White Paper

The Impact of Biosimilar Competition in Europe

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Introduction

The 11th edition of the 'Impact of Biosimilar Competition in Europe' report builds upon the perspectives from last year's publication and provides a forward-looking view on the upcoming opportunities and challenges for biosimilar competition in Europe.

Biosimilars continue to play a critical role in the European healthcare system 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. However, the biosimilar pipeline signals future headwinds, which have been highlighted in previous reports and remain relevant today.

The report consists of novel observations on market conditions for 2025, and a streamlined 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 impact of biosimilar in the European healthcare system.

This year's report streamlines the KPI section by focusing on product segments that experienced initial biosimilar entry within the past ten years and have shown recent market changes. The KPIs describe the effects on price, volume, and market share following the arrival of biosimilar competition in Europe. The report has been a longstanding 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: Marco Travaglio, Michael Kleinrock, Urvashi Porwal, Kirstie Scott, Mohit Agarwal, Siobhan Palmer, Sourish Rath and many others.

IQVIA observations

Background

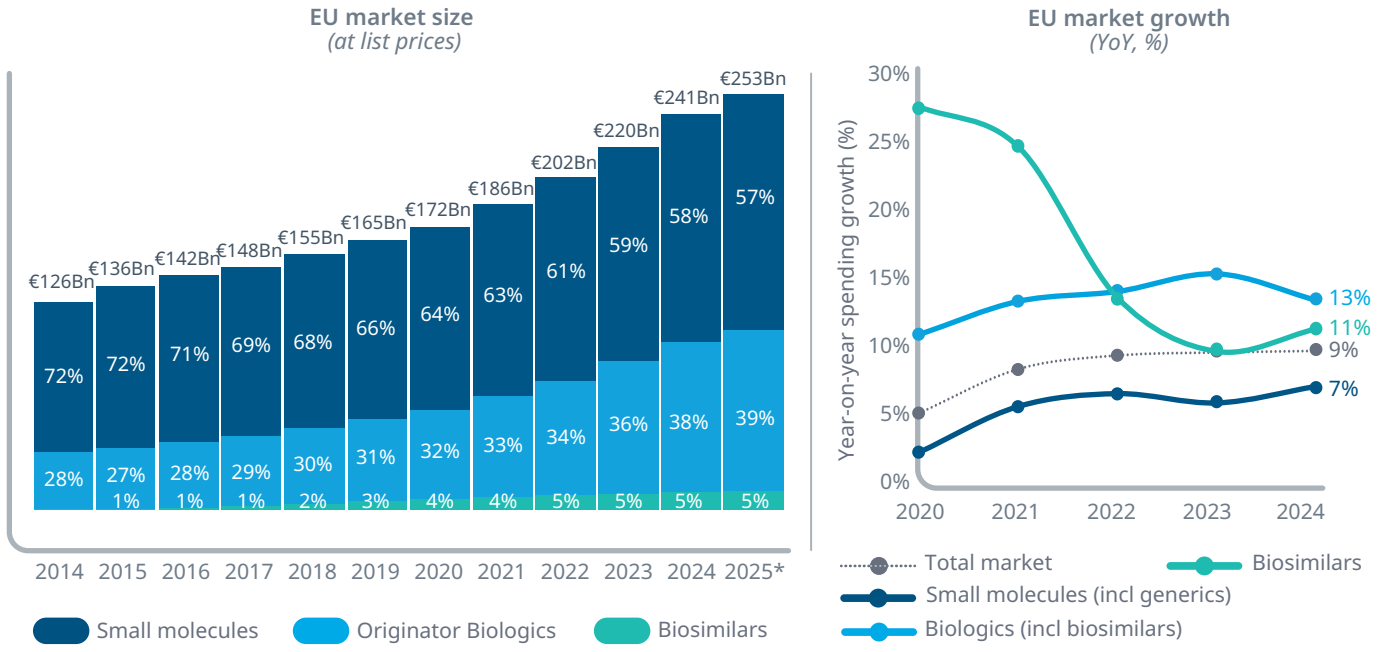
Biologic medicines continue to play an important role in the EU pharmaceutical market, representing 44% of total value at list prices (referring to both originator biologics and biosimilars) (Exhibit 1). The continued launch of new biologic therapies, significant growth in established brands, and the recognition of biologics as advanced treatment options are the key drivers behind the growing share of biologic spending in Europe. This has resulted in sustained double-digit growth for biologics over the past 5 years, and higher annual growth rates than other market segments, such as small molecules.

Within the EU market, biosimilars now represent 5% in value terms (at list prices) and have entered a new phase of maturation. After years of rapid uptake and expansion, growth rates for biosimilars are now closer to other segments within the pharmaceutical market at 11%. This reflects a maturing biosimilar landscape in Europe, as biosimilars shift from high-growth newcomers to established players supported by continued acceptance of the principles of interchangeability and the value biosimilars provide within the system.

Since the creation of this series of reports in 2015, IQVIA has provided observations on the biosimilar market in Europe (Exhibit 2). Each year the report aims to provide novel insights on the market, however previous years' insights remain valid and are referenced for posterity. These include past observations, 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).

Historically, the themes of these observations have been around savings, price, access, and competition, which are the core tenets of a healthy biosimilar ecosystem. The 11th iteration of the 'Impact of Biosimilar Competition in Europe' builds upon the perspectives from last year's publication and provides a forward-looking view of the biosimilar market in Europe. These

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



*Q3 MAT 2025

Source: IQVIA MIDAS (MAT Q3 2025), Rx only; Biologic molecules exclude ATC-V (various) and vaccines, Constant currency € (inflation adjusted).

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

Exhibit 2: IQVIA's historic 5 observations on the biosimilar market (2015–2024)

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

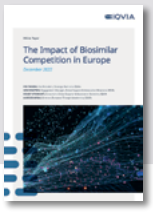
- Biosimilar competition has a significant potential impact on overall drug spend
- Major products see fast uptake and large price reductions
- Originator manufacturers have changed strategy to stay competitive
- Access is not yet increasing for all molecules and in all countries after biosimilar introduction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

2024

- A record number of biologics are due to lose exclusivity, however the pipeline has gaps
- Long-term potential savings for European countries may be at risk
- Competition is increasing, and competitive dynamics are not static
- Success is not guaranteed for all biosimilars
- Leading indicators offer insight into future impact of biosimilar competition

Since the creation of this series of reports in 2015, IQVIA has provided observations on the biosimilar market in Europe. Each year the report aims to provide novel insights on the market, however previous years' insights remain valid and are referenced for posterity.

Source: The Impact of Biosimilar Competition in Europe 2025.

leading indicators will help to identify and anticipate the future impact of biosimilar competition, and include observations on the pipeline, commercial attractiveness, international competitiveness, access disparity, and advanced planning.

Whilst the report has provided indicators on biosimilar competition for the past 11 years in various formats, it is important to adjust the focus to reflect emerging trends, new dynamics, and archive elements with limited value / recent changes. Therefore, in the 2025 report, the KPI section has been streamlined to focus on product segments that experienced initial biosimilar entry within the past ten years and have shown recent market changes. The KPI section includes a full-year update (2024 data) versus the prior report, while the observations reference IQVIA's most up to date information (Q2 MAT 2025) to track the approaches, successes, and challenges for all stakeholders in this important segment.

In 2025, key novel observations on the impact of biosimilar competition are as follows, and build on previous observations that remain relevant and continue to build the knowledge base for stakeholders in the healthcare ecosystem:

1. **Pipeline**: The biosimilar void increases when accounting for biosimilars not expected to reach Europe
2. **Commercial attractiveness**: Biosimilar regulatory streamlining will offer incremental opportunities, but is unlikely to solve the entirety of the biosimilar void
3. **International competitiveness**: Europe still leads in biosimilars policy and uptake, but other regions are catching up
4. **Access inequality**: Disparities in access to biologics persist across Europe, and are challenging to resolve
5. **Advanced planning**: Advanced metrics can support an understanding of the future impact of biosimilar competition

Observation 1: Pipeline

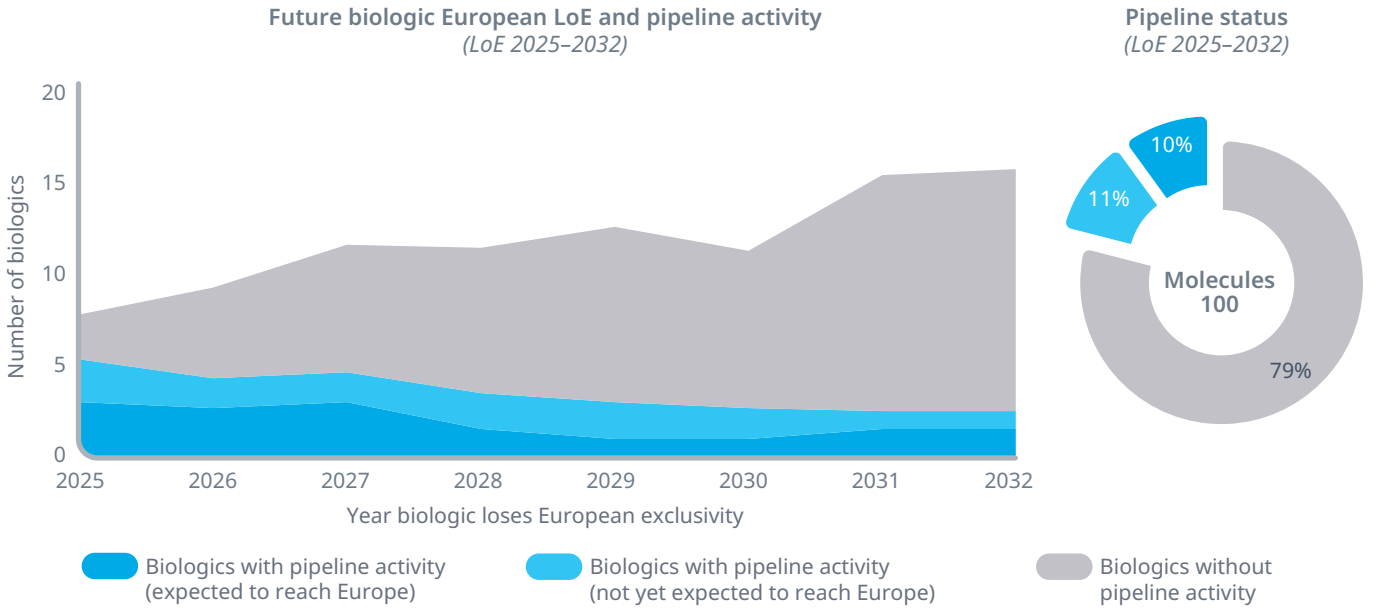
THE BIOSIMILAR VOID INCREASES WHEN ACCOUNTING FOR BIOSIMILARS NOT EXPECTED TO REACH EUROPE

Our latest analysis indicates that approximately 100 biological medicines are expected to lose exclusivity in Europe by 2032. Of these, 79% currently have no biosimilars in development (Exhibit 3). When accounting for the fact that not all biosimilars in development are expected to reach Europe, calculated by examining the geographic footprint of their clinical trials, the biosimilar void is further exacerbated. Therefore, only 10% of biologics nearing loss of exclusivity in Europe will likely have biosimilar competition.

For molecules without European pipeline activity, the primary locations for clinical trials are China, Russia, India, where the intended destination for these biosimilars are local or regional markets. The analysis is based on a global view of pipeline activity, encompassing all stages from pre-clinical to pre-registration. The potential exists for future biosimilar clinical development to expand into the European region, particularly considering the recent move towards regulatory streamlining which will remove the barrier of running clinical efficacy studies. Continued monitoring of the biosimilar pipeline will be necessary to monitor the evolution of the void and increase the depth and quality of information available.

Our latest analysis indicates that approximately 100 biological medicines are expected to lose exclusivity in Europe by 2032. Of these, 79% currently have no biosimilars in development.

Exhibit 3: Biologics at risk of no or limited competition



Source: IQVIA Patent Intelligence (2025); IQVIA analysis of the IQVIA Global Biosimilar Database (Q3 2025).

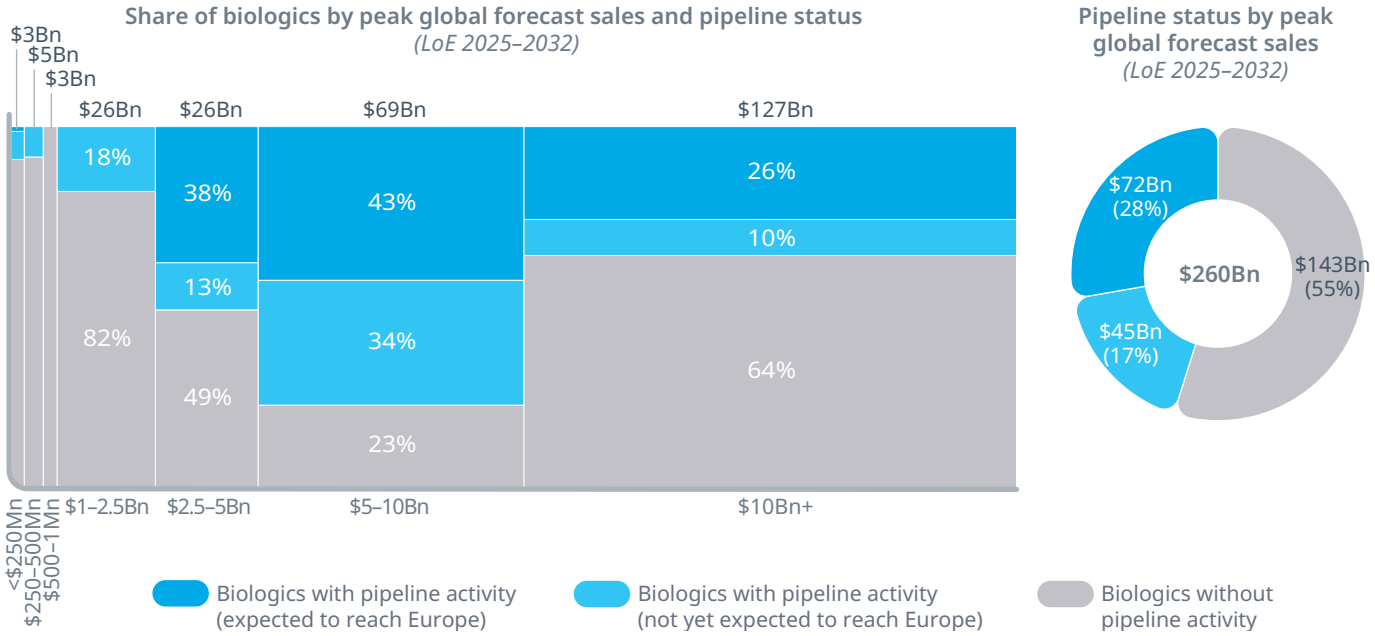
Notes: Timeframe is limited to 2032 (low pipeline potential >7 years into the future due to the biosimilar development timeline); Global pipeline analysis includes all biosimilars in development from pre-clinical to pre-registration; excl. approvals. Biosimilars are expected to reach Europe if the Highest Trial Geography Coverage is in Europe or US (ClincialTrials.gov). Biosimilars not (yet) expected to reach Europe if the Highest Trial Geography Coverage is not in Europe or US, or is unknown. To reduce uncertainty in pipeline forecast data, data from 2025 onwards is shown as a 3-year rolling average. Analysis is based on European LoE. 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 2025.

