL B.V.
MVASI	bevacizumab	Carcinoma, Renal Cell;Peritoneal Neoplasms;Ovarian Neoplasms;Breast Neoplasms;Carcinoma, Non-Small-Cell Lung;Fallopian Tube Neoplasms	15/01/2018	Amgen Technology (Ireland) UC
HERZUMA	trastuzumab	Stomach Neoplasms;Breast Neoplasms	09/02/2018	Celltrion Healthcare Hungary Kft.
SEMGLEE	insulin glargine	Diabetes Mellitus	23/03/2018	Biosimilar Collaborations Ireland Limited
KANJINTI	trastuzumab	Stomach Neoplasms;Breast Neoplasms	16/05/2018	Amgen Europe BV
ZESSLY	infliximab	Arthritis, Psoriatic;Psoriasis;Crohn Disease;Arthritis, Rheumatoid;Colitis, Ulcerative;Spondylitis, Ankylosing	18/05/2018	Sandoz GmbH
TRAZIMERA	trastuzumab	Stomach Neoplasms;Breast Neoplasms	26/07/2018	Pfizer Europe MA EEIG
HYRIMOZ	adalimumab	Arthritis, Rheumatoid;Arthritis, Psoriatic;Spondylitis, Ankylosing; Uveitis;Hidradenitis Suppurativa;Colitis, Ulcerative;Arthritis, Juvenile Rheumatoid;Crohn Disease;Skin Diseases, Papulosquamous	26/07/2018	Sandoz GmbH
HEFIYA	adalimumab	Spondylitis, Ankylosing;Hidradenitis Suppurativa;Psoriasis;Arthritis, Juvenile Rheumatoid;Uveitis	26/07/2018	Sandoz GmbH
HULIO	adalimumab	Hidradenitis, Suppurativa; Psoriasis;Uveitis;Arthritis, Rheumatoid; Spondylitis, Ankylosing;Crohn Disease;Colitis, Ulcerative;Arthritis, Psoriatic	17/09/2018	Biosimilar Collaborations Ireland Limited
PELGRAZ	pegfilgrastim	Neutropenia	21/09/2018	Accord Healthcare S.L.U.
PELMEG	pegfilgrastim	Neutropenia	20/11/2018	Mundipharma Corporation (Ireland) Limited
FULPHILA	pegfilgrastim	Neutropenia	20/11/2018	Biosimilar Collaborations Ireland Limited
ZIEXTENZO	pegfilgrastim	Neutropenia	22/11/2018	Sandoz GmbH
OGIVRI	trastuzumab	Stomach Neoplasms;Breast Neoplasms	12/12/2018	Biosimilar Collaborations Ireland Limited
ZIRABEV	bevacizumab	Colorectal Neoplasms;Breast Neoplasms; Carcinoma, Non-Small-Cell Lung;Carcinoma, Renal Cell;Uterine Cervical Neoplasms	14/02/2019	Pfizer Europe MA EEIG
IDACIO	adalimumab	Arthritis, Rheumatoid;Arthritis, Psoriatic; Psoriasis;Spondylitis, Ankylosing;Uveitis; Hidradenitis Suppurativa;Colitis, Ulcerative; Crohn Disease;Arthritis, Juvenile Rheumatoid	02/04/2019	Fresenius Kabi Deutschland GmbH
GRASUSTEK	pegfilgrastim	Neutropenia	20/06/2019	Juta Pharma GmbH

MEDICINE NAME	INTERNATIONAL NON-PROPRIETARY NAME (INN)/COMMON NAME	THERAPEUTIC AREA	MARKETING AUTHORISATION DATE	MARKETING AUTHORISATION HOLDER/COMPANY NAME
CEGFILA (PREVIOUSLY PEGFILGRASTIM MUNDIPHARMA)	pegfilgrastim	Neutropenia	19/12/2019	Mundipharma Corporation (Ireland) Limited
AMSPARITY	adalimumab	Arthritis, Rheumatoid;Arthritis, Psoriatic; Psoriasis;Spondylitis, Ankylosing; Uveitis;Hidradenitis Suppurativa;Colitis, Ulcerative;Crohn Disease;Arthritis, Juvenile Rheumatoid	13/02/2020	Pfizer Europe MA EEIG
RUXIENCE	rituximab	Leukemia, Lymphocytic, Chronic, B-Cell;Arthritis, Rheumatoid;Microscopic Polyangiitis;Pemphigus	01/04/2020	Pfizer Europe MA EEIG
NEPEXTO	etanercept	Arthritis, Rheumatoid;Arthritis, Juvenile Rheumatoid;Arthritis, Psoriatic;Spondylarthropathies;Spondylitis, Ankylosing;Psoriasis	20/05/2020	Biosimilar Collaborations Ireland Limited
INSULIN ASPART SANOFI	insulin aspart	Diabetes Mellitus	25/06/2020	Sanofi Winthrop Industrie
ZERCEPAC	trastuzumab	Breast Neoplasms;Stomach Neoplasms	27/07/2020	Accord Healthcare S.L.U.
