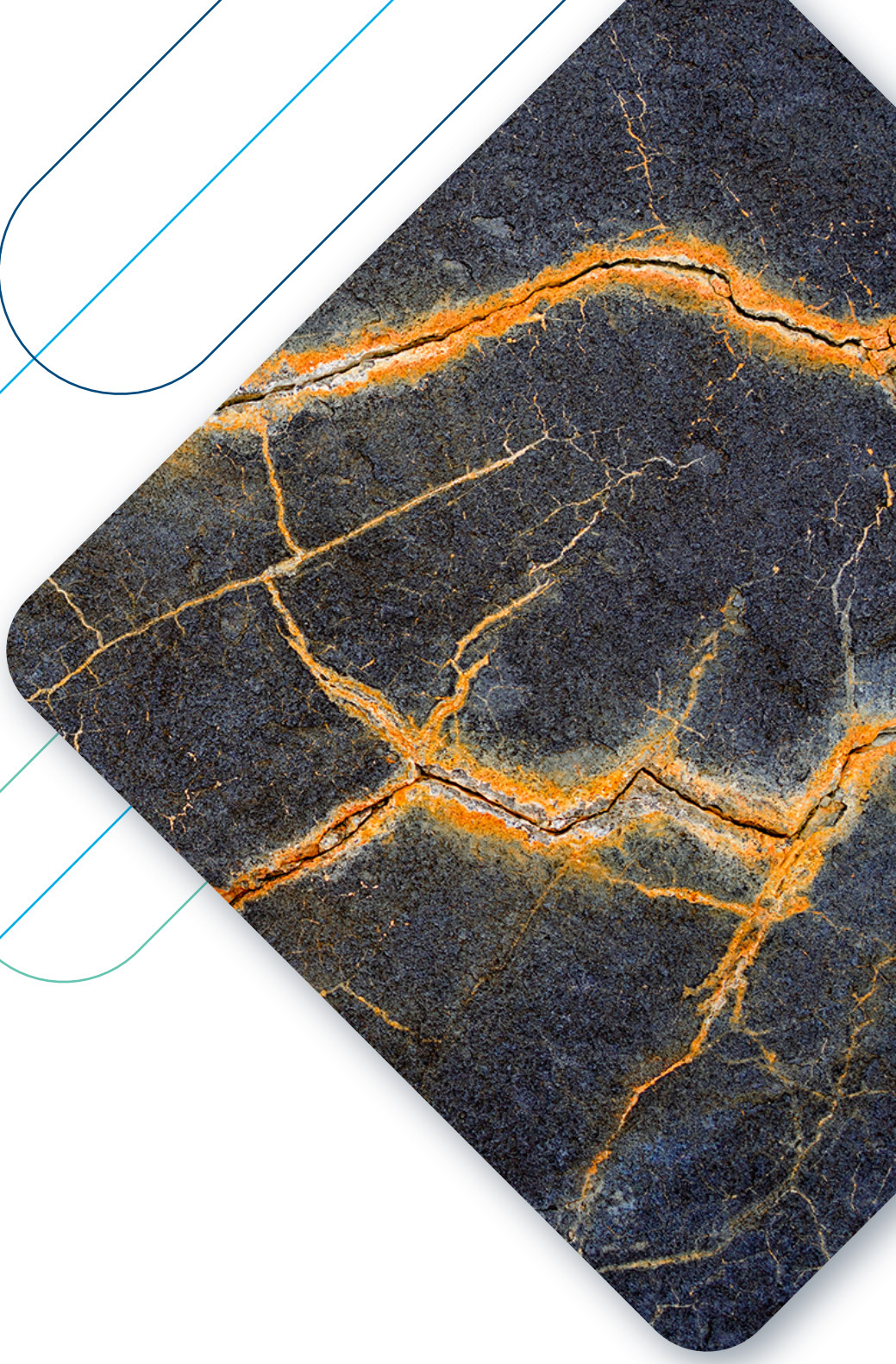

White Paper

The Impact of Biosimilar Competition in Europe

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Introduction

The 9th iteration of the 'Impact of Biosimilar Competition in Europe' report describes the effects on price, volume, and market share following the arrival of biosimilar competition in Europe. The report consists of observations on competitive markets, and a set of Key Performance Indicators (KPIs) to monitor the impact of biosimilars in 23 European markets. The report has been a long-standing source of information on the status of the biosimilars market.

Biosimilars are a critical part of the European healthcare system, and are able to balance spending by generating savings for payers, create headroom for innovation, and expand access to biologic therapy for patients. Since the first biosimilar was launched in 2006, biosimilar medicines have become a core component of an effective healthcare system, but headwinds are increasing with the challenges of orphan biosimilar development, and the disparity in access across Europe becoming more acute.

The reports continues to add and track new therapy areas as we must adapt to for this report 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 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, Vibhu Tewary, Michael Kleinrock, Urvashi Porwal, Kirstie Scott, Mohit Agarwal, and many others.

IQVIA observations

Background

Biologics represent a large share of total spend in the EU

The importance of biologic medicines and the sustainability of biosimilar competition is an increasingly critical success factor for healthcare systems pre-, and post-COVID-19. Biologics represent 40% of total pharmaceutical expenditure in the EU, which has increased from 28% 10 years ago (Exhibit 1).

Figures on the biologic share of spend are subject to upward pressures that are a direct result of new launches, significant growth in established brands, and the increased appreciation for biologics as advanced treatment options. However, they are also subject to downward pressures due to biosimilar competition, and signficant rebates, discounts, and clawbacks.

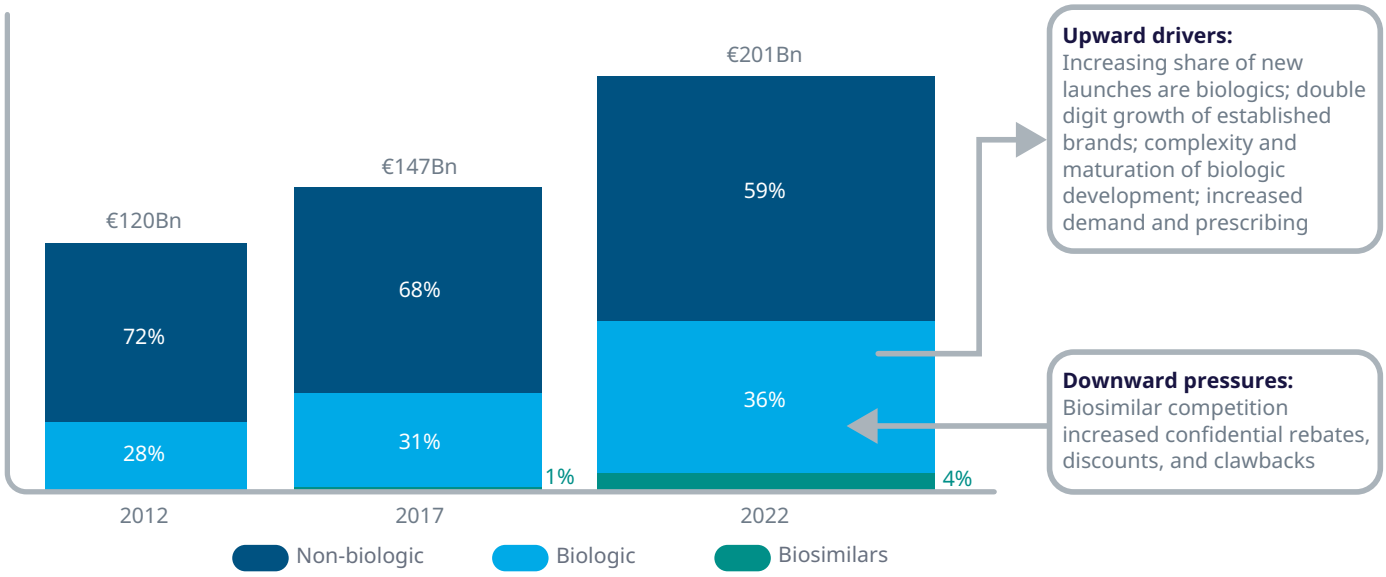
Within this, biosimilars represent 4% (~€9 billion in 2022) across the European Union, which is a small but growing share of absolute spend but the competition they provide has far reaching benefits for patients, payers, and the healthcare system.

Biologics continue to grow faster than non-biologic medicines

Biologic medicines are an increasingly important component of pharmaceutical expenditure, due to their efficacy as treatments for complex conditions. In total, biologic spend grew at 9.9% in the most recent period, compared to a compound annual growth rate (CAGR) of 5.5.% for the total prescription market (Exhibit 2).