A POTENTIAL $143BN (55%) IS THE MISSED OPPORTUNITY IN FORECAST SALES DUE TO LACK OF BIOSIMILAR PIPELINE

Previous iterations of this analysis have evaluated the biosimilar void using European forecasted sales potential of originator molecules, however the decision to develop a biosimilar often remains a global one. Although Europe provides the largest market opportunity for biosimilars, it is important to consider the global forecast sales potential of originator biologics alongside European LoE dates. This approach provides a more accurate picture of the global challenges facing biosimilar manufacturers when deciding whether to pursue development opportunities, whilst also highlighting the broader implications for European healthcare systems at point of LoE.

This revised analysis echoes previous findings that pipeline activity is concentrated on biologics with high market value, as measured by projected global sales in the year before European loss of exclusivity (Exhibit 4). At present, a potential $143 billion (55%) of LoE-1 sales is the missed opportunity due to lack of biosimilar pipeline activity. This is largely driven by current gaps in the pipeline for some of the highest value biologics. However, it is important to note that many of these biologics are set to lose exclusivity after 2030, indicating the potential for future pipeline activity that is not yet publicly disclosed. Also, the estimate is based on global sales at the point of expiry and does not account for price reductions that may occur post-LoE.

Exhibit 4: Peak global forecast sales and status of biosimilar pipeline (2025–2034)



Source: IQVIA Patent Intelligence (2025); IQVIA analysis of the IQVIA Global Biosimilar Database (Q3 2025); IQVIA ForecastLink (Q3 2025).

Notes: Peak global forecast sales refers to the originator's global forecast sales in the year before LoE. Global pipeline analysis includes all biosimilars in development from pre-clinical to pre-registration; excl. approvals. Analysis is based on European LoE (2025-2032). The IP profile of individual biologics is subject to change as new patents and/or patent extensions become available during a product lifecycle. Biosimilars are expected to reach Europe if the Highest Trial Geography Coverage is in Europe or US (ClincialTrials.gov). Biosimilars not (yet) expected to reach Europe if the Highest Trial Geography Coverage is not in Europe or US, or is unknown. The data shown in this chart is accurate as of November 2025.

Observation 2: Commercial attractiveness

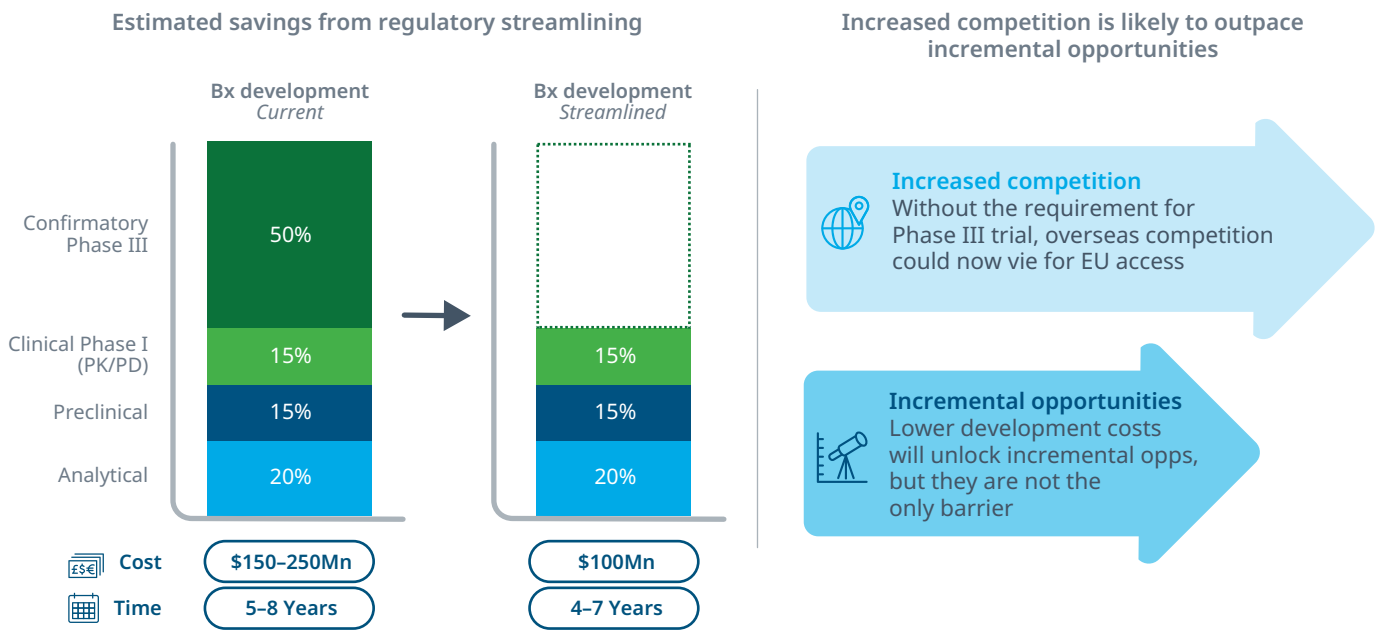
BIOSIMILAR REGULATORY STREAMLINING REDUCES DEVELOPMENT COSTS, BUT IS UNLIKELY TO FILL THE BIOSIMILAR VOID

Regulatory streamlining in biosimilar approval processes by the EMA will reduce the requirement for comparative efficacy studies,[1] leading to significant decreases in both the costs and timelines associated with biosimilar development. There are many variable estimates of the cost of biosimilar development, and uncertainty in the final cost. Therefore, a range has been given to highlight that some development costs may be higher than others (i.e. oncology vs non-oncology therapy areas, cost of reference drugs, etc.).

Collated evidence suggests that removing comparative efficacy studies could cut development costs by up to 50%, although actual costs and savings will depend on a range of factors such as geographic location, trial sites, patient numbers, reference drug pricing, trial duration, type of biologic, and the therapy area under consideration (Exhibit 5). This regulatory shift will undoubtedly unlock new opportunities for biosimilar development; however, it is unlikely fully address the existing biosimilar void. For example, there are 26 biologics approaching EU loss of exclusivity (up until 2032) with projected global sales below $100 million in the year before LoE, highlighting the challenge of attracting pipeline activity for lower-value products. The impact on the erosion of originator share for larger sales value molecules is likely to be increasing the fierce competition, and is also dependent on the policies and approaches by payers to support biosimilar uptake and access growth.

The removal of comparative efficacy study requirements may also open the European market to overseas competitors, who would not have to run extensive clinical development programs from afar, intensifying competition. A plausible scenario is that the pace of increased competition could surpass the incremental opportunities generated by regulatory streamlining. Already, there is significant

Exhibit 5: Estimated savings from regulatory streamlining



Source: Evaluating Biosimilar Development Projects: An Analytical Framework Utilizing Net Present Value (https://pubmed.ncbi.nlm.nih.gov/40165807/); Production costs and potential prices for biosimilars of human insulin and insulin analogues (https://gh.bmj.com/content/3/5/e000850#ref-25)

Notes: Biosimilar development cost are estimated based on global development costs and are not specific to therapy area or asset archetype, excludes regulatory fees.

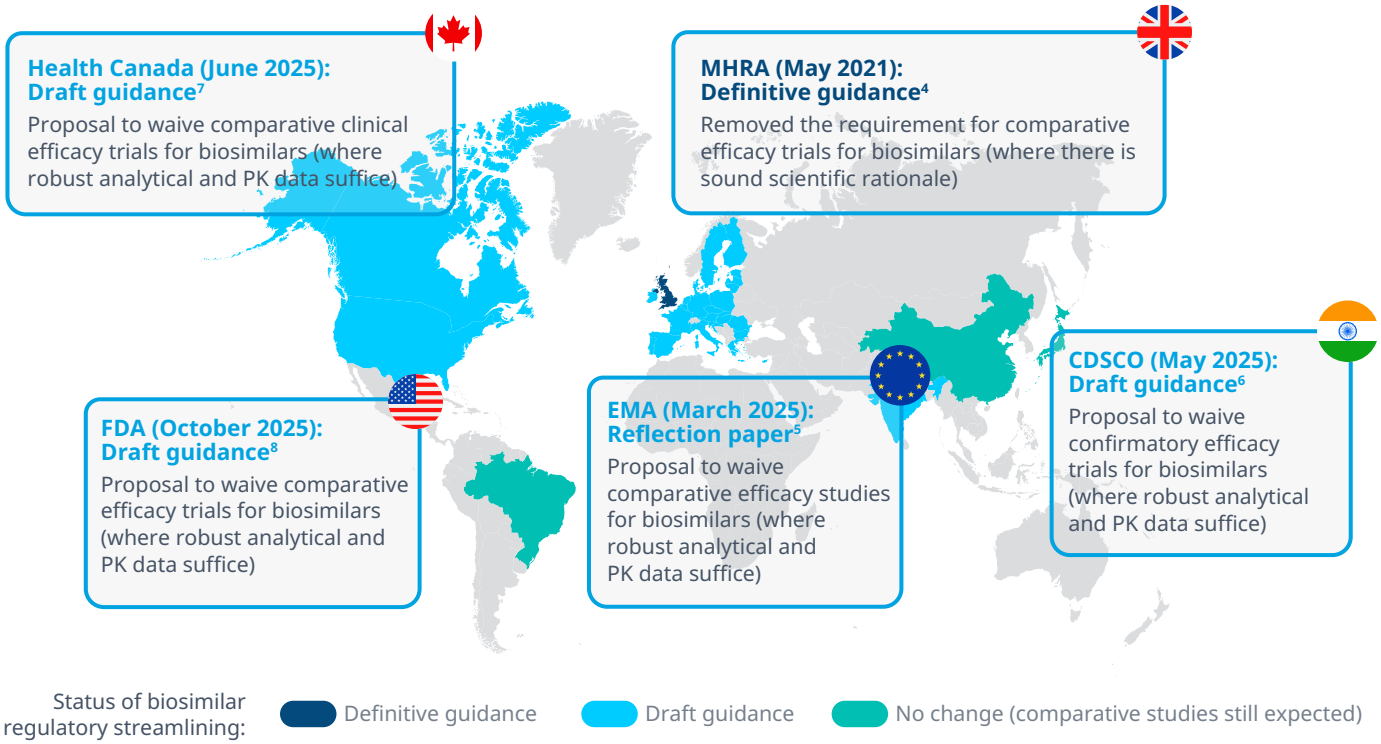
biosimilar uptake, high levels of competition, and payer preparedness for major LoE events. The impact of regulatory streamlining may further intensify competition in these major molecules, where cost of entry has been lowered, and accelerate the current trend of rapid biosimilar uptake, fierce competition and payer preparedness. The impact of this will be limited by manufacturers ability to supply the market and maintain pre-LoE originator volumes.

THE FULL IMPACT OF REGULATORY STREAMLINING WILL BECOME CLEAR AFTER INTERNATIONAL HARMONISATION

The EMA is not the only regulatory agency to propose changes to their biosimilar development policy. The FDA in U.S., Health Canada in Canada, and CDSCO in India have all drafted new guidance in relation to biosimilar regulatory streamlining in the last year, moving to waive the requirement for confirmatory efficacy trials for biosimilars (Exhibit 6).[2,3,4] These major countries are looking to join the MHRA in the UK, who paved the way by removing the requirement for comparative efficacy trials for biosimilars (where there is sound scientific rationale) in 2021.[5] These recent changes represent a pivotal shift in biosimilar regulation, signalling greater acceptance of biosimilar comparability and the harmonisation of scientific standards across leading agencies.

Despite these advancements, some major markets are yet to revise their regulatory frameworks and still mandate comparative efficacy trials for biosimilar approval (as of November 2025). Countries such as Japan, China and Brazil still require confirmatory efficacy trials for biosimilars, maintaining a barrier for manufacturers seeking global market entry. Biosimilar development decisions are often made at a global level, and therefore companies must comply with the most stringent requirements or risk exclusion from key markets. Until there is international consensus and uniform adoption of regulatory streamlining, the full benefits of these changes are unlikely to be seen.