AYBINTIO	bevacizumab	Colorectal Neoplasms;Breast Neoplasms;Ovarian Neoplasms;Fallopian Tube Neoplasms;Peritoneal Neoplasms;Carcinoma, Non-Small-Cell Lung;Carcinoma, Renal Cell;Uterine Cervical Neoplasms	19/08/2020	Samsung Bioepis NL B.V.
LIVOGIVA	teriparatide	Osteoporosis	27/08/2020	Theramex Ireland Limited
NYVEPRIA	pegfilgrastim	Neutropenia	18/11/2020	Pfizer Europe MA EEIG
KIRSTY (PREVIOUSLY KIXELLE)	insulin aspart	Diabetes Mellitus	05/02/2021	Biosimilar Collaborations Ireland Limited
YUFLYMA	adalimumab	Arthritis, Rheumatoid;Arthritis, Psoriatic; Psoriasis;Spondylitis, Ankylosing; Uveitis;Hidradenitis Suppurativa;Colitis, Ulcerative;Crohn Disease;Arthritis, Juvenile Rheumatoid	11/02/2021	Celltrion Healthcare Hungary Kft.
OYAVAS	bevacizumab	Colorectal Neoplasms;Breast Neoplasms;Ovarian Neoplasms;Fallopian Tube Neoplasms;Peritoneal Neoplasms;Carcinoma, Non-Small-Cell Lung;Carcinoma, Renal Cell;Uterine Cervical Neoplasms	26/03/2021	STADA Arzneimittel AG
ALYMSYS	bevacizumab	Colorectal Neoplasms;Breast Neoplasms;Ovarian Neoplasms;Peritoneal Neoplasms;Carcinoma, Non-Small-Cell Lung;Carcinoma, Renal Cell;Uterine Cervical Neoplasms	26/03/2021	Mabxience Research SL
ABEVMY	bevacizumab	Colorectal Neoplasms;Breast Neoplasms;Ovarian Neoplasms;Fallopian Tube Neoplasms;Peritoneal Neoplasms;Carcinoma, Non-Small-Cell Lung;Carcinoma, Renal Cell;Uterine Cervical Neoplasms	21/04/2021	Biosimilar Collaborations Ireland Limited
BYOOVIZ	ranibizumab	Wet Macular Degeneration;Macular Edema;Diabetic Retinopathy;Myopia, Degenerative	18/08/2021	Samsung Bioepis NL B.V.
LIBMYRIS	adalimumab	Arthritis, Rheumatoid;Arthritis, Juvenile Rheumatoid;Spondylitis, Ankylosing;Arthritis, Psoriatic;Psoriasis;Hidradenitis Suppurativa; Crohn Disease;Colitis, Ulcerative;Uveitis	12/11/2021	Stada Arzneimittel AG
HUKYNDRA	adalimumab	Arthritis, Psoriatic;Arthritis, Juvenile Rheumatoid;Arthritis, Rheumatoid;Colitis, Ulcerative;Crohn Disease;Hidradenitis Suppurativa;Psoriasis;Spondylitis, Ankylosing;Uveitis	15/11/2021	Stada Arzneimittel AG
SONDELBAY	teriparatide	Osteoporosis	24/03/2022	Accord Healthcare S.L.U.