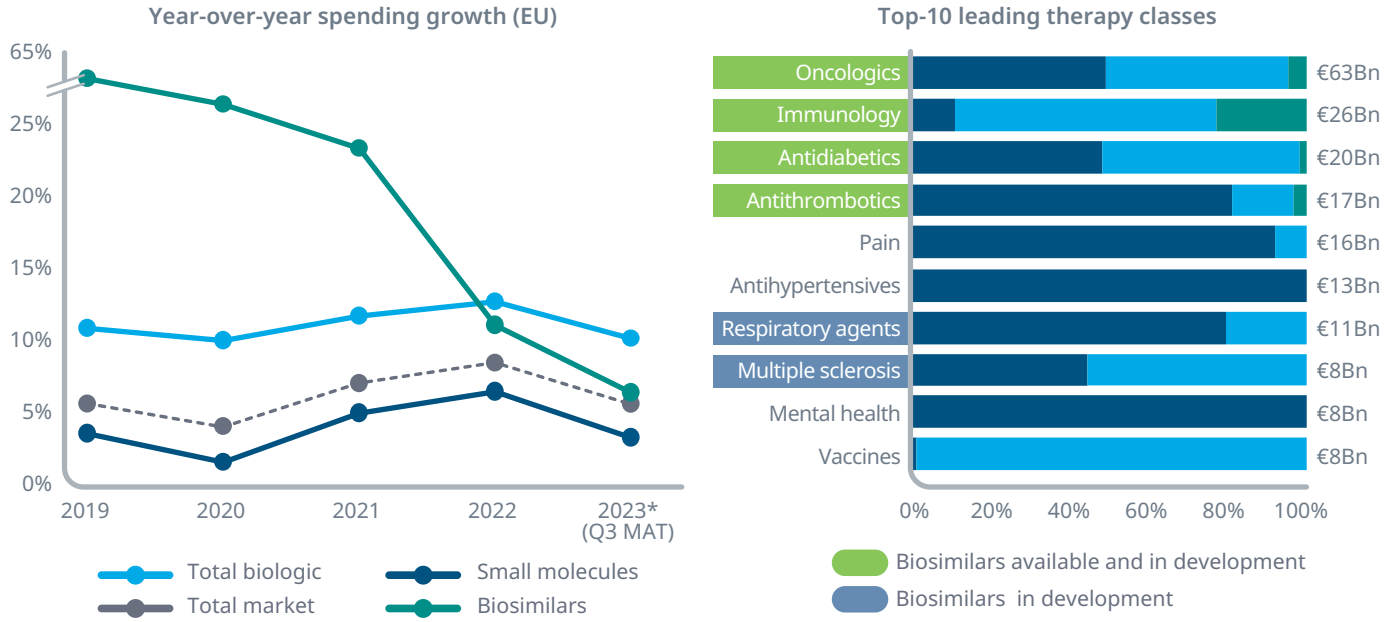
Biologics are increasingly important and have continued to grow faster than non-biologic medicines, which have been the dominant market segment for over a decade. In aggregate, biosimilar market growth has declined compared to previous years as it matures. It however remains above the total pharmaceutical market growth rate, fuelled by the use in anti-TNFs which peaked with the loss of exclusivity (LoE) of adalimumab in 2018. The decline in recent years was expected and is correlated to the more limited LoE opportunities in this period. Biosimilar molecules are present in four of the top-10 major therapy classes that dominate the spending in the EU, with other classes either entirely small molecule dominated (antihypertensives, mental health), or with progress towards biosimilar competition through pipeline activity (such as in respiratory and M.S.).

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



Source: IQVIA MIDAS (2022), Rx only; Biologic molecules exclude ATC-V (vaccines, and various), LC€ (inflation adjusted).
Notes: Biologic market includes originator biologics and biosimilars; and EU country scope (excludes Norway, UK, and Switzerland).

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



Source: IQVIA MIDAS (Q3 2023), Rx only; Biologic molecules exclude ATC-V (vaccines, and various), LC€ (inflation adjusted); Total biologic growth includes biosimilars.
Notes: EU country scope (excludes Norway, UK, and Switzerland).

Biosimilar competition is a small share of spend, but has wider importance

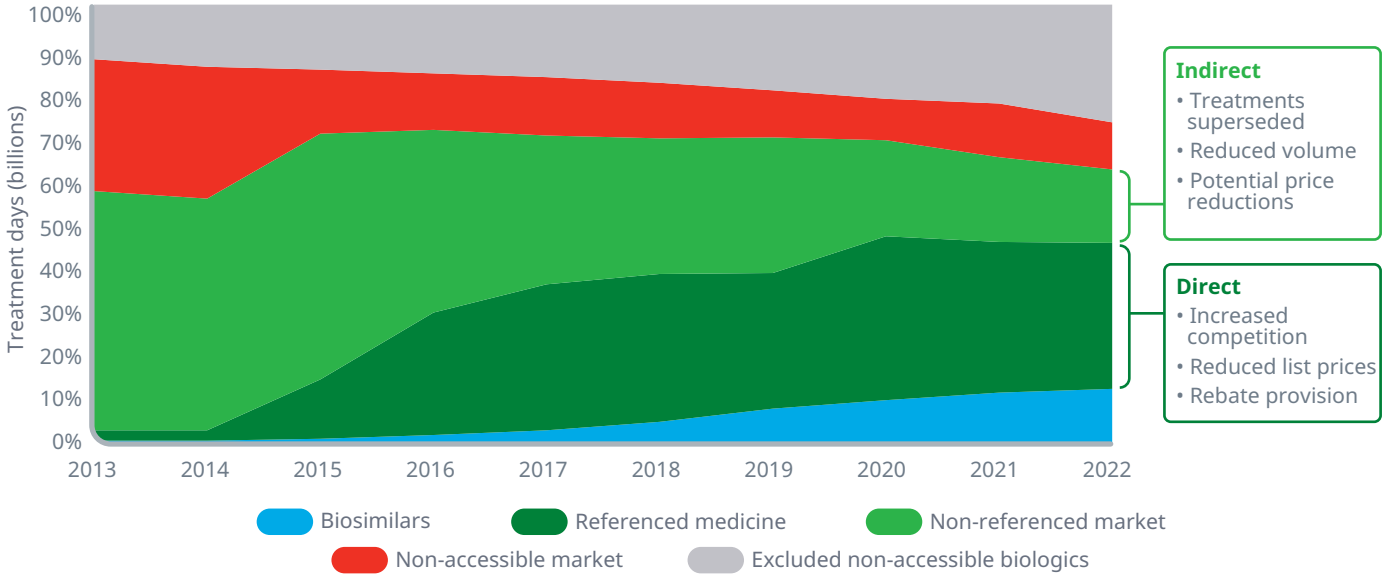
The impact of biosimilar competition should primarily be viewed in terms of the volume of treatment (measured in treatment days). However, the presence of biosimilars cannot be viewed in isolation or without an appreciation for the savings they generate, their indirect benefits, and the potential for treatment that they generate. The exhibit below illustrates:

- the direct impact that biosimilars have on the accessible biologics market, providing 20% of the volume of treatment and generating savings from reduced list and net prices of the referenced medicines
- the indirect impact on the non-referenced market (i.e. newer on-patent biologics), where molecules are superseded in clinical practice by biologic access options provided by biosimilars
- the direct and/or indirect effect of biosimilar competition on prices to stay relevant in the treatment landscape
- the reduction of the non-accessible market upon loss of exclusivity.

'The Impact of Biosimilar Competition' series covers the main therapy areas with biosimilar competition but it is an incomplete view of the market. With the dynamic development of new patent protected medicines, there is a segment of the biologic market that is not covered (Excluded non-accessible market), which in volume terms includes important clinical alternative products such as interleukin inhibitors and interferons. For completeness, we have visualised the volume of this segment which reflects a steady growth of the innovative medicines share (Excluded non-accessible market) in the overall biologic market. IQVIA's definition of biologicals covers "medicinal products whose active substances are derived from a living organism (such as blood components, allergenics, recombinant therapeutic proteins, etc)", and therefore is not a direct match for products that can be granted a biosimilar but covers the complete biologics universe.

Biologics are increasingly important and have continued to grow faster than non-biologic medicines, which have been the dominant market segment for over a decade.

Exhibit 3: Scope of the IQVIA report, 10 key therapy areas with biosimilar competition



Source: IQVIA MIDAS (Q2 2023), Rx only; Biologic molecules exclude ATC-V (vaccines, and various), LC€ (inflation adjusted).
Notes: Biologic market includes originator biologics and biosimilars; and EU country scope (excludes Norway, UK, and Switzerland).

Historic insights remain valid but new trends emerge rapidly

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

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

In 2023 IQVIA's observations remain focused on the European Commission's priority areas, and the benefits of biosimilar competition, but have an emphasis on the pipeline and competitor entry which under increased scrutiny given the potential from future loss of exclusivity (LoE) events.

The report returns to its original format of full prior year data (2022) and therefore provides a 6-month update on the KPIs within the second segment of the report versus the prior report, while the observations reference IQVIA's most up to date information (September 2023) to track the approaches, successes, and challenges for all stakeholders in this important segment. In 2023, the observations on the impact of biosimilar competition are as follows:

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

Exhibit 4: IQVIA's historic 5 observations on the biosimilar market (2015–2022)

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

Sources: IQVIA/IMS Health, The Impact of Biosimilar Competition in Europe (2015–2022) .