Exhibit 6: Status of biosimilar regulatory streamlining across major countries (as of November 2025)



Biosimilar regulatory streamlining timeline:

Early shift signals flexibility[1,2]	Case-by-case waivers (G-CSF)[3]	Definitive guidance[4]	Reflection paper[5]	Draft guidance[6]	Draft guidance[7]	Draft guidance[8]
2014/15	2018	May '21	Mar '25	May '25	Jun '25	Oct '25

Sources: 1. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-similar-biological-medicinal-products-rev1_en.pdf; 2. https://www.fda.gov/media/82647/download; 3. https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-similar-biological-medicinal-products-containing-recombinant-granulocyte-colony-stimulating-factor-rg-csf-revision-1_en.pdf; 4. https://www.gov.uk/government/publications/guidance-on-the-licensing-of-biosimilar-products; 5. https://www.ema.europa.eu/en/news/streamlining-development-assessment-biosimilar-medicines; 6. https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/DgSimilaBiologics25.pdf; 7. https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/draft-information-submission-requirements-biosimilar-biologic-drugs.html; 8. https://www.fda.gov/media/189366/download

Observation 3: International competitiveness

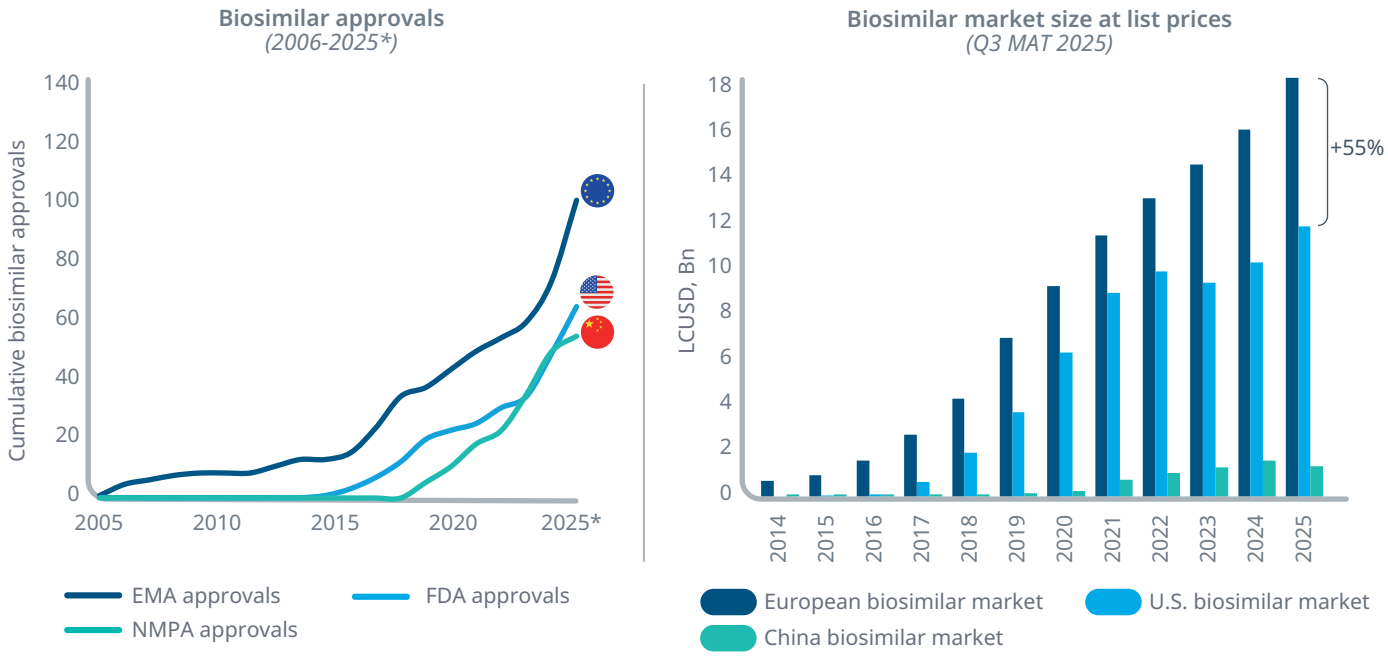
EUROPE IS STILL THE LEADING REGION FOR BIOSIMILARS, ALTHOUGH OTHER MARKETS ARE CATCHING UP

International competitiveness has become a key topic for Europe in 2025, driven by a continued focus on supply security, persistent economic headwinds, and shifting geopolitical priorities. Maintaining competitiveness is essential for Europe to attract pharmaceutical innovation, expand patient access to medicines, and strengthen supply chain resilience. This report examines the competitiveness of the biosimilar sector in Europe compared to other markets, while recognizing that biosimilars do not operate in isolation, but within the broader pharmaceutical and healthcare ecosystem.

Since the approval of the first biosimilar in 2006, Europe has consistently maintained its position as a global leader in the biosimilar sector. There are several ways to measure this: regulatory frameworks, manufacturing capabilities, streamlined approval processes, product approvals, market uptake, and market size. While regulatory developments have already been discussed in the previous section, Europe continues to set the pace in other key metrics, such as the number of biosimilar marketing authorisations and overall biosimilar market size.

Over the past decade, markets such as the United States and China have made notable progress, particularly with the number of biosimilar approvals (Exhibit 7). Nevertheless, Europe's biosimilar market remains 55% larger than that of the US, valued at $18 billion at list prices, and far surpasses the scale of the Chinese market. These serve as key indicators of Europe's ongoing competitiveness in biosimilars and a reflection of the maturity of the clinical acceptance and policies that support biosimilar competition.

Exhibit 7: Biosimilar regulatory approvals and market size in Europe, US and China (2006–2025)

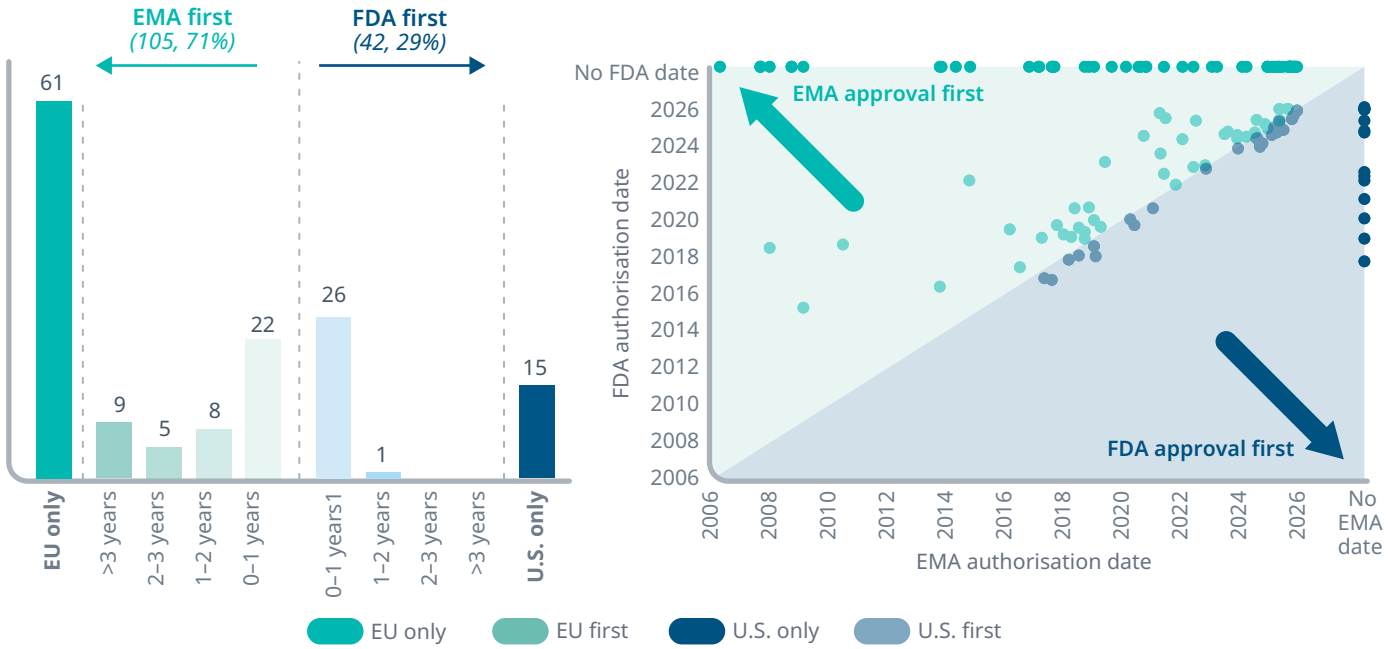


*Data for 2025 up to October 2025 for EMA and FDA, and July 2025 for NMPA.

Source: EMA EPAR list (Accessed October 2025); FDA Biosimilar Product Information (Accessed October 2025); NMPA approvals (Accessed October 2025, latest information for July 2025); IQVIA MIDAS sales at list prices (Q3 2025)

Notes: Where two biosimilars (different brand names for the same active substance) are approved on the same day, these are counted as two separate approvals in this analysis (for both EMA and FDA approvals). European market includes 27 countries (incl Norway, Switzerland, UK).

Exhibit 8: Biosimilar regulatory approval date differences between EU and US (2006–2025*)



*Data for 2025 only includes biosimilars approved between January and September 2025.

Source: EMA EPAR list (Accessed October 2025); FDA Biosimilar Product Information (Accessed October 2025); IQVIA Global Biosimilar Database (Q3 2025).

Notes: Where two biosimilars (different brand names for the same active substance) are approved on the same day, these are counted as two separate approvals in this analysis (for both EMA and FDA approvals).

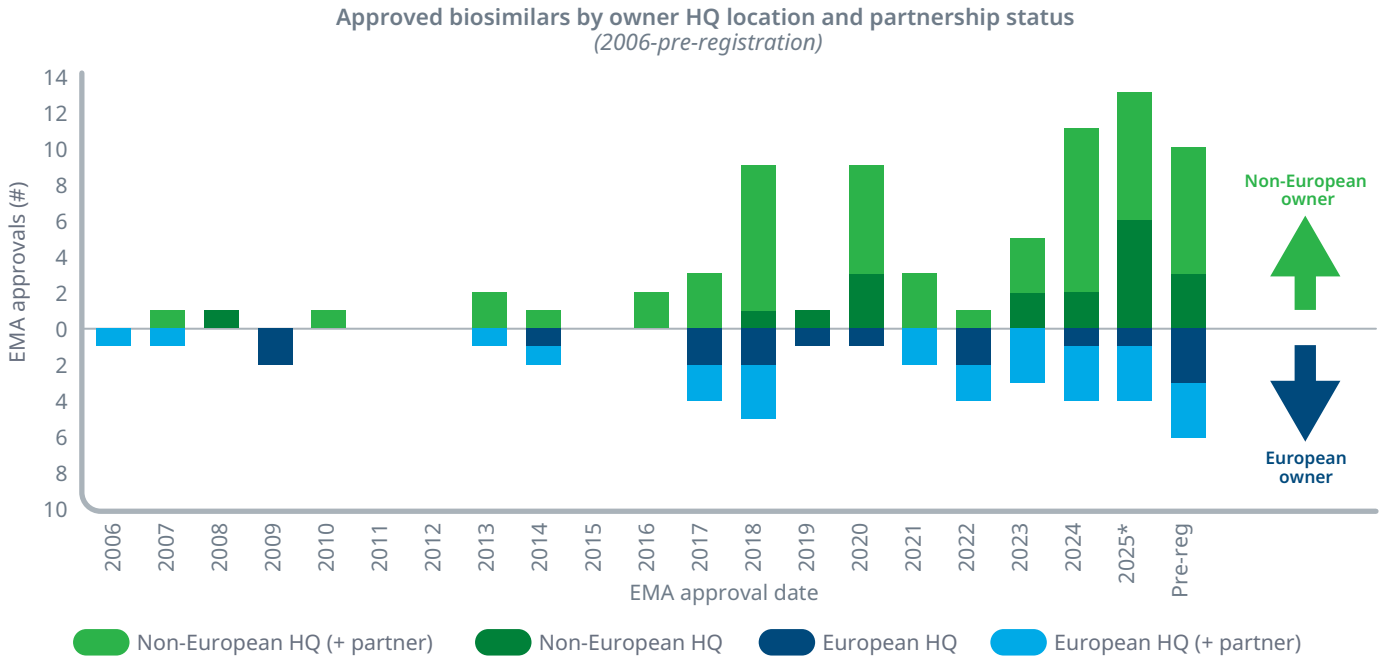
The timing and sequence of biosimilar approvals reinforces Europe's position, with 71% of biosimilars approved by the EMA before the FDA (Exhibit 8). However, there is a rising portion of biosimilars that receive FDA approval before EMA or have only received FDA approval so far, reflecting the growth of the US market. While this trend points to the US closing the gap with Europe, approval dates alone do not provide the full picture, and they are often influenced by the originator's loss of exclusivity, which can vary between the US and Europe. These factors are not considered in the current analysis but merit further investigation to strengthen the understanding of the changing biosimilar dynamics across geographies.

NON-EU PLAYERS AND PARTNERSHIPS ARE GROWING

In recent years, the landscape of biosimilar ownership has evolved, with a growing presence of non-EU companies entering the European market. While European manufacturers historically dominated biosimilar approvals, the sector now reflects strong participation from companies headquartered in the United States, India, and, more recently, South Korea (Exhibit 9). This shift highlights not only the expanding global interest in biosimilars but also increasing investments from regions outside Europe, which is indicative of healthy competition rather than a cause for concern. The regional distribution of biosimilar developers demonstrates that Europe remains a key player, whilst the market continues to diversify as new entrants establish their footprint. The recent biosimilar regulatory streamlining is likely to accelerate this trend, with the European market becoming more attractive and accessible to non-EU players without the requirement of comparative efficacy studies.

It is important to note that current data on biosimilar ownership does not capture the location of manufacturing or the supply available in manufacturing facilities, a metric of growing relevance when discussing security of supply in Europe. Another emerging trend is the rise of strategic partnerships, where experienced non-EU companies collaborate

Exhibit 9: EMA biosimilar approvals by owner HQ location and partners (2006–2025)



*Data for 2025 only includes biosimilars approved between Jan and September 2025.

Source: IQVIA Patent Intelligence (2025); IQVIA Global Biosimilar Database (Q3 2025).

Note: Partnerships are defined as R&D, out-licensing or marketing collaborations that involve two or more biosimilar manufacturers. European HQ = approval obtained by one European biosimilar owner only, without any partnership. European HQ (+ partner)= collaboration between European owner and another company. Non-European HQ = approval obtained by one non-European owner only, without any partnership. Non-European HQ (+ partner)= collaboration between non-European owner and another company. 'European' includes EU27 countries plus Iceland, Switzerland, Turkey, and UK.

with established European manufacturers to facilitate product launches. Such alliances enhance the capacity for innovation and market reach, reinforcing Europe's role as a hub for biosimilar development while fostering greater global integration within the sector.