STIMUFEND	pegfilgrastim	Neutropenia	28/03/2022	Fresenius Kabi Deutschland GmbH

MEDICINE NAME	INTERNATIONAL NON-PROPRIETARY NAME (INN)/COMMON NAME	THERAPEUTIC AREA	MARKETING AUTHORISATION DATE	MARKETING AUTHORISATION HOLDER/COMPANY NAME
TRUVELOG MIX 30	insulin aspart	Diabetes Mellitus	25/04/2022	Sanofi Winthrop Industrie
VEGZELMA	bevacizumab	Colorectal Neoplasms;Breast Neoplasms; Ovarian Neoplasms;Fallopian Tube Neoplasms;Peritoneal Neoplasms;Carcinoma, Non-Small-Cell Lung;Carcinoma, Renal Cell;Uterine Cervical Neoplasms	17/08/2022	Celltrion Healthcare Hungary Kft.
RANIVISIO	ranibizumab	Wet Macular Degeneration;Macular Edema;Diabetic Retinopathy;Diabetes Complications	25/08/2022	Midas Pharma GmbH
XIMLUCI	ranibizumab	Wet Macular Degeneration;Macular Edema; Diabetic Retinopathy;Diabetes Complications	09/11/2022	STADA Arzneimittel AG
KAULIV	teriparatide	Osteoporosis;Osteoporosis, Postmenopausal	12/01/2023	Strides Pharma (Cyprus) Limited
BEKEMV	eculizumab	Hemoglobinuria, Paroxysmal	19/04/2023	Amgen Technology (Ireland) UC
EPYSQLI	eculizumab	Hemoglobinuria, Paroxysmal	26/05/2023	Samsung Bioepis NL B.V.
TYENNE	tocilizumab	Arthritis, Rheumatoid;Cytokine Release Syndrome;Arthritis, Juvenile Rheumatoid; COVID-19 virus infection;Giant Cell Arteritis	15/09/2023	Fresenius Kabi Deutschland GmbH
YESAFILI	aflibercept	Macular Edema;Retinal Vein Occlusion;Diabetic Retinopathy;Myopia, Degenerative;Diabetes Complications	15/09/2023	Biosimilar Collaborations Ireland Limited
TYRUKO	natalizumab	Multiple Sclerosis, Relapsing-Remitting;Multiple Sclerosis	22/09/2023	Sandoz GmbH
HERWENDA	trastuzumab	Breast Neoplasms;Stomach Neoplasms	15/11/2023	Sandoz GmbH
UZPRUVO	ustekinumab	Psoriasis;Arthritis, Psoriatic;Crohn Disease;Colitis, Ulcerative	05/01/2024	Stada Arzneimittel AG
RIMMYRAH	ranibizumab	Wet Macular Degeneration;Macular Edema;Diabetes Complications;Myopia, Degenerative;Choroidal Neovascularization	05/01/2024	Qilu Pharma Spain S.L.
PYZCHIVA	ustekinumab	Crohn Disease;Colitis, Ulcerative;Arthritis, Psoriatic	19/04/2024	Samsung Bioepis NL B.V.
OMLYCLO	omalizumab	Asthma;Urticaria	16/05/2024	Celltrion Healthcare Hungary Kft.
JUBBONTI	denosumab	Osteoporosis;Osteoporosis, Postmenopausal;Bone Resorption	16/05/2024	Sandoz GmbH
WYOST	denosumab	Giant Cell Tumor of Bone;Neoplasms, Bone Tissue	17/05/2024	Sandoz GmbH
WEZENLA	ustekinumab	Psoriasis;Arthritis, Psoriatic;Crohn Disease	20/06/2024	Amgen Technology (Ireland) UC
AVZIVI	bevacizumab	Colorectal Neoplasms;Carcinoma, Non-Small-Cell Lung;Carcinoma, Renal Cell;Ovarian Neoplasms;Fallopian Tube Neoplasms;Peritoneal Neoplasms;Uterine Cervical Neoplasms	26/07/2024	FGK Representative Service GmbH
EKSUNBI	ustekinumab	Crohn Disease;Colitis, Ulcerative;Psoriasis;Arthritis, Psoriatic	12/09/2024	Samsung Bioepis NL B.V.