Observation 1: Access

THE DISPARITY IN ACCESS ACROSS EUROPE PERSISTS

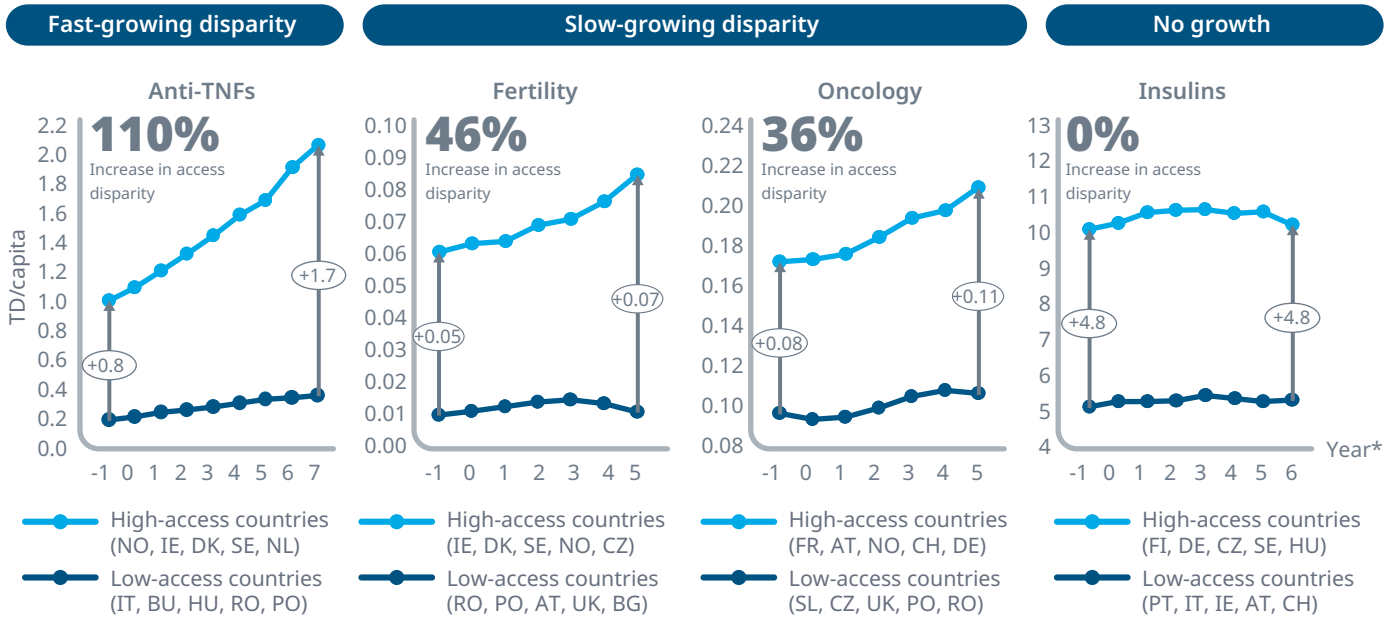
Access to medicines is a critical priority for all stakeholders. However, the ability for countries to capitalise on the promise of biosimilar competition has not occurred evenly. Biosimilar entry and uptake measures have revealed huge disparities, including in terms of individual Member state or therapy area starting point (biologic medicines use at LoE). The different policy approaches have been documented routinely in this report and others,[1] and is reflected in the growing divergence between the highest and lowest biologic medicines prescribing countries, (Exhibit 5).

In other therapeutic classes, although the access disparity has not grown, it instead persists for years beyond biosimilar entry, underlining untapped biosimilar opportunity. For example, high-access countries have had on average twice the usage volume per capita of insulin therapies dispensed compared to low access countries consistently since biosimilar entry. Usage across European countries cannot be explained by prevalence differences, as countries with low insulin access, such as Portugal, have some of the highest shares of adults with diabetes.[2]

ACCESS TO BIOLOGICS SIGNALS FUTURE CHALLENGES

Current access to novel biologic medicines indicates one of the challenges faced by the biosimilar industry and healthcare systems beyond the forecast dates for LoE. In the current paradigm, both the pharmaceutical expenditure and the associated cost-containment policy measures, including controlled or restricted use of biologic medicines remain largely unchanged. Biosimilar success benefits from dynamic horizon scanning and re-assessment, of cost-containment and use restriction policies: treatment guidelines, prescription guidelines, and reimbursement policies. In addition, clinical experience and additional data contribute to awareness and confidence in the healthcare community. Countries with the highest restrictions on biologic medicines use at LoE appear to be those that are generally missing out on or at risk of not benefitting from the biosimilar opportunity.

Exhibit 5: A growing/constant delta between high access and low access markets in Europe

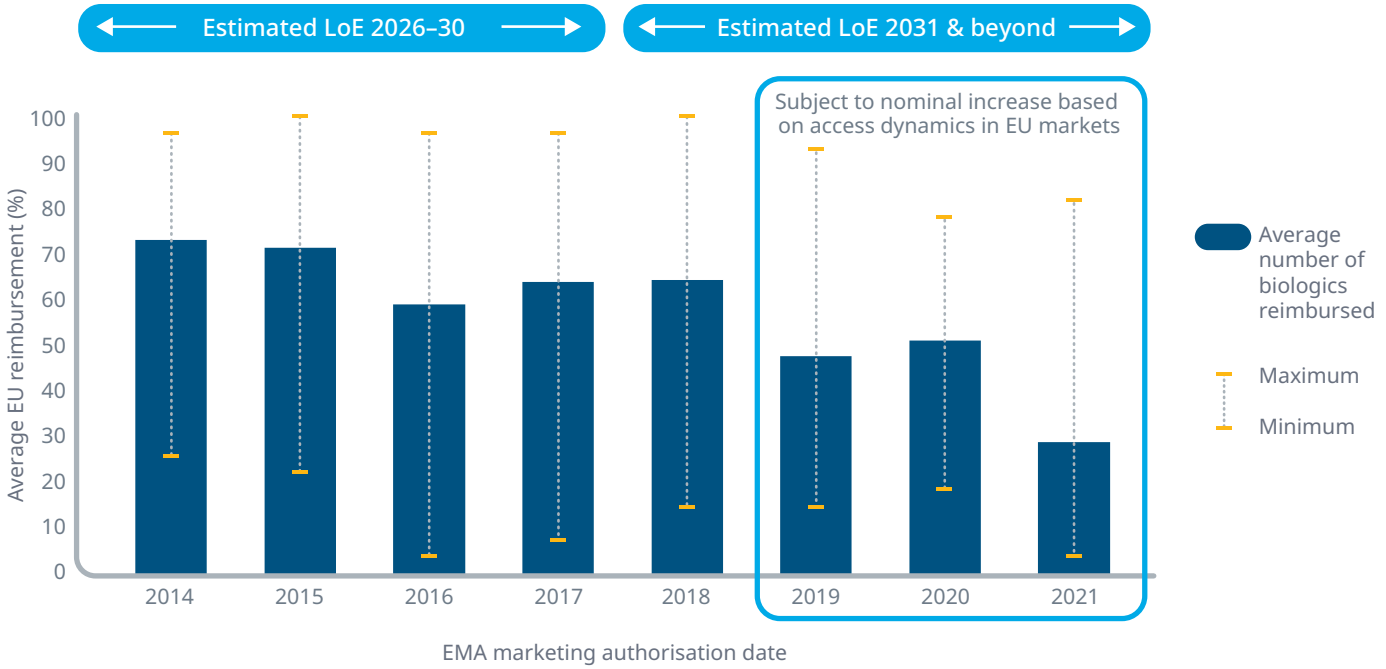


*Normalised to the year before first recorded biosimilar sales in each country, to account for markets that are delayed in using biosimilars after loss of patent protection.

Source: IQVIA MIDAS sales data.

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

Exhibit 6: Availability of innovative biologics across EU27 by marketing authorisation date



Source: IQVIA EFPIA Patients W.A.I.T. Indicator 2022 Survey (2023).

Notes: European Union average (27 countries). In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. Some countries did not complete a full dataset and therefore availability may be unrepresentative.

This analysis is based on the public reimbursement status of new active substances authorised in EU between 2014–2021, which are therefore expected to lose protection from 2026 onwards. The availability of these medicines on public reimbursement lists in EU27 is lower for biologics approved in recent years (Exhibit 6). On average, biologics approved in 2019 are available in 48% of EU27 markets, compared to almost 75% for those approved in 2014. Recently approved medicines might be subject to a nominal increase based on access dynamics in EU, considering their recent approval. However, country-level reimbursement rarely increases for products 3 years after launch, creating an estimated ceiling reimbursement rate.