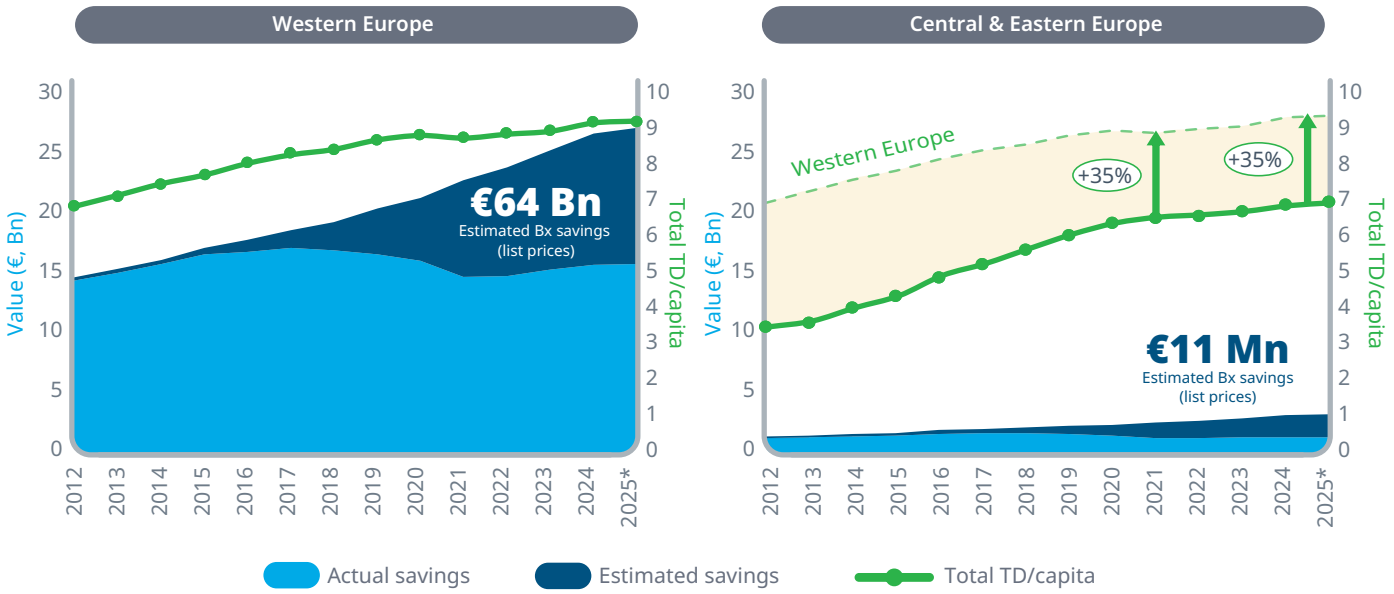
Observation 4: Access inequality

IMPROVING ACCESS TO TREATMENTS IS CHALLENGING WITHOUT BEING ABLE TO GENERATE SAVINGS FROM BIOSIMILARS

In the last 5 years, the gap between patient volumes in Western Europe and Central & Eastern Europe (CEE) has not decreased, even with biosimilar entry and competition. Patient Treatment Days (TD) per capita for all biologics studied remain 35% higher in Western Europe than in CEE (Exhibit 10). Notably, the majority of the increase in CEE patient volumes from 2012 to 2021 is attributable to originator molecules, with biosimilars accounting for only a small share. Overall patient volumes rose by 3.0 treatment days TD/capita, of which biosimilars contributed just 0.7 TD/capita.

Using pre-biosimilar list prices and post-biosimilar sales volumes, it is possible to estimate the list price savings that are generated following biosimilar entry. These estimates likely represent an overestimate of savings due to use of list prices, but in the absence of information on rebates and commercial discounts, it is the best available option. As of 2025 (Q2 MAT 2025 data), it is estimated that Europe has generated €75 billion in list price savings from biosimilar competition. However, when segmented by region, the extent of the savings generated are much greater at €64 billion in Western Europe, compared to €11 billion in CEE. Despite significant price differences between Western and CEE markets, the underlying challenge persists; without sufficient savings, improving access to biologic therapies following biosimilar entry remains difficult.

Exhibit 10: Savings from the impact of biosimilar competition at list prices and total treatment days per capita



*Q2 MAT 2025.

Source: IQVIA MIDAS data from 2012-2025 (Q2 MAT 2025), using Euros at constant exchange rates.

Notes: 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. Value includes originator products with approved biosimilars from 2006–2025 (Adalimumab, Bevacizumab, Enoxaparin sodium, Epoetin alfa, Etanercept, Filgrastim, Follitropin alfa, Infliximab, Insulin aspart, Insulin glargine, Insulin lispro, Pegfilgrastim, Rituximab, Somatropin, Teriparatide, Trastuzumab), covering EEA+UK, calculated volume is in treatment days determined by WHODDD, and where values are unavailable via Oncology Dynamics Physician Survey (2017) DDD estimates. Treatment days per capita measures total molecule volumes (originator and biosimilars). Western Europe (Austria, Belgium, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, UK), CEE (Bulgaria, Croatia, Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia).

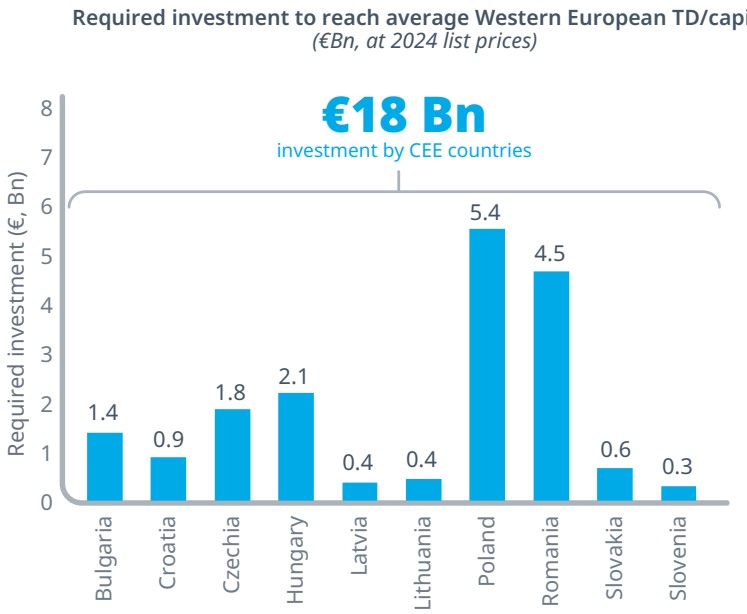
ADDITIONAL INVESTMENT IN BIOLOGICS IS REQUIRED TO REDUCE THE ACCESS DISPARITY BETWEEN WESTERN EUROPE AND CEE COUNTRIES

IQVIA has modelled the required investment in biologic medicine use for CEE markets to reduce access disparities and achieve the average treatment days per capita (TD/capita) seen in Western Europe. The approach uses the current TD/capita per molecule per CEE country and calculates the difference compared to the Western European average TD/capita per molecule. Using current 2024 list prices per molecule and the difference in TD/capita, the required investment can be calculated per molecule per country.

While increased funding alone will not fully close the gap and other factors such as market readiness, health system infrastructure, and non-drug healthcare delivery costs remain essential, this analysis provides valuable perspective on one aspect of the challenge. The modelling indicates that approximately €18 billion in investment would be needed for CEE countries to match Western European patient volumes, though this figure is likely an overestimate as it is based on list prices (Exhibit 11). The required investment varies by country and by molecule, reflecting differences in current usage and pricing.

The modelling indicates that approximately €18 billion in investment would be needed for CEE countries to match Western European patient volumes, though this figure is likely an overestimate as it is based on list prices.

Exhibit 11: Estimated investment for CEE countries to reach Western European patient volumes (at 2024 list prices)



Known caveats/considerations

- Data does not include rebates / discounts and is based on list prices; therefore, it is an overestimation of required investment
- Regardless of the amount of funding available, any investment will have to be made over a time horizon to be implemented effectively (i.e., 5-10 years); no immediate fix would occur
- Analysis is based on 2024 list prices, which may vary in the future
- Some molecule volumes already exceed Western European average
- Increased funding for medicine use alone will not fully close the gap and other factors such as market readiness, health system infrastructure, and non-drug healthcare delivery costs are also essential.

Source: IQVIA MIDAS data (Q2 MAT 2025), using Euros at constant exchange rates.

Notes: Analysis includes originator products with approved biosimilars from 2006 – 2025 (Adalimumab, Bevacizumab, Enoxaparin sodium, Epoetin alfa, Etanercept, Filgrastim, Follitropin alfa, Infliximab, Insulin aspart, Insulin glargine, Insulin lispro, Pegfilgrastim, Rituximab, Somatropin, Teriparatide, Trastuzumab); Required investment is estimated at country and molecule level using 2024 TD/capita and 2024 prices/TD in each CEE country, compared to the average TD/capita per product in Western Europe in 2024, and converted to investment required. Molecules where TD/capita already exceed Western average are not included in the calculation. The data does not include the impact of rebates or discounts, as it is based on publicly available list prices. Western Europe (Austria, Belgium, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, UK), CEE (Bulgaria, Croatia, Czech Republic, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia); Estonia and Greece excluded as retail only sales coverage.

This remains an estimate based on best available data, and there are a number of considerations and limitations of the analysis which include: the data does not account for rebates or discounts and relies on list prices, resulting in a probable overstatement of the investment requirement; regardless of available funding, any increase in investment must be phased over a multi-year period (typically 5–10 years) for effective implementation, and a rapid solution is not feasible; the analysis is based on 2024 list prices, which may change over time; and, for some molecules, patient volumes in certain CEE countries already exceed the Western European average and require no further investment.

While increased funding alone will not fully close the gap and other factors such as market readiness, health system infrastructure, and non-drug healthcare delivery costs remain essential, this analysis provides valuable perspective on one aspect of the challenge.

Observation 5: Advanced planning

ADVANCED METRICS CAN SUPPORT AN UNDERSTANDING OF FUTURE SAVINGS, ACCESS, AND MARKET SUSTAINABILITY PROVIDED BY BIOSIMILARS

Forecasting the future potential from biosimilar competition is a challenging activity, given the uncertainty regarding originator LoE dates, the extent of biosimilar competition, ongoing regulatory changes to streamline biosimilar development, and various other factors. Based on past learnings, it would be valuable to take a more holistic view towards planning for biosimilar entry and competition, to ensure long-term market sustainability.

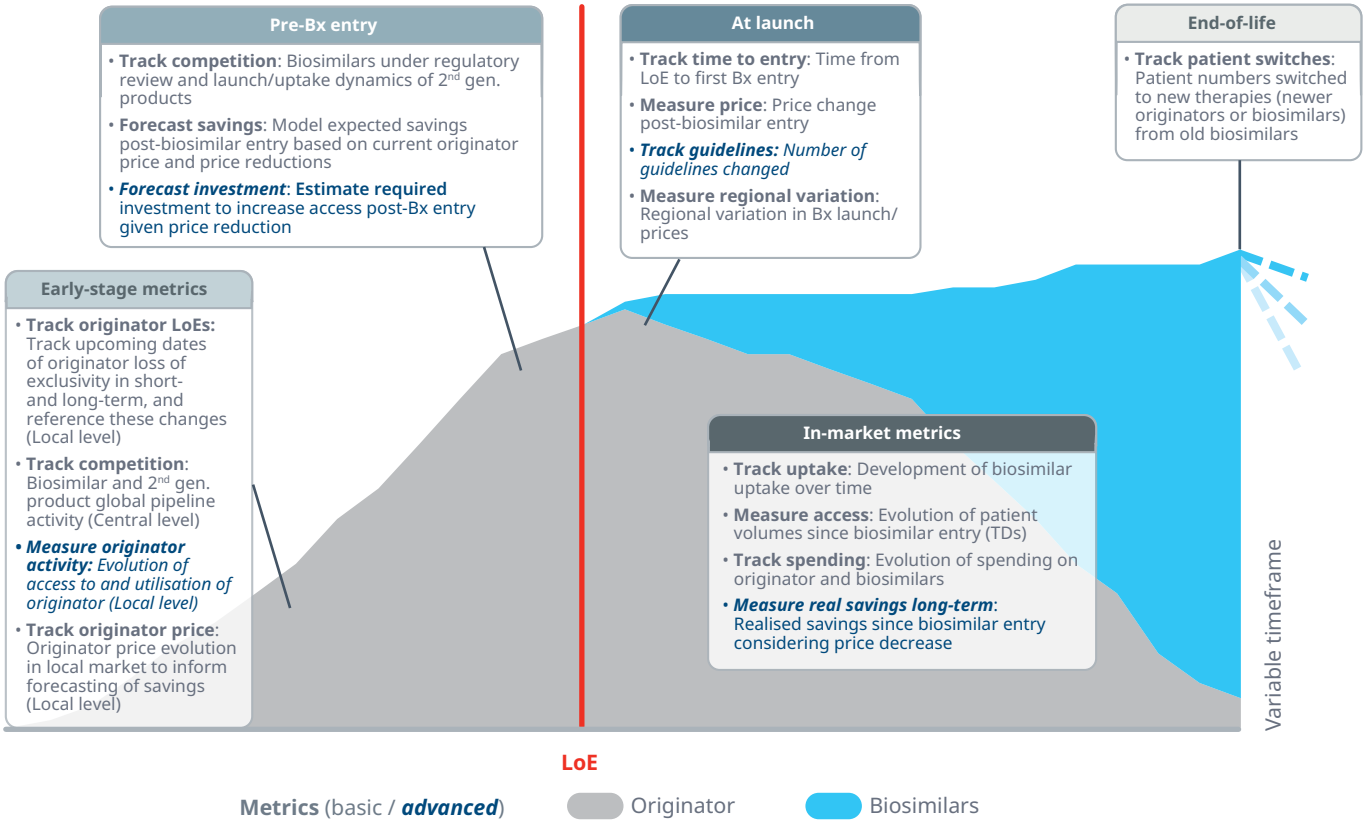
This is a form of horizon scanning, though differentiated from the usual definition of horizon scanning which generally refers to the preparation for entry of novel therapeutics, however the concept is similar in this context.

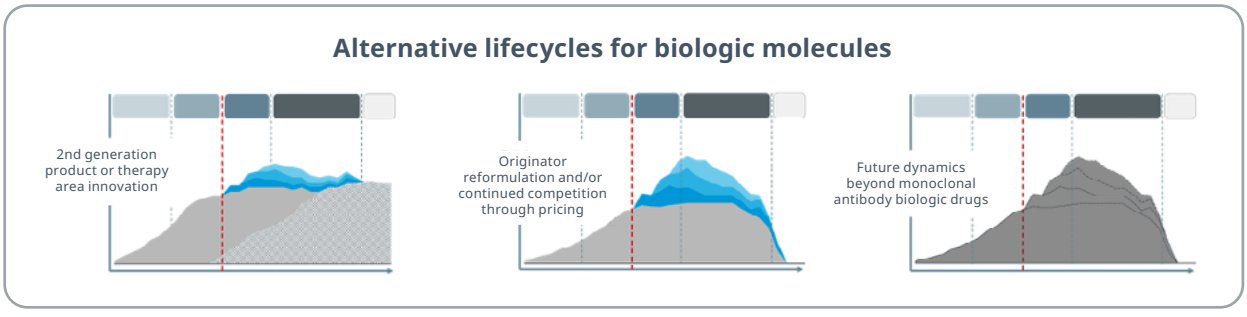
The product lifecycle below is illustrative only, and there are various alternative lifecycles for biologic molecules, however it provides a basis for the advanced metrics required for optimal planning by payers and strategic planners at National Competent Authorities (NCAs) (Exhibit 12).