FYMSKINA	ustekinumab	Crohn Disease;Colitis, Ulcerative;Psoriasis;Arthritis, Psoriatic	25/09/2024	Formycon AG
OTULFI	ustekinumab	Crohn Disease;Colitis, Ulcerative	25/09/2024	Fresenius Kabi Deutschland GmbH

Table 2: Most recent list of Biosimilars under review by EMA

(https://www.ema.europa.eu/en/documents/report/applications-new-human-medicines-under-evaluation-october-2024_en.xlsx)

INTERNATIONAL NON-PROPRIETARY NAME (INN)/ COMMON NAME	THERAPEUTIC AREA (ATC LEVEL 2)	ORPHAN PRODUCT	GENERIC, HYBRID OR BIOSIMILAR	START OF EVALUATION
AFLIBERCEPT	Ophthalmologicals	N	Y	28/12/2023
AFLIBERCEPT	Ophthalmologicals	N	Y	28/12/2023
AFLIBERCEPT	Ophthalmologicals	N	Y	29/02/2024
AFLIBERCEPT	Ophthalmologicals	N	Y	01/03/2024
AFLIBERCEPT	Ophthalmologicals	N	Y	28/03/2024
AFLIBERCEPT	Ophthalmologicals	N	Y	28/05/2024
AFLIBERCEPT	Ophthalmologicals	N	Y	18/07/2024
AFLIBERCEPT	Ophthalmologicals	N	Y	15/08/2024
DENOSUMAB	Medicines for bone diseases	N	Y	28/03/2024
DENOSUMAB	Medicines for bone diseases	N	Y	28/03/2024
DENOSUMAB	Medicines for bone diseases	N	Y	28/03/2024
DENOSUMAB	Medicines for bone diseases	N	Y	28/03/2024
DENOSUMAB	Medicines for bone diseases	N	Y	28/03/2024
DENOSUMAB	Medicines for bone diseases	N	Y	28/03/2024
DENOSUMAB	Medicines for bone diseases	N	Y	23/05/2024
DENOSUMAB	Medicines for bone diseases	N	Y	23/05/2024
DENOSUMAB	Medicines for bone diseases	N	Y	23/05/2024
DENOSUMAB	Medicines for bone diseases	N	Y	23/05/2024
DENOSUMAB	Medicines for bone diseases	N	Y	23/05/2024
DENOSUMAB	Medicines for bone diseases	N	Y	23/05/2024
DENOSUMAB	Medicines for bone diseases	N	Y	20/06/2024
DENOSUMAB	Medicines for bone diseases	N	Y	20/06/2024
DENOSUMAB	Medicines for bone diseases	N	Y	18/07/2024
DENOSUMAB	Medicines for bone diseases	N	Y	18/07/2024
DENOSUMAB	Medicines for bone diseases	N	Y	15/08/2024
DENOSUMAB	Medicines for bone diseases	N	Y	15/08/2024
DENOSUMAB	Medicines for bone diseases	N	Y	03/10/2024
DENOSUMAB	Medicines for bone diseases	N	Y	03/10/2024
DENOSUMAB	Medicines for bone diseases	N	Y	03/10/2024
FILGRASTIM	Immunostimulants	N	Y	28/12/2023
INSULIN ASPART	Medicines used in diabetes	N	Y	28/09/2023
INSULIN GLARGINE	Medicines used in diabetes	N	Y	17/08/2023
INSULIN HUMAN	Medicines used in diabetes	N	Y	26/01/2023
INSULIN LISPRO	Medicines used in diabetes	N	Y	28/09/2023
PEGFILGRASTIM	Immunostimulants	N	Y	01/02/2024
PEGFILGRASTIM	Immunostimulants	N	Y	29/02/2024
RILONACEPT	Immunosuppressants	Y	Y	03/10/2024
TERIPARATIDE	Calcium homeostasis	N	Y	13/07/2023
TOCILIZUMAB	Immunosuppressants	N	Y	29/02/2024
TRASTUZUMAB	Antineoplastic medicines	N	Y	01/02/2024
USTEKINUMAB	Immunosuppressants	N	Y	13/07/2023
USTEKINUMAB	Immunosuppressants	N	Y	29/02/2024
USTEKINUMAB	Immunosuppressants	N	Y	30/04/2024
USTEKINUMAB	Immunosuppressants	N	Y	18/07/2024

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