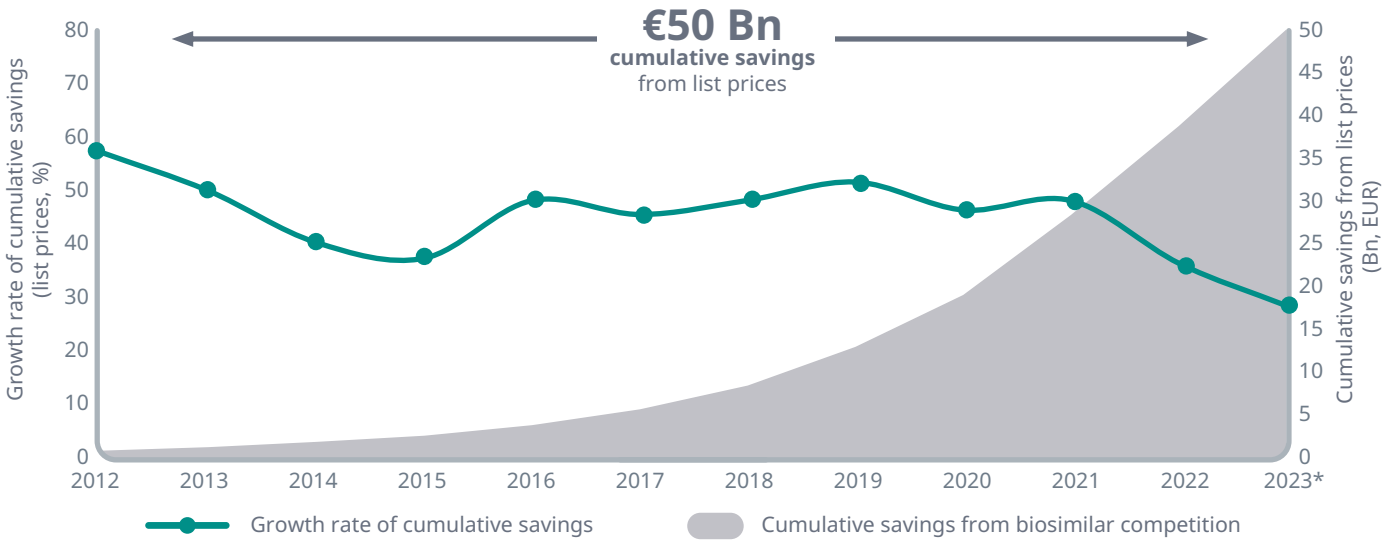
Observation 2: Savings

SAVINGS CONTINUE IN ALL MARKETS BUT GROWTH PLATEAUS DUE TO PROFILE OF LoE EVENTS

Over the last 10 years, the cumulative patient treatment days for EU approved biosimilar medicines has doubled every ~1.5 years, with the total clinical experience with biosimilars now 5.8 billion patient treatment days (as of September 2023). It is possible to estimate the list price savings that are generated on 'post-biosimilar' volume, using the 'pre-biosimilar' prices. Direct savings are linked to the replacement of the originator spend by spend on cost-effective biosimilars. However, the true (i.e. post-discounts, rebates and clawbacks) cost of biologic therapy (originator or biosimilar) is commercially sensitive. List prices across Europe act as a base-case to estimate savings generated in European markets.

Direct savings from biosimilars can be generated using a number of different mechanisms. Many markets automatically reduce list prices, others regulate price reductions, market forces create price differentials, and a mix of biosimilar policies and levers all contribute to effective market competition leading to healthcare system savings. Between 2016–2021, the cumulative savings at list prices from the impact of biosimilar competition doubled every 2 years, with the total cumulative savings now reaching €50 billion (Exhibit 7). However, IQVIA's model suggests that the growth of cumulative savings from list prices has slowed in

Exhibit 7: Total European savings from the impact of biosimilar competition at list prices and growth grate of cumulative savings



*Q3 MAT data

Source: IQVIA MIDAS™ data from 2012 – 2023, 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 all originator products with approved biosimilars from 2006 – 2023, covering EEA+UK, calculated volume is in treatment days determined by WHO-DDD, and where values are unavailable via Oncology Dynamics Physician Survey (2017) DDD estimates.

recent years. This directly reflects the changing profile of LoE opportunity, which has almost halved to €4.3 billion (2021–2023) from the historic peak of €7.8 billion in 2018–2020.

The upcoming LoE potential of biologics promises significant opportunities for further savings. In Europe, a total of 110 biological medicines are anticipated to lose intellectual property (IP) protection in the next 10 years (by the end of 2032), with LoE opportunities peaking around €30Bn between 2030 and 2032.

However, future savings are not guaranteed and will depend on:

1. **Countries creating a robust set of policies** that support a timely, competitive, and sustainable market for biosimilar competition
2. **Dynamic assessment and revision of biologic use restrictions and cost-containment policies** which act as a cap to biosimilar entry and uptake
3. **Biosimilar development feasibility** which is a precursor for uptake
4. **Improved physician awarenes**

SAVINGS ARE A FUNCTION OF USAGE, UPTAKE, POLICIES, AND REMAINING OPPORTUNITY

Biosimilar uptake remains high across European markets and is a key contributor to the savings generated (Exhibit 8). The newest oncology molecule, bevacizumab, has reached over 90% biosimilar uptake only three years post-entry, highlighting this continuing trend. However, disparities still persist depending on the healthcare setting.

In Europe, a total of 110 biological medicines are anticipated to lose intellectual property (IP) protection in the next 10 years (by the end of 2032), with LoE opportunities peaking around €30Bn between 2030 and 2032. However, future savings are not guaranteed

Exhibit 8: Biosimilar uptake metrics across care settings in select European and Global countries (Q2 2023, % treatment days)

	infliximab	etanercept	rituximab	rituximab IV	trastuzumab	trastuzumab IV	pegfilgrastim	bevacizumab	teriparatide	adalimumab	Ranibizumab	Insulin Glargine	Insulin Lispro
UK	96%	87%	83%	95%	20%	82%	92%	66%	94%	90%	64%	15%	1%
Germany	86%	82%	88%	94%	84%	96%	63%	93%	55%	77%	0%	17%	6%
France	82%	56%	73%	97%	45%	99%	86%	99%	43%	51%	1%	30%	0%
Italy	97%	84%	91%	99%	80%	100%	86%	99%	81%	85%	0%	14%	12%
Spain	87%	59%	76%	98%	72%	97%	90%	78%	67%	69%	2%	20%	0%
Netherlands	92%	37%	98%	100%	87%	100%	98%	96%	60%	74%	0%	29%	16%
Denmark	99%	94%	89%	99%	98%	99%	100%	100%	60%	98%	0%	38%	0%
Finland	99%	67%	86%	100%	59%	100%	91%	95%	10%	74%	0%	3%	44%
Norway	99%	92%	96%	100%	96%	100%	100%	92%	89%	93%	9%	32%	2%
Poland	100%	96%	100%	100%	35%	100%	100%	100%	0%	100%	0%	26%	26%
Canada	50%	72%	66%	100%	89%	89%	99%	94%	61%	63%	0%	48%	32%
Japan	29%	51%	79%	79%	71%	71%	0%	35%	77%	14%	26%	50%	22%
US	54%	0%	71%	71%	85%	85%	44%	86%	0%	2%	23%	28%	6%

High uptake — Low uptake

Source: IQVIA EMEA Thought Leadership; IQVIA MIDAS QTR June 2023.

The retail market for biologics, with more new originators coming to market every year, sees significantly lower penetration of biosimilar medicines, limited competition dynamics, lower list prices change, and a greater challenge to generating savings through the retail channel.

Europe still leads other global markets, where although there are shifts in the acceptance of biosimilars by healthcare stakeholders, uptake has not yet reached expected potential. Recent IQVIA analyses found that 63% of physicians in Europe reported that their perceptions of biosimilars had evolved over time, with 83% of physicians surveyed had a positive or very positive perception of biosimilars after they had gained experience with biosimilar use.[3] Greater experience and acceptance of interchangeability along with lower price are key drivers of the use of biosimilars and consequently the rise in savings.

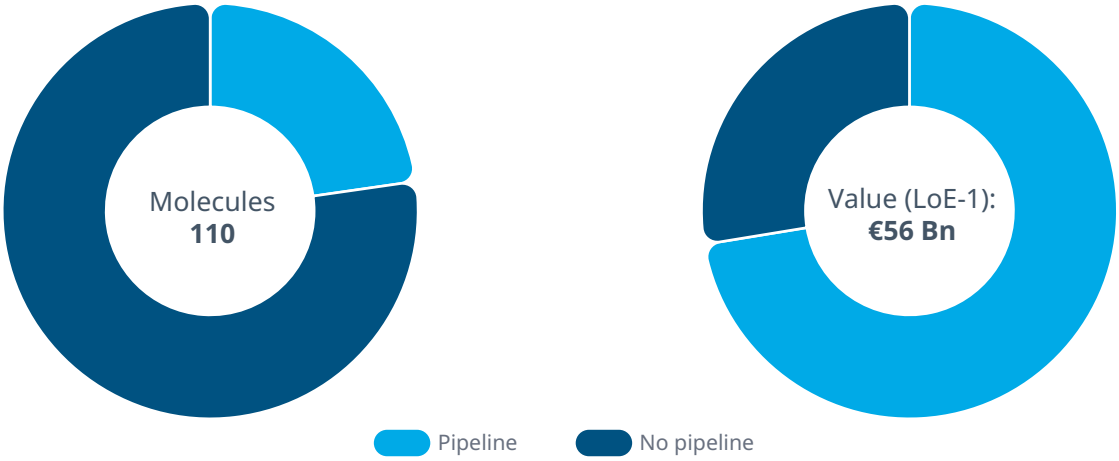
Observation 3: Pipeline

SEGMENTS OF BIOLOGICS MAY NOT BENEFIT FROM BIOSIMILAR COMPETITION

In the next 10 years, a total of 110 biological medicines are anticipated to lose exclusivity in Europe. The forecast value of these products in their year before LoE is ~€55 Bn between 2023 and 2032.

New research indicates that categories exist which are subject to the risk of not gaining biosimilar competition:[4] oncology medicines (with high comparator costs), low commercial value molecules (sales forecasts below $500Mn), orphan biologics (treating small patient groups), one-off biologic therapies, 2nd-generation molecules and complex biologics (next biotechnological wave of biologics: e.g. anti-body drug conjugates, cell & gene therapies, and oligonucleotides). At present, the challenges related to evolving biotechnological platforms are high and the regulatory-science and pathways for some of these products remains unclear.

Exhibit 9: Biologics at risk of no, or limited competition (molecules, forecast value LoE-1, 2023–2032)



High commercial value biologics (high sales, <$1bn)	**Oncology medicines** (with high comparator costs)	**Low commercial value biologics** (lowsales, <$500bn)	**Orphan biologics** (treating small patient groups)	**One-off biologic therapies** (often orphan molecules)	**2nd generation biologics** (new formulations of delivery)	**Complex biologics** (ADCs, C&GT, and oligonucleotides)

Source: IQVIA MIDAS; IQVIA Ark Intelligence; IQVIA Forecast Link; IQVIA Global Biosimilar Database;IQVIA Institute 'Assessing the biosimilar void: Achieving sustainable levels of competition in Europe' (2023).