1. **Early-stage metrics**: Gathering insights early in the process, before originator LoE and biosimilar entry, provides incremental value to payers and strategic planners. The main value is in supporting later-stage planning (such as the tracking of originator LoEs) and should be run at both a central and local level depending on the metric to understand the likelihood of savings and competition which is not guaranteed or consistent across countries.
    - **Track originator LoEs**: Track upcoming dates of originator loss of exclusivity in short- and long-term, and reference these changes (local level)
    - **Track competition**: Biosimilar and 2nd gen product global pipeline activity (central level)
    - **Measure originator activity**: Evolution of access to and utilisation of originator (local level)
    - **Track originator price**: Originator price evolution in local market to inform forecasting of savings (local level)
2. **Pre-biosimilar entry metrics**: In the year before LoE and biosimilar entry, tracking upcoming competition and forecasting its impact are important activities for payers to support budget planning discussions. Tracking competition should be conducted primarily at a central level, whilst forecasting activities are more beneficial at the local level.
    - **Track competition**: Biosimilars under regulatory review and launch/uptake dynamics of 2nd gen. products
    - **Forecast savings**: Model expected savings post-biosimilar entry based on current originator price and price reductions
    - **Forecast investment**: Estimate required investment to increase access post-Bx entry given price reductions
3. **At launch metrics**: At the point of biosimilar launch, various metrics can be gathered to help predict the true impact of biosimilar competition. Time to biosimilar entry, price changes, and adaptations of treatment guidelines will all provide early signals on the future impact biosimilars will have. These metrics should be conducted at the local level, with regional variations also relevant.
    - **Track time to entry**: Time from LoE to first Bx entry
    - **Measure price**: Price change post-biosimilar entry
    - **Track guidelines**: Number of guidelines changed
    - **Measure regional variation**: Regional variation in Bx launch/prices

4. **In-market metrics**: In the years after biosimilar entry, traditional market indicators should be monitored and published to understand the ongoing impact of biosimilar competition. Biosimilar uptake, patient volumes and spending are important metrics, as well as the realised savings to budget holders following biosimilar entry. These should be conducted at the local level.
   - **Track uptake**: Development of biosimilar uptake over time
   - **Measure access**: Evolution of patient volumes since biosimilar entry (TDs)
   - **Track spending**: Evolution of spending on originator and biosimilars
   - **Measure real savings long-term**: Realised savings since biosimilar entry considering price decrease
5. **End-of-life metrics**: Finally, towards the end of a product lifecycle, it is relevant for payers/NCAs to measure the number of patients switching from older biosimilars to newer therapies, whether that be originators or newer biosimilars. This should be conducted at a local level.
   - **Track patient switches**: Patient numbers switched to new therapies (newer originators or biosimilars) from old biosimilars

Exhibit 12: Metrics for lifecycle planning for payers / strategic planners at National Competent Authorities





Source: IQVIA expertise.
Notes: Lifecycle curve is illustrative only.

Methodology

'The Impact of Biosimilar Competition' series covers the main product segments with biosimilar competition, that have seen recent market developments or biosimilar entry. Older product segments (such as Human Growth Hormones, Epoetins, Fertility, and Low-molecule-weight heparins) have been discontinued from this series, as they first faced biosimilar competition over a decade ago and / or have not seen any major market developments in recent years. The data behind the KPIs for these product segments are still available, so reach out to IQVIA if these are still of interest.

This does mean that the KPI segment of the report provides an incomplete view of the biosimilar competition market. With the dynamic development of new originator medicines, there is a segment of the biologic market that is not covered (Excluded non-accessible market), which is growing in volume terms. Once these major biologics lose exclusivity and receive biosimilar competition, they will be considered for inclusion in the report.

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 Organisation (WHO) Defined Daily Doses (DDD), which can introduce bias. Consumption measures are therefore not adjusted 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 2024 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 2024 versus year before biosimilar entry.
- **Volume per capita 2024:** Number of Treatment Days consumed in 2024 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 centralised 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

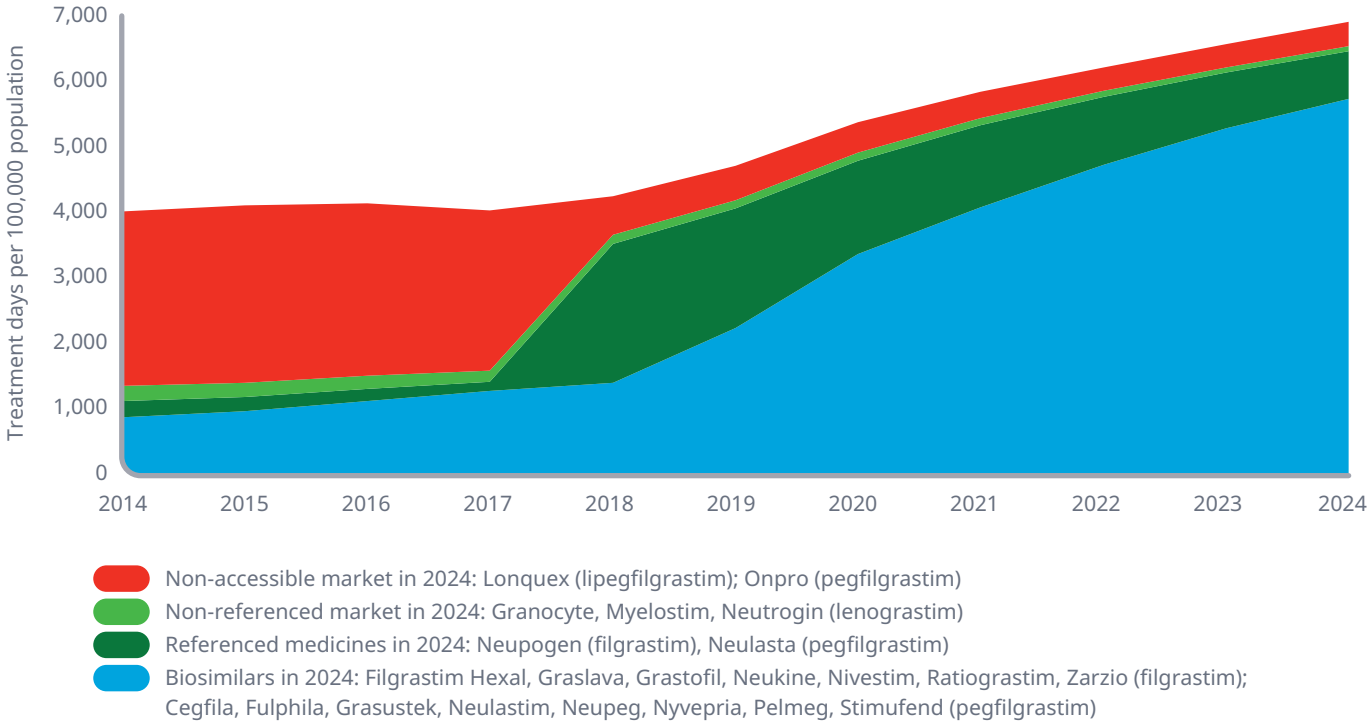
Granulocyte-colony Stimulating Factor (GCSF)

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	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	CYTOTOXIC CHEMOTHERAPY 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 DIAGNOSIS 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 (2024)	Biosimilar vs.Referenced product	73%	75%	86%	100%	100%	93%	91%	75%	100%	100%	37%	91%	98%	92%	100%	100%	97%	100%	62%	89%	99%	87%	90%	89%
	Biosimilar vs.Accessible market	73%	75%	86%	100%	100%	93%	88%	74%	100%	100%	37%	91%	98%	92%	100%	100%	97%	100%	62%	89%	99%	87%	88%	88%
	Biosimilar vs. Total market	63%	46%	57%	94%	100%	92%	87%	66%	94%	100%	34%	85%	98%	92%	100%	100%	97%	90%	59%	89%	99%	87%	88%	82%
PRICE PER TD (2024/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-80%	-72%	-89%	-89%	-67%	-87%	-79%	-75%	-72%	-90%	-74%	-59%	-72%	-62%	-92%	-98%	-81%	-91%	-90%	-53%	-79%	-62%	-23%	-76%
	Biosimilar accessible market	-80%	-72%	-89%	-89%	-67%	-87%	-77%	-74%	-72%	-90%	-74%	-59%	-72%	-62%	-92%	-98%	-81%	-91%	-90%	-53%	-79%	-62%	-22%	-75%
	Total market	-68%	-57%	-85%	-85%	-44%	-79%	-63%	-64%	-56%	-87%	-51%	-40%	-53%	-37%	-90%	-93%	-80%	-86%	-84%	-43%	-70%	-37%	-8%	-65%
VOLUME TD (2024/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	1014%	1229%	6667%	2966%	1291%	1336%	2575%	965%	4630%	758%	1130%	556%	1545%	3155%	1286%	823%	2788%	3919%	1633%	107%	1079%	579%	718%	1065%
	Biosimilar accessible market	1014%	1229%	6667%	2966%	1291%	1336%	2663%	985%	4630%	758%	1141%	557%	1545%	3155%	1286%	824%	2788%	3919%	1633%	107%	1079%	579%	734%	1080%
	Total market	163%	172%	6200%	1126%	123%	109%	142%	177%	-31%	99%	104%	36%	31%	252%	476%	6%	2632%	1318%	441%	-31%	201%	99%	176%	141%
	TD per capita (2024)	0.14	0.12	0.12	0.06	0.09	0.11	0.12	0.07	0.01	0.07	0.10	0.04	0.04	0.09	0.10	0.04	0.09	0.12	0.09	0.02	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.

Notes: 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)

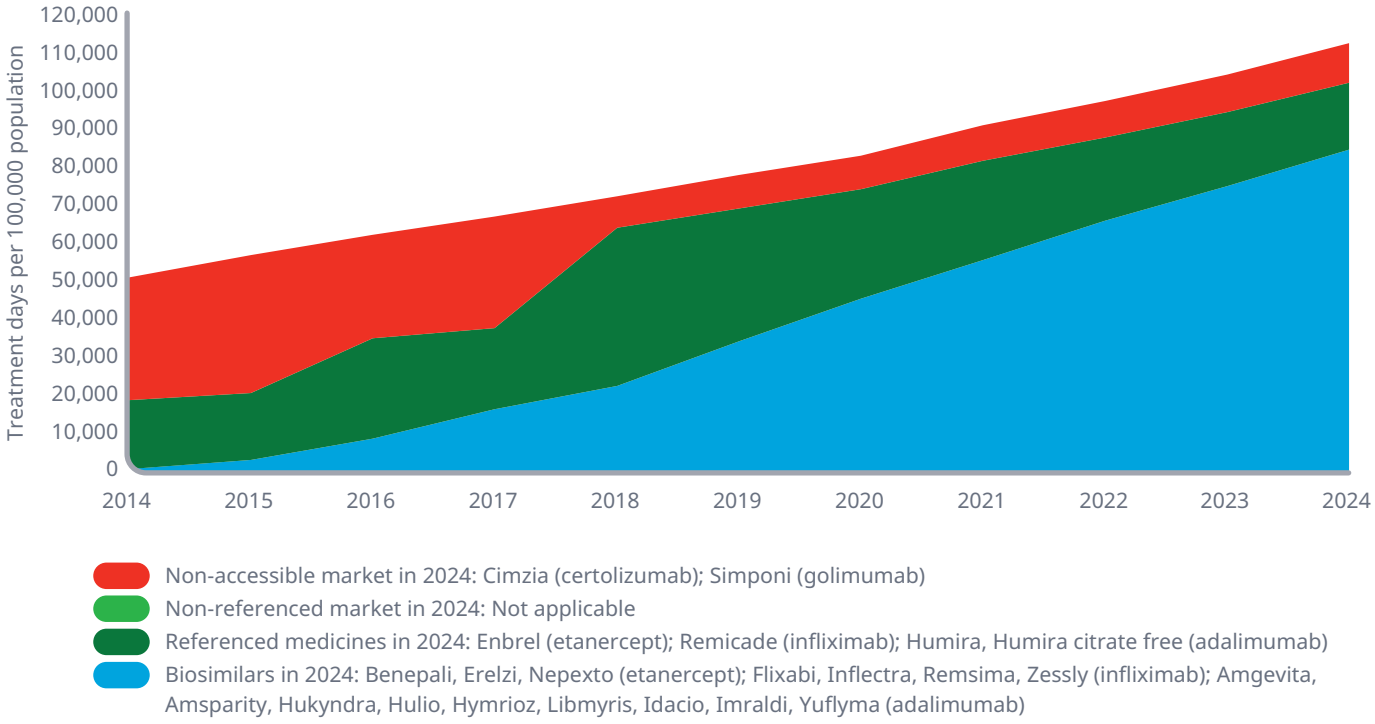
Anti-TNF drugs are a class of drugs that are used to treat inflammatory conditions such as Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, Juvenile Arthritis, Crohn's Disease, Ulcerative Colitis, Psoriasis and Hidradinitis Suppurativa. These drugs are able to reduce inflammation and 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	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	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	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	Every 2 weeks	SC	N
	HUMIRA (citrate free)			●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		SC	Y
	AMGEVITA					●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		SC	Y
	HULIO					●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		SC	Y
	HYRIMOZ					●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		SC	N
	IMRALDI					●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		SC	Y
	IDACIO					●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		SC	N
	AMSPARITY					●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		SC	Y
	YUFLYMA					●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		SC	Y
	LIBMYRIS					●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		SC	Y
	HUKYNDRA					●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		SC	Y
CERTOLIZUMAB PEGOL	CIMZIA	●	●	●	●	●	●	●	●	●	●	●	●		●	●				●			Monthly	SC	n/a
ETANERCEPT	ENBREL	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●				●			Once or twice weekly	SC	n/a
	BENEPALI			●	●	●	●	●	●	●	●	●	●	●	●	●				●				SC	n/a
	ERELZI				●	●	●	●	●	●	●	●	●	●	●	●				●				SC	n/a
	NEPEXTO				●	●	●	●	●	●	●	●	●	●	●	●				●				SC	n/a
GOLIMUMAB	SIMPONI	●	●	●	●	●	●	●	●	●	●	●	●		●	●			●				Monthly	SC	n/a
INFLIXIMAB	REMICADE	●	●	●	●	●	●	●	●	●	●	●	●		●	●		●	●	●			Every 8 weeks	IV	n/a
	REMSIMA	●	●	●	●	●	●	●	●	●	●	●	●		●	●		●	●	●				BOTH	n/a
	INFLECTRA	●	●	●	●	●	●	●	●	●	●	●	●		●	●		●	●	●				IV	n/a
	FLIXABI	●		●	●	●	●	●	●	●	●	●	●		●	●		●	●	●				IV	n/a
	ZESSLY	●		●	●	●	●	●	●	●	●	●	●		●	●		●	●	●				IV	n/a

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

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 (2024)	Biosimilar vs.Referenced product	53%	65%	33%	71%	98%	93%	69%	83%	69%	92%	82%	94%	79%	86%	99%	86%	61%	37%	62%	91%	95%	56%	94%	81%
	Biosimilar vs.Accessible market	53%	65%	33%	71%	98%	93%	69%	83%	69%	92%	82%	94%	79%	86%	99%	86%	61%	37%	62%	91%	95%	56%	94%	81%
	Biosimilar vs. Total market	44%	59%	29%	64%	92%	78%	61%	73%	58%	82%	76%	82%	75%	83%	78%	81%	56%	35%	57%	83%	92%	44%	89%	73%
PRICE PER TD (2024/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-59%	-28%	-43%		-1%		-37%	-4%	-48%	-11%	-12%	33%	-24%		-72%	-67%	-16%	-53%	-63%	-11%	-59%	-13%	26%	-19%
	Biosimilar accessible market	-59%	-28%	-43%		-1%		-37%	-4%	-48%	-11%	-12%	33%	-24%		-72%	-67%	-16%	-53%	-63%	-11%	-59%	-13%	26%	-19%
	Total market	-58%	-44%	-52%	-49%	-33%	-57%	-52%	-44%	-43%	-34%	-38%	-19%	-46%	-28%	-74%	-77%	-44%	-63%	-69%	-35%	-70%	-36%	-9%	-45%
VOLUME TD (2024/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	1087%	212%	>1MN%		497%		328%	496%	174%	357%	1076%	437%	379%		1679%	814%	219%	319%	440%	472%	551%	228%	722%	466%
	Biosimilar accessible market	1087%	212%	>1MN%		497%		328%	496%	174%	357%	1076%	437%	379%		1679%	814%	219%	319%	440%	472%	551%	228%	722%	466%
	Total market	857%	53%	521%	298%	167%	193%	109%	107%	102%	80%	226%	82%	95%	228%	371%	294%	40%	125%	106%	137%	153%	83%	147%	125%
	TD per capita (2023)	1.51	1.38	0.70	0.92	2.31	1.84	1.27	1.00	0.01	0.60	2.86	0.68	1.83	3.30	0.21	1.13	0.30	1.12	0.95	1.30	2.20	1.42	1.44	1.04
	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.