TWO IN THREE HIGH-COMMERCIAL VALUE BIOLOGICS HAVE BIOSIMILARS IN DEVELOPMENT

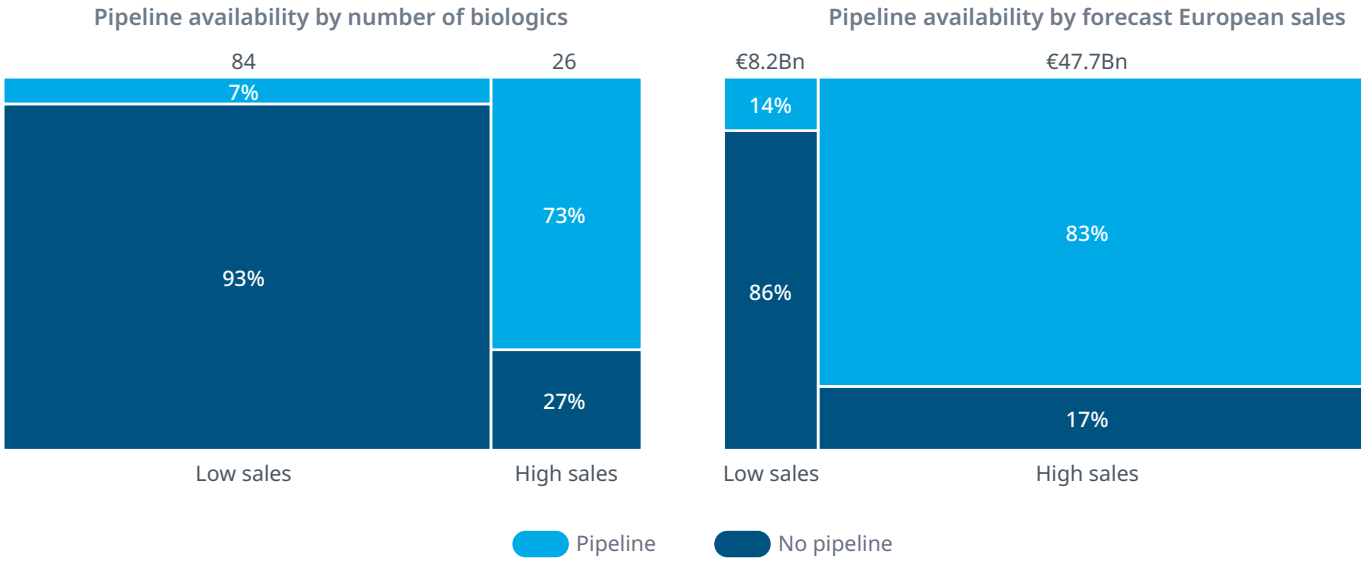
Biologics with more than €500Mn in annual European sales at the time of expiry have historically attracted high levels of competition, new analyses of pipeline activity suggest that high development costs and regulatory barriers may constrain the supply of an increasing number of biosimilars referencing commercially successful products. Of the 26 high-sales products exposed to LoE events in the next 10 years (by end of 2032), almost one in three (27%) does not yet have a biosimilar candidate in the pipeline (Exhibit 10).

The sustainability of the biosimilar proposition is yet more challenging for products anticipated to achieve less than €500mn in annual sales in Europe at the time of expiry. The relative importance to payers and patients of these molecules is an important caveat, and it is necessary to segment by the relative value of these molecules in Europe (and globally) to understand their relevance to payers.

Based on the forecast annual sales value of all upcoming biologic LoEs until 2023, currently available information suggests that areas where biosimilar competition is not expected could cost impact a minimum of ~€15 billion in sales, approximately 28% of the total LoE opportunity by 2032 at forecast list prices as only 23% of lower value molecules have a competitor in development. This takes into consideration historic development timelines for biosimilars which has taken approximately 7–10 years for the existing pipeline.

Based on the forecast annual sales value of all upcoming biologic LoEs until 2032, currently available information suggests that areas where biosimilar competition is not expected could cost impact a minimum of ~€15 billion in sales.

Exhibit 10: Biosimilar pipeline for low- vs. high-sales biologics based on European forecast sales



Source: IQVIA MIDAS; IQVIA Ark Intelligence; IQVIA Forecast Link; IQVIA Global Biosimilar Database; IQVIA Institute 'Assessing the biosimilar void: Achieving sustainable levels of competition in Europe' (2023).

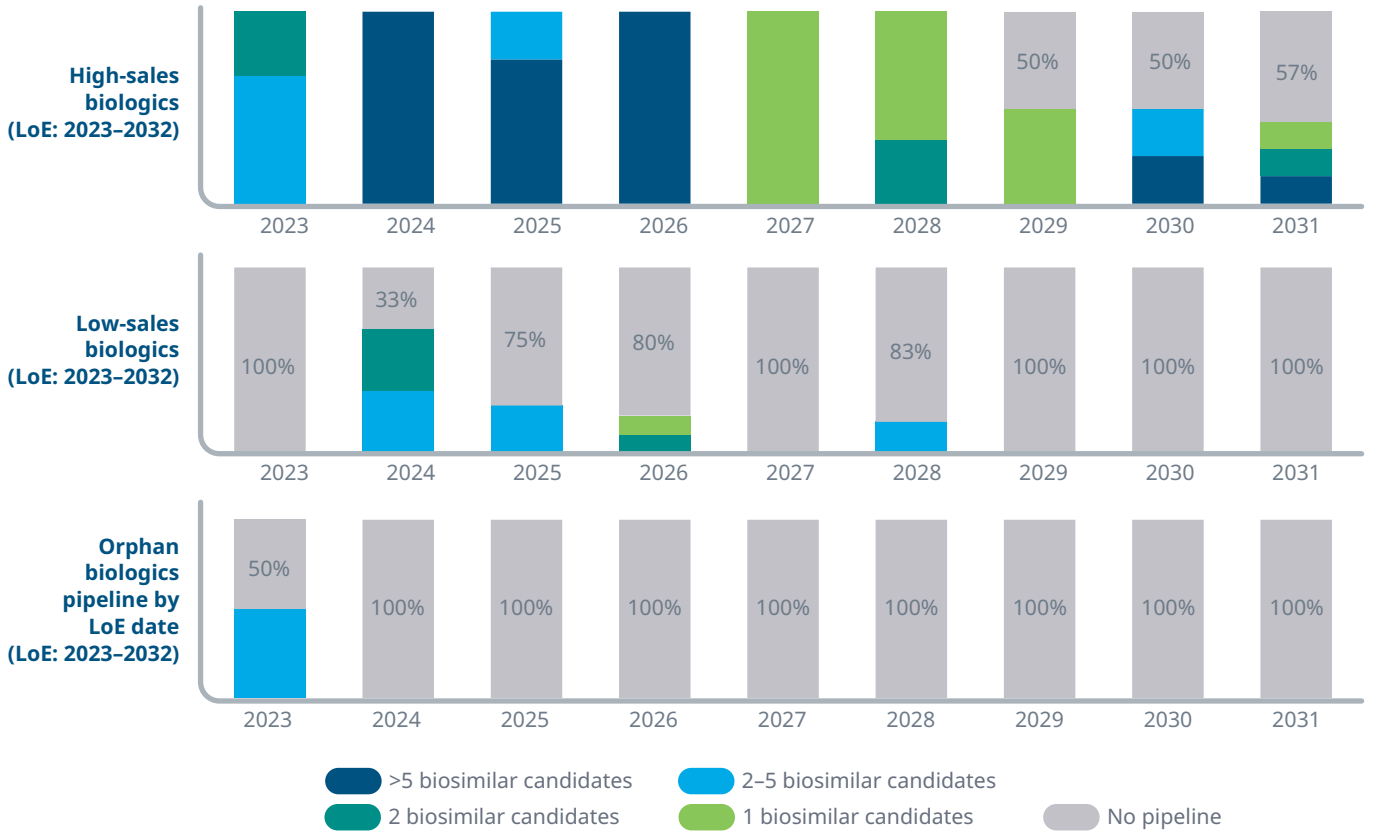
THE CHALLENGE IS MOST ACUTE FOR LOW-SALES AND ORPHAN BIOLOGICS

While there are several segments at variable risk from no or limited biosimilar competition, the sustainability of the biosimilar proposition is yet more challenging for products anticipated to achieve less than €500mn in annual sales in Europe at the time of expiry, or for biologics with orphan drug designation (Exhibit 11).

Based on the forecast annual sales value of these upcoming LoEs, currently available information suggests that the biosimilar "void" for low-sales biologics could cost impact a minimum of ~€7 billion in sales. In total, approximately 28% of the LoE opportunity (low- & high-sales) by 2032 at forecast list prices, and the number of potential competitors entering in the 10-year period studied is rarely greater than two. This falls short of the number of suppliers required to maintain healthy competition dynamics and market resilience.

The sustainability of the biosimilar proposition is yet more challenging for products anticipated to achieve less than €500mn in annual sales in Europe at the time of expiry, or for biologics with orphan drug designation.

Exhibit 11: Biosimilar pipeline for biologic segments by LoE date (2023–2031)



Source: IQVIA MIDAS; IQVIA Ark Intelligence; IQVIA Forecast Link; IQVIA Global Biosimilar Database. Notes: Pipeline data only includes biosimilars in development (phase I to phase III, including pre-registration). No approved biosimilar is included in the analysis. Caveat: biosimilar pipeline data is based on publicly available information only. High sales= biologics with over €500 in European sales before LoE (LoE-1). No high-sales biologic medicine is expected to lose exclusivity in 2032 (data not shown).

Observation 4: Policy

A SUSTAINABLE BIOSIMILAR MARKET BALANCES ACCESS, REGULATION, COMPETITION, AND INCENTIVES

Biosimilars make an important contribution to the sustainability of health systems by providing alternatives to originator biologic products once those products no longer have patent or other forms of market exclusivity. Biosimilar sustainability improves patient access and physician prescription choice of safe and high-quality biologic medicines, in a framework that considers the ongoing needs of all stakeholders (patients, healthcare professionals/providers, payers and manufacturers), provides a means to manage existing healthcare budgets while safeguarding a health level of competition and supply.

In order to cultivate a sustainable biosimilar market, countries must focus on the following areas (Exhibit 12):

- Access to biologics
- Regulation and Pricing & Market Access
- Competitive pressure
- Incentives

Implementation of policies relating to these four areas directly contribute to establishing sustainable market conditions for biosimilars.

INTERCHANGEABILITY IS ONE PIECE OF THE PUZZLE

Biosimilar interchangeability, which is related to physician-led switching, is a key element of a sustainable biosimilar market (Exhibit 12). In the European Union, decisions on the interchangeability of biosimilars are implemented at the national level. However, in September 2022, the EMA and HMA issued a joint statement promoting biosimilar interchangeability,[5] aiming to harmonize the scientific rationale across the EU and better inform the decision-making of member states. This has been a positive step towards improving the overall sustainability of biosimilar markets across all EU countries, especially in some Central and Eastern European markets that were yet to accept biosimilars as interchangeable.

However, the acceptance of interchangeability is not likely to move the needle on its own and it is only one piece of the puzzle for countries aiming to achieve an ideal biosimilar market. The greatest impact will come from a coordinated approach to biosimilar sustainability, and implementing policies that incorporate all aspects of access, regulation, competition, and incentives.

Exhibit 12: Criteria for a sustainable biosimilar market

ACCESS TO BIOLOGICS

1. Signficant increase to biologics since biosimilar entry*

REGULATORY AND PMA

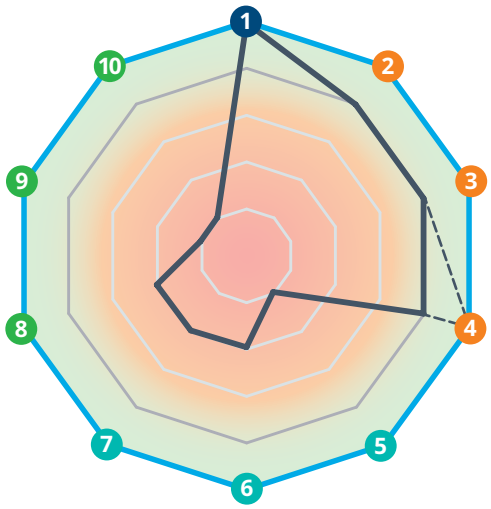
2. **Regulatory and PMA pathway:** ensuring timely access to biosimilars following EMA approval
3. **Treatment guidelines:** recommending biosimilar use
4. **Switching and substitution policies:** at physicians' discretion while preventing automatic pharmacy substitution

COMPETITIVE PRESSURE

5. **Level of competition:** high level of competition with multiple players
6. **Pricing rules and dynamics:** prices driven by competition only
7. **Procurement:** systems which support competition and drive uptake in the market

INCENTIVES

8. **Patient benefits:** effective benefits encouraging biosimilar use
9. **Provider and prescriber benefits:** effective benefits supporting biosimilar usage
10. **Awareness and education** strong awareness of biosimilar benefits and sustainable practices across stakeholder groups



In an ideal **biosimilar market**, all data points lie on the outer-most perimeter

Market A Ideal market

Not sustainable Ideal/most sustainable

* Defined as >25% increase in DDD per capita

Source: IQVIA Institute report (June 2021) "Spotlight on Biosimilars: Optimizing the Sustainability of Healthcare Systems."

Observation 5: Evolution

ORPHAN BIOLOGICS ARE A NEW CLASS OF MOLECULES LOSING EXCLUSIVITY

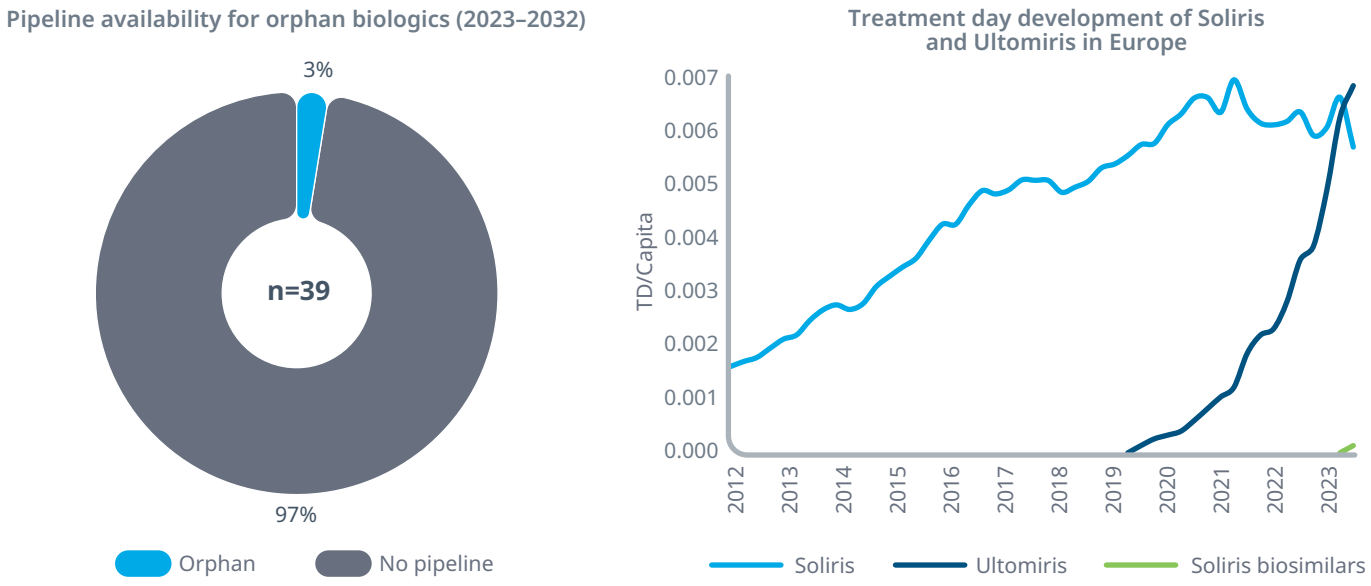
As discussed, current orphan medicines face even greater biosimilar pipeline availability and development challenges. Despite a significant increase in the number of orphan biologics losing exclusivity in the next 10 years (39 products) compared to historically (1 product), very few biosimilars are currently in development for this specific product category. Only one orphan biologic (Soliris, eculizumab) has so far attracted biosimilar development, corresponding to less than 3% of the entire cohort (Exhibit 13).

While there are biologics with orphan indications that already have biosimilar competition such as bevacizumab, adalimumab, and filgrastim, these are difficult to differentiate at an indication-level. A recent study by NORD[6] for the US market, showed these molecules have upwards of 5 orphan indications, but the emergence of a biologic product that treats only orphan indications and retains its orphan drug exclusivity is a first for Europe.

Two biosimilar medicines referencing Soliris (Bekmev and Epysqli) were granted EMA approval earlier this year for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), whilst four more candidates are also in development. Despite being the only orphan biologic of interest to biosimilar manufacturers, early indicators show slow uptake of Soliris biosimilars so far (2%) (Exhibit 13) and signs of further challenges ahead.

In 2019, Alexion launched a 2nd generation complement C5 inhibitor (Ultomiris) in the same indications, but with a less frequent dosing regimen. In the past year, Ultomiris has surpassed Soliris in volume terms (TD/capita) suggesting a considerable proportion of patients have either been switched to or started on the successor product. The extent of Soliris biosimilar uptake in Europe will be closely followed by biosimilar manufacturers over the coming months, as the future of orphan biosimilar medicines remains uncertain.

Exhibit 13: Pipeline availability for orphan biologics (2023–2032) and Soliris (eculizumab), eculizumab biosimilars and Ultomiris (ravulizumab) uptake curves



Source: IQVIA Institute 'Assessing the biosimilar void: Achieving sustainable levels of competition in Europe' (2023); IQVIA MIDAS Q3 2023
Notes: European countries included in Solirs / Ultomiris analyses are EEA+UK.

FUTURE BIOSIMILAR WAVES WILL HAVE NEW, AND UNKNOWN DYNAMICS

Since 2006, European prescribers, patients, payers, and manufacturers have developed their experience with biosimilars which had led to shifts in the market dynamics across a number of parameters.

The past few years have shown the greatest potential for savings to be generated from major LoE events. This post-adalimumab era has been one of significant access growth in anti-TNFs, but the market moves into a time period that is characterised with need for savings in healthcare, coupled with lower easy opportunity from LoE events in the short-term. Competition is increasingly fierce leaving some companies to reassess their biosimilar portfolios and the molecules to pursue since the average size of molecules losing LoE is falling.