Notes: 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 2024 (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.

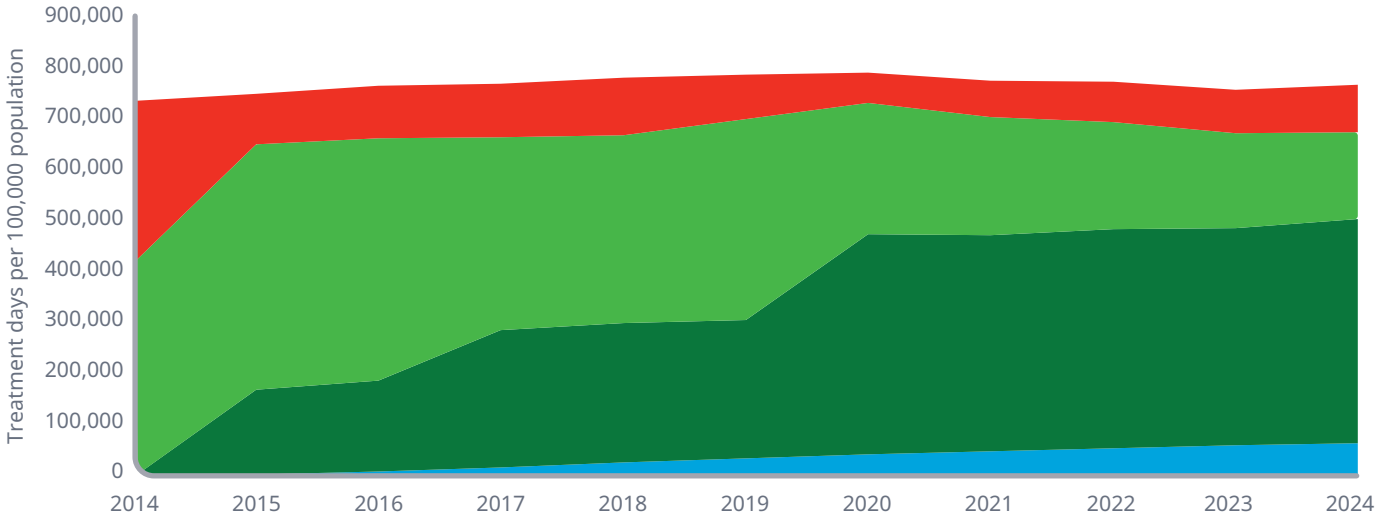
Insulins

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 2024: Ryzodeg (insulin aspart / insulin degludec); Tresiba (insulin degludec); Xultophy (insulin degludec / liraglutide); Toujeo (insulin glargine); Soliqua (insulin glargine / lixisenatide)
- Non-referenced market in 2024: 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 2024: Novorapid (insulin aspart), Lantus (insulin glargine); Humalog / Liprolog (insulin lispro)
- Biosimilars in 2024: Insulin aspart Sanofi, Kirsty (insulin aspart); Truvelog Mix 30 (insulin aspart / protamine); Abasaglar, Semglee (insulin glargine); Ademlog / insulin lispro Sanofi (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	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	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	Long-acting
INSULIN HUMAN*	ACTRAPID HUMULIN PROTAPHANE	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	Before every meal Once/twice a day Once/twice a day	Long-acting Long-acting Long-acting
INSULIN LISPRO	HUMALOG/LIPROLOG ADEMLOG/ INSULIN LISPRO SANOFI	●	●	●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	Before every meal before every mealB	Long-acting Long-acting
INSULIN LISPRO#INSULIN LISPRO PROTAMINE	HUMALOG /LIPROLOG MIX	●	●	●	●	●	●	●	●	●	●	●	●	Determined by physician	Long-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 (2024)	Biosimilar vs.Referenced product	8%	1%	4%	3%	20%	5%	17%	10%	9%	2%	0%	10%	35%	20%	23%	14%	7%	13%	5%	15%	31%	1%	5%	14%
	Biosimilar vs.Accessible market	5%	1%	1%	3%	19%	4%	15%	7%	8%	1%	0%	9%	28%	15%	11%	10%	5%	8%	3%	12%	25%	1%	3%	10%
	Biosimilar vs. Total market	5%	1%	1%	2%	14%	3%	13%	7%	6%	1%	0%	7%	24%	13%	10%	8%	4%	6%	2%	11%	23%	1%	3%	9%
PRICE PER TD (2024/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-34%	-38%					-44%		-25%		-42%	-32%				-30%	-17%		-49%					-26%
	Biosimilar accessible market	-1%	-11%		22%	-25%	-2%	-26%	28%	-6%	36%	-19%	-10%	-1%	23%	9%	1%	14%	23%	-21%	19%	17%	-14%	12%	4%
	Total market	1%	-6%		29%	-25%	-24%	-14%	13%	24%	80%	-14%	32%	-12%	43%	10%	4%	41%	50%	4%	-10%	3%	-6%	-1%	6%
VOLUME TD (2024/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	467%	263%					163%		107%		311%	162%				157%	153%		359%					562%
	Biosimilar accessible market	-7%	11%		38%	65%	158%	24%	15%	-8%	2%	46%	-3%	90%	31%	13%	7%	13%	43%	-13%	149%	64%	86%	122%	27%
	Total market	-5%	13%		27%	3%	-2%	22%	-13%	4%	-7%	37%	-6%	-2%	17%	0%	10%	31%	7%	-6%	3%	2%	11%	28%	2%
	TD per capita (2024)	4.98	7.17	5.65	9.48	6.52	11.09	7.44	9.79	7.51	8.87	5.82	5.52	8.76	7.61	7.04	5.90	7.03	7.04	7.79	7.03	9.38	4.77	8.71	7.62
	TD/capita (Yr before BS entrance)	5.50	6.69	0.00	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.

Notes: 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.

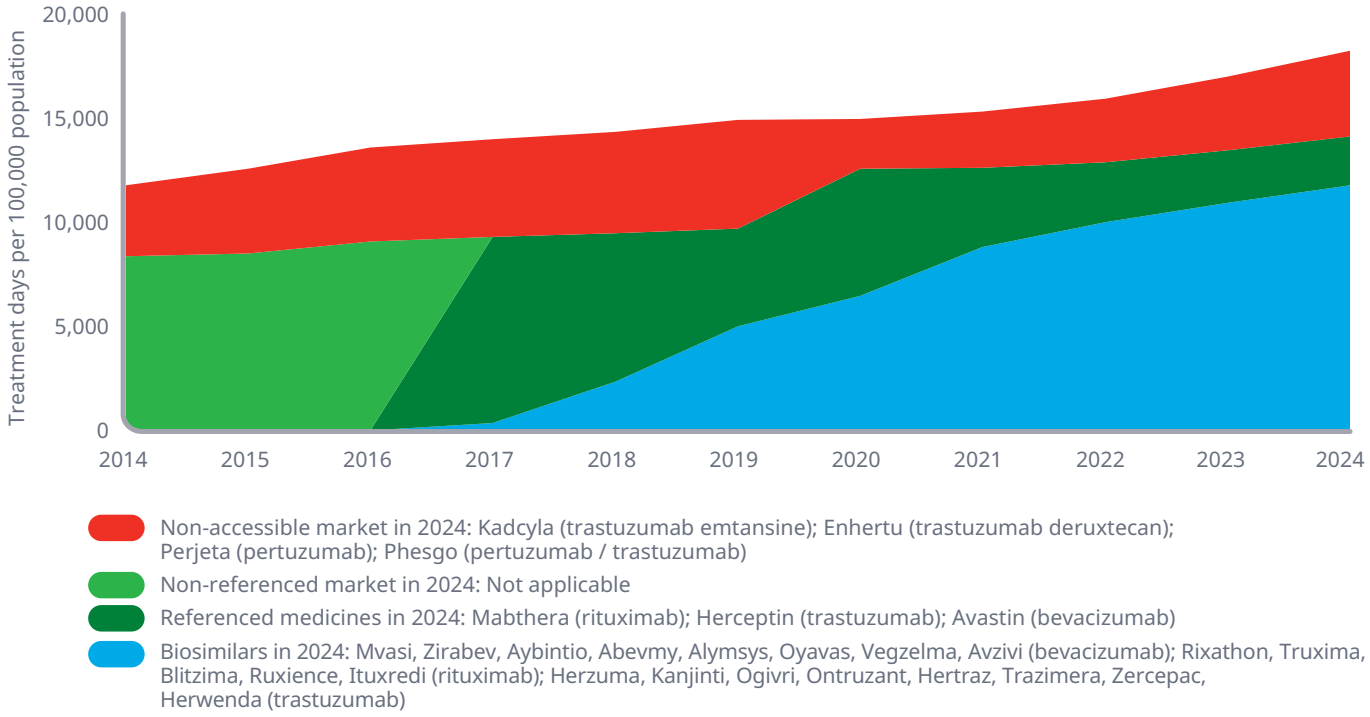
In this market the non-accessible products are classified by identifying products which have a similar mechanism of action, and are used for similar indications to rituximab. There are both IV and SC forms of Mabthera available, but because the biosimilar is only available in IV form, Mabthera IV is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



Oncology approved indications

NAMING		CLASSIFICATION											INDICATIONS									DOSING	
MOLECULE	PRODUCT	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	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 AVZIVI	●	●	●	●	● ●	● ●	● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●			● ● ● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ● ● ●		● ● ● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ● ● ●	IV IV IV IV IV IV IV IV IV IV IV	2 – 3 week cycles (indication/ combination dependent)
RITUXIMAB*	MABTHERA RIXATHON TRUXIMA BLITZIMA RITEMVIA RUXIENCE ITUXREDI	●	●	●	● ●	● ● ● ●	● ● ● ●	● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ●	● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ●	● ● ● ● ● ● ●									SC/IV IV IV IV IV IV IV	3 – 4 week cycles (indication/ combination dependent)
TRASTUZUMAB**	HERCEPTIN HERZUMA KANJINTI OGIVRI ONTRUZANT HERTRAZ TRAZIMERA ZERCEPAC HERWENDA	●	●	●	● ●	● ● ● ● ●	● ● ● ● ● ●	● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●				● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ●						SC/IV 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
PERTUZUMAB-#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 (2024)	Biosimilar vs.Referenced product	92%	59%	64%	65%	96%	82%	81%	92%		89%	65%	89%	95%	96%	70%	74%		81%	69%	91%	96%	68%	69%	85%
	Biosimilar vs.Accessible market	92%	59%	64%	65%	96%	82%	81%	92%		89%	65%	89%	95%	96%	70%	74%		81%	69%	91%	96%	68%	69%	85%
	Biosimilar vs. Total market	71%	45%	47%	49%	81%	69%	67%	72%		75%	52%	62%	78%	75%	49%	57%		62%	50%	70%	80%	50%	49%	66%
PRICE PER TD (2024/ YR BEFORE BS ENTRY)	Biosimilar and Referenced product	0%	-29%	-53%	-39%		1%				-28%					-69%			-52%	-53%		-18%	-29%		-32%
	Biosimilar accessible market	0%	-29%	-53%	-39%	-19%	1%	-56%	-37%		-28%	-31%	-12%	-34%	17%	-69%	-62%		-52%	-53%	-31%	-18%	-29%	0%	-37%
	Total market	20%	-13%	-18%	-1%	-1%	13%	-25%	-19%		-17%	-9%	27%	-24%	57%	-20%	-22%		-11%	-20%	-4%	11%	-9%	45%	-10%
VOLUME TD (2024/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	65%	67%	129%	19%		60%				89%					28%			64%	11%		23%	28%		663%
	Biosimilar accessible market	65%	67%	129%	19%	39%	60%	159%	54%		89%	38%	17%	51%	59%	28%	99%		64%	11%	64%	23%	28%	-10%	68%
	Total market	18%	43%	69%	11%	12%	35%	84%	16%		24%	26%	10%	30%	56%	48%	93%		22%	20%	53%	13%	16%	11%	37%
	TD per capita (2024)	0.21	0.23	0.20	0.12	0.18	0.21	0.31	0.21		0.15	0.19	0.17	0.17	0.20	0.10	0.18		0.13	0.15	0.20	0.16	0.20	0.13	0.19
	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.

Notes: 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.