Considering the learnings from historic biosimilar competition and implementing optimal sustainable policies to maximise the available benefits, and prepare for the future is a time-bound activity as we enter the next wave biologic LoEs. Current systems must adapt to meet the changing profile of molecules, competitors, and competitor strategies that will emerge.

Exhibit 14: Archetypes of historic and emerging biologics LoEs

		EARLY YEARS ('06 - '11)	EMERGENCE ('11 - '15)	PREPARATION ('16 - '18)	CAPITALIZATION ('19-'21)	OPTIMISATION ('22 - '25)	APEX ('26 - '29)	STRATIFICATION ('30+)
Profile of LoE	EU opportunity	Hundreds of millions	Billions	Tens of billions	Tens of billions	Billions	Tens of billions	Billions
	Therapy areas	hGH, GCSF, EPO	EPOs, anti-TNF (inflix.), insulin	anti-TNFs, insulins, onco., and fertility	anti-TNF (ada), LMWHs, PTH	Ophthalmology, orphan (eculiz.)	Oncology (PD-1s), ophthalmology, orphan	Oncology, orphan medicines
	Molecule size	Few major molecules	Few major molecules	Broadening range	Large molecule and others	Smaller biologics	Large molecules and many others	Smaller biologics and orphans
Market dynamics	Savings	Hundreds of millions	Hundreds of millions	Hundreds of millions	Billions	Hundreds of millions	Billions	Hundreds of millions
	Uptake	Emerging	Increasingly slowly	Variable	High and rapid	High, some variability	High and rapid	Unknown
	Competition	Up to 5 competitors	Up to 5 competitors	Up to 5 competitors	Tens of competitors	Up to 5 competitors to no competitors	Tens of competitors to no competitors	Few competitors to no competitors
	Access	Single digit but variable	Single digit but variable	More than double	More than double	Single digit but variable	Unknown	Unknown
	Tender/ Policy	Single-winner tenders	Single-winner tenders	Multi-winner tenders	Multi-winner tenders	Interchangeability	Unknown	Unknown
	Originator strategy	Differentiation	Differentiation	Price / 2nd Gen. therapies	Price / 2nd Gen. therapies	Price competition and 2nd gen therapies	Price / 2nd Gen. therapies, and combinations	Antibody drug conjugates

Source: IQVIA expertise

Notes: Segments are reflective of the major LoE events within the periods with appreciation for the known variability that exists across markets and molecules; Gen. = generation; ada. = adalimumab; eculiz. = eculizumab; onco. = oncology;

Methodology

The indicators are intended to give a broad overview of the uptake and the implications on price and volume evolution after introduction of biosimilar medicines. There are differences in perspective between payers, providers, and different types of manufacturers. Focusing on the payer perspective, there are caveats that should be considered when interpreting the results.

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

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

Volume estimates: the pack volumes reported are based on IQVIA collected data which may have been unknowingly impacted by issues such as parallel exporting. The volumes have been converted to daily doses using the published World Health Organization (WHO) defined daily doses (DDD), which can introduce bias. Consumption measures are therefore not adjusted 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 2022 (full year) 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 2022 (full year) versus year before biosimilar entry.
- **Volume per capita 2022 (full year):** number of Treatment Days consumed in 2022 (full year) 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 regulatory approval, demonstrating similarity to the Reference Medicinal Product in terms of quality characteristics, biological activity, safety and efficacy.	
	NON-ACCESSIBLE MARKET	**Non-Accessible Category:** Products within the same ATC4 code as the accessible category products. These are typically second-generation products; this category may include products within different dosing schedules and/or route of administration to those in the accessible category, and have valid protection status.	

Country and therapy area KPIs

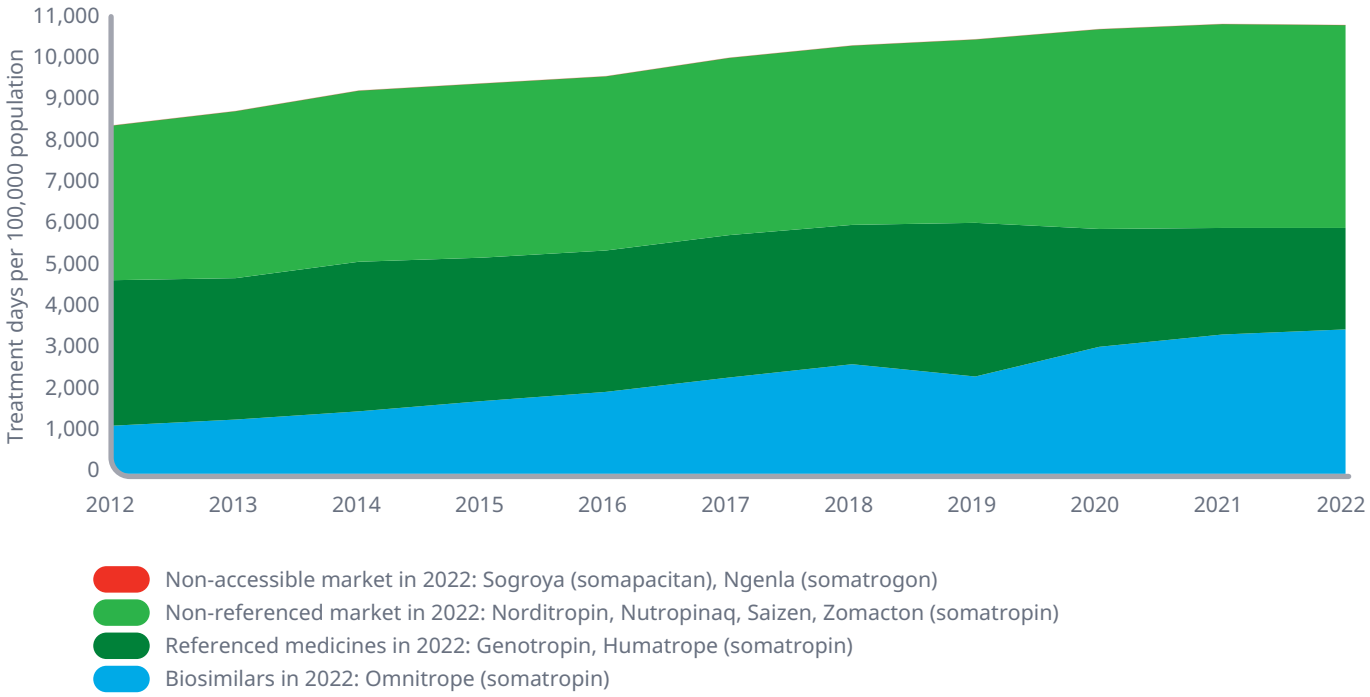
Human growth hormone (HGH)

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

HGH MARKET DEVELOPMENT

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

HGH market development status



ADDITIONAL INFORMATION ABOUT HGH MEDICINES

Subcutaneous injection is typically used to administer Human Growth Hormone treatment. The dosage of administration should be individualized for each patient, with a weight-based regimen. The duration of treatment, usually a period of several years, will depend on maximum achievable therapeutic benefit. Fast-acting GH (somatropin) is typically administered daily, whilst long-acting GHs (somapacitan and somatrogon) are typically administered weekly.

HGH approved indications

NAMING		CLASSIFICATION												INDICATIONS									DOSING/ ADMINISTRATION	
MOLECULE	PRODUCT	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	PEDIATRIC GROWTH HORMONE DEFICIENCY	ADULT GROWTH HORMONE DEFICIENCY	TURNER SYNDROME	GROWTH FAILURE DUE TO CHRONIC RENAL INSUFFICIENCY (CRI)	SGA - SMALL FOR GESTATIONAL AGE	PWS - PRADER-WILLI SYNDROME	IDIOPATHIC SHORT STATURE	SHOX - SHORT-STATURE HOMEBOX-CONTAINING GENE DEFICIENCY	NOONAN SYNDROME	FREQUENCY	MODE OF ACTION
SOMATROPIN	GENOTROPIN HUMATROPE* OMNITROPE NORDITROPIN NUTROPINAQ SAIZEN ZOMACTON	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	Daily	Fast-acting
SOMATROPIN	SOGROYA											●	●	●	●								Weekly	Long-acting
SOMATROPIN	NGENLA												●	●									Weekly	Long-acting