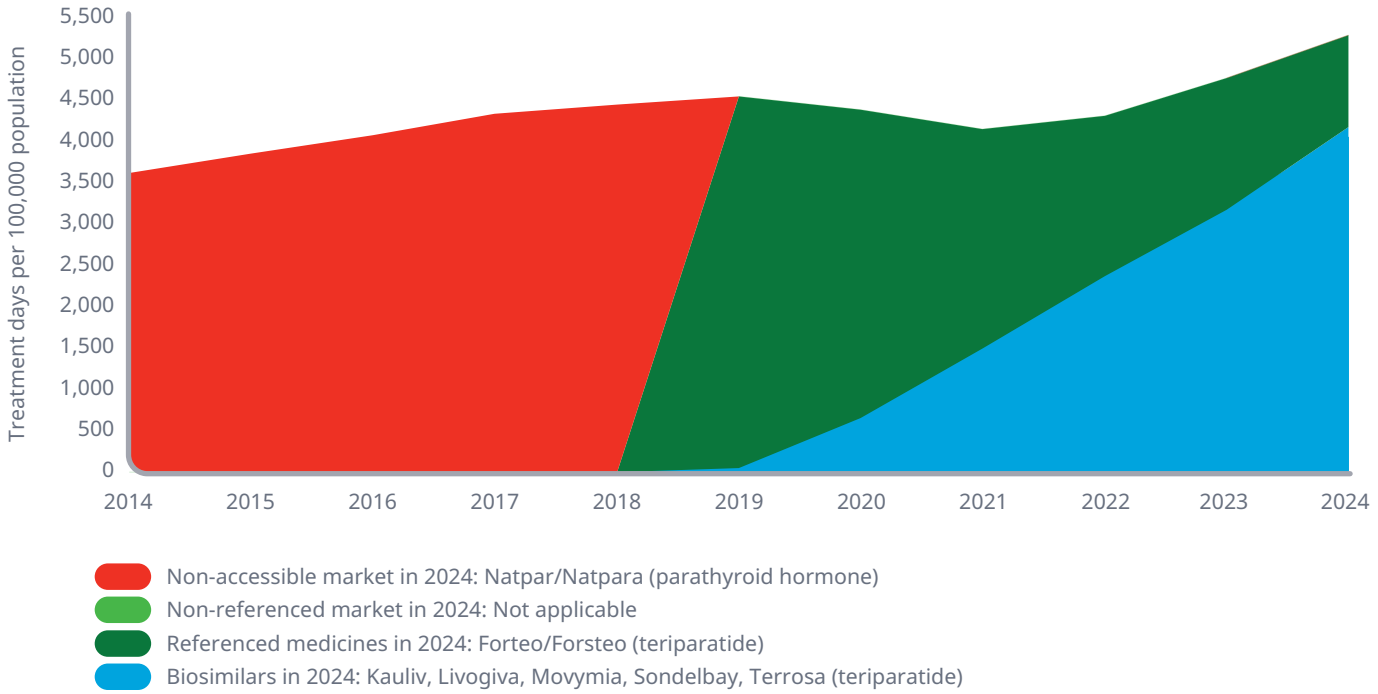
Parathyroid hormones

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	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	OSTEOPOROSIS (IN POST MENOPAUSAL WOMEN 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.

Notes: Sondelbay = Terifrac in MIDAS (for select EU countries).

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 (2024)	Biosimilar vs.Referenced product	82%	0%	100%	68%	100%	63%	70%	59%	18%	96%	82%	90%	100%	92%		56%	93%	100%	92%	74%	86%	47%	97%	78%
	Biosimilar vs.Accessible market	82%	0%	100%	68%	100%	63%	70%	59%	18%	96%	82%	90%	100%	92%		56%	93%	100%	92%	74%	86%	47%	97%	78%
	Biosimilar vs. Total market	82%	0%	100%	68%	100%	63%	70%	59%	18%	96%	82%	90%	100%	92%		56%	93%	100%	92%	74%	86%	47%	97%	78%
PRICE PER TD (2024/YR BEFORE BS ENTRY)	Biosimilar and Referenced product		-8%	-73%			-46%			-24%				-28%	-39%		-34%	-50%							-29%
	Biosimilar accessible market		-8%	-73%			-46%			-24%				-28%	-39%		-34%	-50%							-29%
	Total market	-59%	-8%	-73%	-49%	-57%	-29%	-40%	-13%	-24%	-34%	-46%	-45%	-28%	-23%		-34%	-49%	-52%	-54%	-42%	-34%	-17%	-4%	-24%
VOLUME TD (2024/YR BEFORE BS ENTRY)	Biosimilar and Referenced product		-1%	381%			-21%			-99%				35%	47%		61%	188%							987%
	Biosimilar accessible market		-1%	381%			-21%			-99%				35%	47%		61%	188%							987%
	Total market	129%	-1%	381%	44%	-29%	-21%	14%	93%	-99%	103%	76%	-19%	35%	47%		61%	188%	25%	127%	30%	36%	-54%	69%	3%
	TD per capita (2024)	0.13	0.00	0.01	0.02	0.05	0.02	0.06	0.03	0.00	0.07	0.13	0.07	0.05	0.08		0.03	0.06	0.02	0.06	0.16	0.02	0.03	0.03	0.06
	TD/capita (Yr before BS entrance)	0.06	0.00	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	2024	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.

Notes: 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.

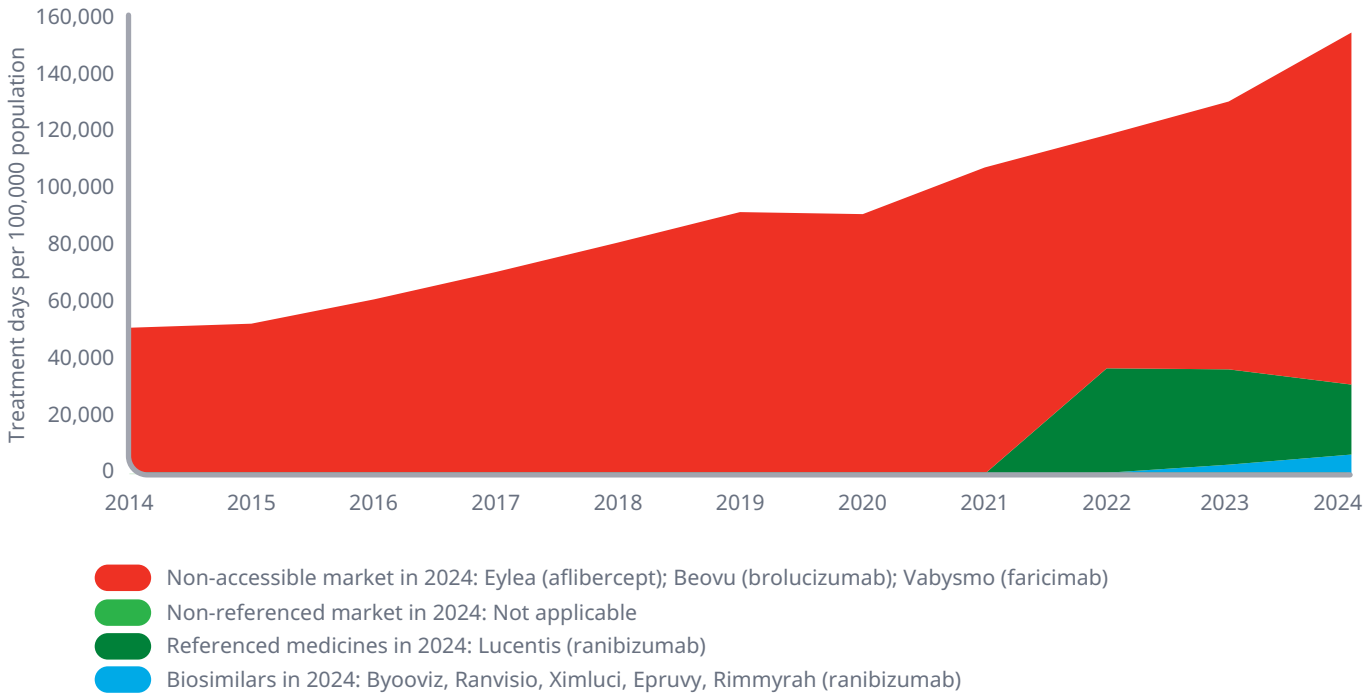
Eylea (aflibercept) and Lucentis (ranibizumab) are anti-VEGF agents used to treat several ocular inflammatory conditions, including wet Age-Related Macular Degeneration (AMD), macular edema, and diabetic retinopathy. They work by preventing the growth of abnormal blood vessels in the eye caused by the 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	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	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	ROUTE	FREQUENCY
AFLIBERCEPT	EYLEA YESAFILI OPUVIZ AFQLIR	●	●	●	●	●	●	●	●	●	●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ●			Intravitreal	Every 8 wks
BROLUCIZUMAB	BEOVU							●	●	●	●	●	●		●				Intravitreal	Every 8 wks
FARICIMAB	VABYSMO									●	●	●	●		●				Intravitreal	Every 4 wks
RANIBIZUMAB	LUCENTIS BYOOVIZ RANIVISIO* XIMLUCI EPRUVY RIMMYRAH	●	●	●	●	●	●	●	●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ● ●	● ● ● ● ● ●	● ● ● ● ● ●	● ● ● ● ● ●	● ● ● ● ● ●	●	Intravitreal	Every 4 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.

Notes: Eylea includes both 2mg and 8mg dose.

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 (2024)	Biosimilar vs.Referenced product		3%		83%			8%	2%		98%		18%	22%	48%	50%	44%	100%	27%	1%	30%	23%	8%	93%	13%
	Biosimilar vs.Accessible market		3%		83%			8%	2%		98%		18%	22%	48%	50%	44%	100%	27%	1%	30%	23%	8%	93%	13%
	Biosimilar vs. Total market		1%		20%			3%	0%		33%		3%	2%	0%	4%	10%	1%	4%	0%	5%	1%	1%	15%	3%
PRICE PER TD (2024/YR BEFORE BS ENTRY)	Biosimilar and Referenced product		-9%		-51%			-31%	-4%		-62%		-10%	-15%	-9%	-34%	-25%		-39%	-10%	-56%	-8%	-18%		-22%
	Biosimilar accessible market		-9%		-51%			-31%	-4%		-62%		-10%	-15%	-9%	-34%	-25%		-39%	-10%	-56%	-8%	-18%		-22%
	Total market		0%		-25%			-22%	-21%		-22%		-7%	-4%	-7%	0%	-12%	-14%	-17%	-9%	-18%	-47%	-43%	17%	-18%
VOLUME TD (2024/YR BEFORE BS ENTRY)	Biosimilar and Referenced product		-4%		32%			-16%	-16%		421%		-24%	-12%	-77%	-48%	-21%		-40%	-16%	-34%	-28%	-51%		-14%
	Biosimilar accessible market		-4%		32%			-16%	-16%		421%		-24%	-12%	-77%	-48%	-21%		-40%	-16%	-34%	-28%	-51%		-14%
	Total market		13%		73%			26%	39%		72%		19%	25%	55%	31%	35%	21%	40%	41%	25%	89%	76%	9%	41%
	TD per capita (2024)	0.85	2.12	0.55	1.63	3.36	1.36	2.73	1.73	0.01	0.29	0.97	0.77	1.55	1.16	0.55	0.71	0.53	1.63	2.10	1.53	2.93	3.60	1.66	1.49
	TD/capita (Yr before BS entrance)		1.88		0.97			2.17	1.25		0.16		0.65	1.25	0.76	0.40	0.53	0.44	1.15	1.49	1.24	1.56	2.08	1.56	1.06
	First recorded sales of biosimilars		2024		2023			2023	2023		2023		2024	2023	2023	2023	2023	2024	2023	2024	2023	2024	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 2025)

Table 1: EMA list of approved biosimilars; Source: EMA website, data accessed October 2025
(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 (MESH)	MARKETING AUTHORISATION DEVELOPER / APPLICANT / HOLDER	MARKETING AUTHORISATION DATE
OMNITROPE	somatropin	Turner Syndrome; Prader-Willi Syndrome; Dwarfism, Pituitary	Sandoz GmbH	12/04/2006
EPOETIN ALFA HEXAL	epoetin alfa	Anemia;Kidney Failure, Chronic;Blood Transfusion, Autologous; Myelodysplastic Syndromes	Hexal AG	27/08/2007
AB-SEAMED	epoetin alfa	Anemia;Kidney Failure, Chronic;Blood Transfusion, Autologous; Myelodysplastic Syndromes	Medice Arzneimittel Pütter GmbH Co. KG	27/08/2007
BINOCRIT	epoetin alfa	Anemia;Kidney Failure, Chronic; Blood Transfusion, Autologous; Myelodysplastic Syndromes	Sandoz GmbH	28/08/2007
RETACRIT	epoetin zeta	Anemia; Blood Transfusion, Autologous; Kidney Failure, Chronic; Cancer	Pfizer Europe MA EEIG	18/12/2007
SILAPO	epoetin zeta	Anemia; Blood Transfusion, Autologous; Cancer; Kidney Failure, Chronic	Stada Arzneimittel AG	18/12/2007
TEVAGRASTIM	filgrastim	Hematopoietic Stem Cell Transplantation; Cancer	Teva GmbH	15/09/2008
RATI-OGRASTIM	filgrastim	Hematopoietic Stem Cell Transplantation; Cancer	Ratiopharm GmbH	15/09/2008
FILGRASTIM HEXAL	filgrastim	Hematopoietic Stem Cell Transplantation; Cancer	Hexal AG	06/02/2009
ZARZIO	filgrastim	Hematopoietic Stem Cell Transplantation; Cancer	Sandoz GmbH	06/02/2009
NIVESTIM	filgrastim	Hematopoietic Stem Cell Transplantation; Cancer	Pfizer Europe MA EEIG	07/06/2010
INFLECTRA	infliximab	Arthritis, Psoriatic;Spondylitis, Ankylos-ing; Colitis, Ulcerative; Psoriasis; Crohn Disease; Arthritis, Rheumatoid	Pfizer Europe MA EEIG	10/09/2013
REMSIMA	infliximab	Arthritis, Psoriatic; Spondylitis, Ankylosing; Colitis, Ulcerative; Psoriasis;Crohn Disease; Arthritis, Rheumatoid	Celltrion Healthcare Hungary Kft.	10/09/2013
OVALEAP	follitropin alfa	Anovulation	Theramex Ireland Limited	27/09/2013
BEMFOLA	follitropin alfa	Anovulation	Gedeon Richter Plc.	26/03/2014
ABASAGLAR (PREVIOUSLY ABASRIA)	insulin glargine	Diabetes Mellitus	Eli Lilly Nederland B.V.	09/09/2014
ACCOFIL	filgrastim	Hematopoietic Stem Cell Transplantation; Cancer	Accord Healthcare S.L.U.	17/09/2014
BENEPALI	etanercept	Arthritis, Psoriatic; Arthritis, Rheumatoid; Psoriasis	Samsung Bioepis NL B.V.	13/01/2016
FLIXABI	infliximab	Arthritis, Psoriatic; Spondylitis, Ankylosing; Colitis, Ulcerative; Arthritis, Rheumatoid; Crohn Disease;Psoriasis	Samsung Bioepis NL B.V.	26/05/2016
INHIXA	enoxaparin sodium	Venous Thromboembolism	Techdow Pharma Netherlands B.V.	15/09/2016
TERROSA	teriparatide	Osteoporosis	Gedeon Richter Plc.	04/01/2017
MOVYMIA	teriparatide	Osteoporosis	STADA Arzneimittel AG	11/01/2017
TRUXIMA	rituximab	Lymphoma, Non-Hodgkin; Arthritis, Rheumatoid; Wegener Granulomatosis; Leukemia, Lymphocytic, Chronic, B-Cell; Microscopic Polyangiitis	Celltrion Healthcare Hungary Kft.	17/02/2017
AMGEVITA	adalimumab	Arthritis, Psoriatic; Colitis, Ulcerative; Arthritis, Juvenile Rheumatoid; Spondylitis, Ankylosing; Psoriasis; Crohn Disease; Arthritis, Rheumatoid	Amgen Europe B.V.	21/03/2017

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

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

MEDICINE NAME	INTERNATIONAL NON-PROPRIETARY NAME (INN)/COMMON NAME	THERAPEUTIC AREA (MESH)	MARKETING AUTHORISATION DEVELOPER / APPLICANT / HOLDER	MARKETING AUTHORISATION DATE
SONDELBAY	teriparatide	Osteoporosis	Accord Healthcare S.L.U.	24/03/2022
STIMUFEND	pegfilgrastim	Neutropenia; Cancer	Fresenius Kabi Deutschland GmbH	28/03/2022
TRUVELOG MIX 30	insulin aspart	Diabetes Mellitus	Sanofi Winthrop Industrie	25/04/2022
VEGZELMA	bevacizumab	Colorectal Neoplasms; Breast Neoplasms; Ovarian Neoplasms; Fallopian Tube Neoplasms; Peritoneal Neoplasms; Carcinoma, Non-Small-Cell Lung; Carcinoma, Renal Cell; Uterine Cervical Neoplasms	Celltrion Healthcare Hungary Kft.	17/08/2022
RANIVISIO	ranibizumab	Wet Macular Degeneration; Macular Edema; Diabetic Retinopathy; Diabetes Complications	Midas Pharma GmbH	25/08/2022
XIMLUCI	ranibizumab	Wet Macular Degeneration; Macular Edema; Diabetic Retinopathy; Diabetes Complications	STADA Arzneimittel AG	09/11/2022
KAULIV	teriparatide	Osteoporosis; Osteoporosis, Postmenopausal	Strides Pharma (Cyprus) Limited	12/01/2023
BEKEMV	eculizumab	Hemoglobinuria, Paroxysmal	Amgen Technology (Ireland) UC	19/04/2023
EPYSQLI	eculizumab	Hemoglobinuria, Paroxysmal	Samsung Bioepis NL B.V.	26/05/2023
YESAFILI	aflibercept	Macular Edema; Retinal Vein Occlu-sion; Diabetic Retinopathy; Myopia, Degenerative; Diabetes Complications	Biosimilar Collaborations Ireland Limited	15/09/2023
TYENNE	tocilizumab	Arthritis, Rheumatoid; Cytokine Release Syndrome; Arthritis, Juvenile Rheumatoid; COVID-19 virus infection; Giant Cell Arteritis	Fresenius Kabi Deutschland GmbH	15/09/2023
TYRUKO	natalizumab	Multiple Sclerosis, Relapsing-Remitting; Multiple Sclerosis	Sandoz GmbH	22/09/2023
HERWENDA	trastuzumab	Breast Neoplasms; Stomach Neoplasms	Sandoz GmbH	15/11/2023
RIMMYRAH	ranibizumab	Wet Macular Degeneration; Macular Edema; Diabetes Complications; Myopia, Degenerative;Choroidal Neovascularization	Qilu Pharma Spain S.L.	05/01/2024
UZPRUVO	ustekinumab	Psoriasis; Arthritis, Psoriatic; Crohn Disease; Colitis, Ulcerative	Stada Arzneimittel AG	05/01/2024
PYZCHIVA	ustekinumab	Crohn Disease; Colitis, Ulcerative; Arthritis, Psoriatic	Samsung Bioepis NL B.V.	19/04/2024
JUBBONTI	denosumab	Osteoporosis; Osteoporosis, Postmenopausal; Bone Resorption	Sandoz GmbH	16/05/2024
OMLYCLO	omalizumab	Asthma; Urticaria	Celltrion Healthcare Hungary Kft.	16/05/2024
WYOST	denosumab	Giant Cell Tumor of Bone; Neoplasms, Bone Tissue	Sandoz GmbH	17/05/2024
TOFIDENCE	tocilizumab	Arthritis, Rheumatoid; COVID-19 virus infection; Arthritis, Juvenile Rheumatoid	Biogen Netherlands B.V.	20/06/2024
WEZENLA	ustekinumab	Psoriasis; Arthritis, Psoriatic; Crohn Disease	Amgen Technology (Ireland) UC	20/06/2024
AVZIVI	bevacizumab	Colorectal Neoplasms;Carcinoma, Non-Small-Cell Lung; Carcinoma, Renal Cell; Ovarian Neoplasms; Fallopian Tube Neoplasms; Peritoneal Neoplasms; Uterine Cervical Neoplasms	FGK Repre-sentative Service GmbH	26/07/2024
STEQEYMA	ustekinumab	Psoriasis; Arthritis, Psoriatic; Crohn Disease	Celltrion Healthcare Hungary Kft.	22/08/2024
EPRUVY (PREVIOUSLY RANIBIZUMAB MIDAS)	ranibizumab	Wet Macular Degeneration; Macular Edema; Choroidal Neovascularization; Diabetes Complications	Midas Pharma GmbH	19/09/2024
ITUXREDI	rituximab	Lymphoma, Non-Hodgkin; Leukemia, Lymphocytic, Chronic, B-Cell;Arthritis, Rheumatoid	Reddy Hold-ing GmbH	19/09/2024

MEDICINE NAME	INTERNATIONAL NON-PROPRIETARY NAME (INN)/COMMON NAME	THERAPEUTIC AREA (MESH)	MARKETING AUTHORISATION DEVELOPER / APPLICANT / HOLDER	MARKETING AUTHORISATION DATE
OTULFI	ustekinumab	Crohn Disease;Colitis, Ulcerative	Fresenius Kabi Deutschland GmbH	25/09/2024
FYMSKINA	ustekinumab	Crohn Disease;Psoriasis;Arthritis, Psoriatic	Formycon AG	25/09/2024
AFQLIR	aflibercept	Wet Macular Degeneration; Macular Edema; Diabetes Complications; Retinal Vein Occlusion	Sandoz GmbH	13/11/2024
OPUVIZ	aflibercept	Wet Macular Degeneration; Macular Edema; Diabetes Complications; Retinal Vein Occlusion	Samsung Bioepis NL B.V.	13/11/2024
IMULDOSA	ustekinumab	Crohn Disease; Psoriasis; Arthritis, Psoriatic	Accord Healthcare S.L.U.	12/12/2024
ABSIMKY	ustekinumab	Crohn Disease;Colitis, Ulcerative	Accord Healthcare S.L.U.	12/12/2024
AHZANTIVE	aflibercept	Wet Macular Degeneration; Macular Edema; Retinal Vein Occlusion; Choroidal Neovascularization; Diabetes Complications	Formycon AG	13/01/2025
BAIAMA	aflibercept	Wet Macular Degeneration; Macular Edema; Retinal Vein Occlusion; Choroidal Neovascularization; Diabetes Complications	Formycon AG	13/01/2025
EYDENZELT	aflibercept	Wet Macular Degeneration; Macular Edema; Diabetes Complications; Retinal Vein Occlusion; Choroidal Neovascularization	Celltrion Healthcare Hungary Kft.	12/02/2025
OBODENCE	denosumab	Osteoporosis, Postmenopausal; Osteoporosis; Bone Resorption	Samsung Bioepis NL B.V.	12/02/2025
XBRYK	denosumab	Neoplasms, Bone Tissue; Giant Cell Tumor of Bone	Samsung Bioepis NL B.V.	12/02/2025
ZEFYLTI	filgrastim	Neutropenia; Hematopoietic Stem Cell Transplantation; Cancer	CuraTeQ Biologics s.r.o	12/02/2025
STOBOCLO	denosumab	Osteoporosis, Postmenopausal; Osteoporosis; Bone Resorption	Celltrion Healthcare Hungary Kft.	14/02/2025
OSENVELT	denosumab	Giant Cell Tumor of Bone; Neoplasms, Bone Tissue	Celltrion Healthcare Hungary Kft.	14/02/2025
AVTOZMA	tocilizumab	Arthritis, Rheumatoid; Arthritis, Juvenile Rheumatoid; Cytokine Release Syndrome; COVID-19 virus infection	Celltrion Healthcare Hungary Kft.	14/02/2025
YESINTEK	ustekinumab	Psoriasis; Arthritis, Psoriatic; Crohn Disease	Biosimilar Collaborations Ireland Limited	14/02/2025
DYRUPEG	pegfilgrastim	Neutropenia; Cancer	CuraTeQ Biologics s.r.o	28/03/2025
OSVYRTI	denosumab	Bone Resorp-tion;Osteoporosis;Osteoporosis, Postmen-opausal	Accord Healthcare S.L.U.	26/05/2025
JUBEREQ	denosumab	Neoplasms, Bone Tissue; Giant Cell Tumor of Bone	Accord Healthcare S.L.U.	26/05/2025
QOYVOLMA	ustekinumab	Psoriasis; Arthritis, Psoriatic;Colitis, Ulcerative; Crohn Disease	Celltrion Healthcare Hungary Kft.	02/06/2025
YAXWER	denosumab	Neoplasms, Bone Tissue;Giant Cell Tumor of Bone	Gedeon Richter Plc.	23/06/2025
JUNOD	denosumab	Bone Resorption; Osteoporosis; Osteoporosis, Postmenopausal	Gedeon Richter Plc.	23/06/2025
VEVZUO	denosumab	Neoplasms, Bone Tissue; Giant Cell Tumor of Bone	Biosimilar Collaborations Ireland Limited	25/06/2025
IZAMBY	denosumab	Bone Resorption; Osteoporosis; Osteoporosis, Postmenopausal	Mabxience Research SL	26/06/2025
DENBRAYCE	denosumab	Neoplasms, Bone Tissue; Giant Cell Tumor of Bone	Mabxience Research SL	26/06/2025
ZADENVI	denosumab	Bone Resorption; Osteoporosis; Osteoporosis, Postmenopausal	Zentiva k.s.	26/06/2025
EVFRAXY	denosumab	Bone Resorption; Osteoporosis; Osteoporosis, Postmenopausal	Biosimilar Collaborations Ireland Limited	30/06/2025

MEDICINE NAME	INTERNATIONAL NON-PROPRIETARY NAME (INN)/COMMON NAME	THERAPEUTIC AREA (MESH)	MARKETING AUTHORISATION DEVELOPER / APPLICANT / HOLDER	MARKETING AUTHORISATION DATE
DAZUBLYS	trastuzumab	Breast Neoplasms; Stomach Neoplasms	CuraTeQ Biologics s.r.o	30/06/2025
BOMYNTRA	denosumab	Neoplasms, Bone Tissue; Giant Cell Tumor of Bone	Fresenius Kabi Deutschland GmbH	17/07/2025
CONEXXENCE	denosumab	Osteoporosis; Osteoporosis, Postmenopausal; Bone Resorption	Fresenius Kabi Deutschland GmbH	18/07/2025
USYMRO	ustekinumab	Crohn Disease; Psoriasis; Arthritis, Psoriatic	Elc Group s.r.o.	14/08/2025
MYNZEPLI	aflibercept	Wet Macular Degeneration; Macular Edema; Diabetes Complications; Retinal Vein Occlusion; Choroidal Neovascularization	Advanz Pharma Lim-ited	18/08/2025
VIVLIPEG	pegfilgrastim	Neutropenia;Febrile Neutropenia; Chemotherapy-Induced Febrile Neutropenia; Cancer	Biosimilar Collaborations Ireland Limited	18/08/2025
USRENTY	ustekinumab	Crohn Disease	Biosimilar Collaborations Ireland Limited	17/09/2025

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-2025_en.xlsx)

INTERNATIONAL NON-PROPRIETARY NAME (INN)/COMMON NAME	INDICATION - SUMMARY	ORPHAN PRODUCT	GENERIC, HYBRID OR BIOSIMILAR	START OF EVALUATION
BEVACIZUMAB	Treatment of adult patients with hereditary haemorrhagic telangiectasia	Y	Y	02/10/2025
DENOSUMAB	Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures, treatment of bone loss as-sociated with hormone ablation in men with prostate cancer and treatment of bone loss associated with long-term systemic glu-cocorticoid therapy in adult patients.	N	Y	27/12/2024
DENOSUMAB	Prevention of skeletal related events and treatment of giant cell tumour of bone	N	Y	17/07/2025
ETANERCEPT	Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, plaque psoriasis, pae-diatric plaque psoriasis	N	Y	18/08/2025
GOLIMUMAB	Treatment of rheumatoid arthritis, psoriatic arthritis and anky-losing spondylitis	N	Y	23/01/2025
INSULIN ASPART	Treatment of diabetes mellitus	N	Y	28/09/2023
INSULIN ASPART	Treatment of diabetes mellitus	N	Y	17/07/2025
INSULIN GLARGINE	Treatment of diabetes mellitus	N	Y	17/08/2023
INSULIN LISPRO	Treatment of diabetes mellitus	N	Y	28/09/2023
PEGFILGRASTIM	Reduction of neutropoenia in adults	N	Y	02/10/2025
PERTUZUMAB	Treatment of breast cancer	N	Y	27/03/2025
RANIBIZUMAB	Treatment of neovascular (wet) Age-Related Macular Degeneration (AMD), visual impairment and other retinopathies	N	Y	23/01/2025
RANIBIZUMAB	Treatment of adults with neovascular (wet) Age-Related Macular Degeneration (AMD), visual impairment and other retinopathies	N	Y	19/06/2025
TERIPARATIDE	Treatment of osteoporosis	N	Y	20/02/2025
TOCILIZUMAB	Treatment of rheumatoid arthritis and other immunological conditions	N	Y	27/03/2025

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