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

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

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

		AT	BE	BU	CZ	DK	FI	FR	DE	GR*	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD (2022)	Biosimilar vs Referenced product	40%	37%	52%	21%	99%	63%	51%	54%		33%	0%	0.50	0.63	0.07	0.99	0.58	0.69	0.00	0.20	0.46	0.60	0.42	0.67	0.58
	Biosimilar vs Accessible market	13%	24%	52%	8%	55%	13%	18%	28%		13%	0%	0.26	0.49	0.00	0.99	0.35	0.51	0.00	0.10	0.30	0.42	0.08	0.35	0.33
	Biosimilar vs Total market	13%	24%	52%	8%	55%	13%	18%	28%		13%	0%	0.26	0.49	0.00	0.99	0.35	0.51	0.00	0.10	0.30	0.42	0.08	0.35	0.33
PRICE PER TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-24%	-38%	-31%	-30%	-22%	-44%	-32%	-10%	-100%	-36%	-22%	-0.34	-0.63	-0.37	-0.51	-0.59	-0.35	-0.39	-0.41	-0.28	-0.54	-0.44	-0.57	-0.39
	Biosimilar accessible market	-18%	-38%	-31%	-37%	-23%	-48%	-29%	-6%	-100%	-32%	-22%	-0.33	-0.62	-0.30	-0.51	-0.51	-0.48	-0.31	-0.41	-0.28	-0.53	-0.39	-0.36	-0.33
	Total market	-18%	-38%	-31%	-36%	-23%	-48%	-29%	-6%	-100%	-32%	-22%	-0.33	-0.62	-0.30	-0.51	-0.51	-0.48	-0.31	-0.41	-0.28	-0.53	-0.39	-0.36	-0.33
VOLUME TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	21%	47%	88%	111%	63%	3%	16%	15%	-100%	-19%	60%	87%	112%	-88%	178%	64%	296%	23%	76%	95%	-15%	-24%	84%	62%
	Biosimilar accessible market	113%	31%	84%	111%	-6%	108%	66%	32%	-100%	17%	86%	67%	50%	28%	177%	13%	97%	26%	65%	96%	-19%	51%	125%	64%
	Total market	113%	31%	84%	111%	-6%	108%	66%	33%	-100%	17%	86%	67%	50%	28%	177%	13%	97%	26%	65%	96%	-19%	51%	125%	64%
	TD per capita	0.07	0.12	0.05	0.17	0.13	0.12	0.16	0.07	0.00	0.06	0.08	0.11	0.12	0.16	0.12	0.05	0.05	0.08	0.09	0.18	0.12	0.09	0.08	0.11
	TD/capita (Yr before BS entrance)	0.04	0.10	0.02	0.08	0.15	0.06	0.10	0.05	0.00	0.05	0.05	0.06	0.09	0.14	0.04	0.04	0.02	0.06	0.06	0.10	0.16	0.07	0.04	0.07
	First recorded sales of biosimilars	2008	2009	2012	2010	2011	2008	2007	2006	2015	2012	2006	2007	2008	2011	2008	2014	2008	2013	2010	2007	2007	2010	2007	2006

* Only retail panel data is available for Greece

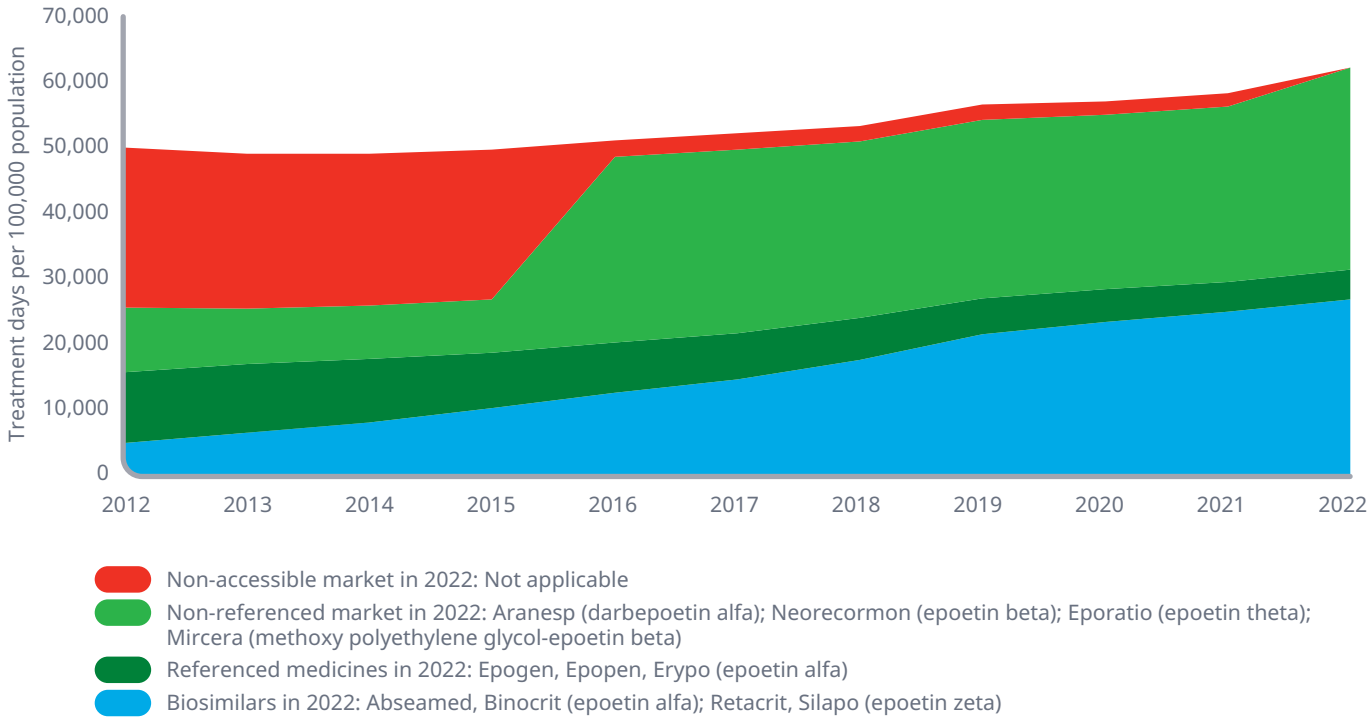
Epoetin (EPO)

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

EPO MARKET DEVELOPMENT

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

EPO market development



EPO approved indications

NAMING		CLASSIFICATION												INDICATIONS					DOSING/ADMINISTRATION	
MOLECULE	PRODUCT	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	ANEMIA FOR CHEMOTHERAPY PATIENTS	ANEMIA FOR PATIENTS WITH CKD*	PREVENTING ANEMIA IN PREMATURE BABIES	ANEMIA IN ADULTS WITH MDS	REDUCTION OF ALLOGENIC TRANSFUSION EXPOSURE IN ORTHAPEDIC SURGERY	PATIENT TYPE** (ADULT OR PEDIATRIC)	FREQUENCY
DARBEPOETIN ALFA	ARANESP	●	●	●	●	●	●	●	●	●	●	●	●	●	●			●	Both	3 x per week
EPOETIN ALFA	ABSEAMED BINOCRIT EPOGEN EPOPEN ERYPO	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●		● ● ● ●	● ● ● ● ●	Both	3 x per week
EPOETIN BETA	NEORECORMON	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	Both	3 x per week
EPOETIN DELTA	DYNEPO***	●	●	●	●									●	●	●			Both	3 x per week
EPOETIN THETA	EPORATIO	●	●	●	●	●	●	●	●	●	●	●	●	●	●				Adult	3 x per week
EPOETIN ZETA	RETACRIT SILAPO	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●				Both	3 x per week
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA	MIRCERA	●	●	●	●	●	●	●	●	●	●	●	●		●				Adult	Every 2 weeks

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

* Anaemia for patients with Chronic kidney disease.

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

*** Dynepo has been discontinued.

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

		AT	BE	BU	CZ	DK	FI	FR	DE	GR*	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD 2022	Biosimilar vs Referenced product	80%	15%	100%	96%	0%	100%	79%	91%	95%	100%	100%	92%	20%	100%	100%	98%	99%	100%	78%	90%	99%	30%	13%	88%
	Biosimilar vs Accessible market	23%	4%	57%	30%	0%	17%	28%	57%	92%	38%	0%	80%	1%	7%	25%	29%	50%	51%	19%	53%	20%	1%	3%	48%
	Biosimilar vs Total market	23%	4%	57%	30%	0%	17%	28%	57%	92%	38%	0%	80%	1%	7%	25%	29%	50%	51%	19%	53%	20%	1%	3%	48%
PRICE PER TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-48%	-25%	-19%	-66%	-16%	-57%	-38%	-60%	-59%	-86%	-39%	-25%	-56%	-49%	-70%	-83%	-63%	-65%	-54%	-74%	-42%	-55%	-17%	-44%
	Biosimilar accessible market	-51%	-15%	-26%	-53%	-36%	-46%	-46%	-58%	-59%	-58%	-39%	-23%	-48%	-33%	-43%	-75%	-52%	-62%	-54%	-57%	-47%	-48%	-21%	-44%
	Total market	-48%	-26%	-35%	-52%	-34%	-43%	-44%	-56%	-59%	-51%	-36%	-21%	-49%	-30%	-39%	-73%	-51%	-60%	-54%	-55%	-46%	-45%	-19%	-42%
VOLUME TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	15%	29%	117%	474%	-100%	2822%	82%	154%	736%	102%	-95%	273%	-73%	112%	8836%	309%	114%	363%	-11%	128%	23%	-57%	153%	155%
	Biosimilar accessible market	75%	215%	94%	392%	130%	315%	136%	93%	409%	133%	49%	143%	113%	491%	641%	237%	-51%	141%	75%	84%	110%	206%	203%	119%
	Total market	-10%	16%	48%	252%	2%	42%	22%	18%	237%	3%	-13%	55%	-8%	41%	374%	10%	-57%	27%	21%	12%	16%	26%	73%	25%
	TD per capita	0.81	0.59	0.39	0.32	0.48	0.47	1.08	0.45	0.07	0.38	0.41	1.32	0.47	0.28	0.13	0.48	0.13	0.57	0.62	0.76	0.51	0.40	0.41	0.66
	TD/capita (Yr before BS entrance)	0.98	0.53	0.23	0.09	0.50	0.35	0.94	0.39	0.02	0.35	0.55	0.85	0.55	0.23	0.03	0.43	0.28	0.45	0.54	0.70	0.51	0.37	0.25	0.54
	First recorded sales of biosimilars	2008	2014	2011	2011	2012	2008	2009	2007	2008	2009	2008	2008	2009	2008	2009	2010	2009	2010	2009	2009	2008	2009	2009	2007

* Only retail panel data is available for Greece

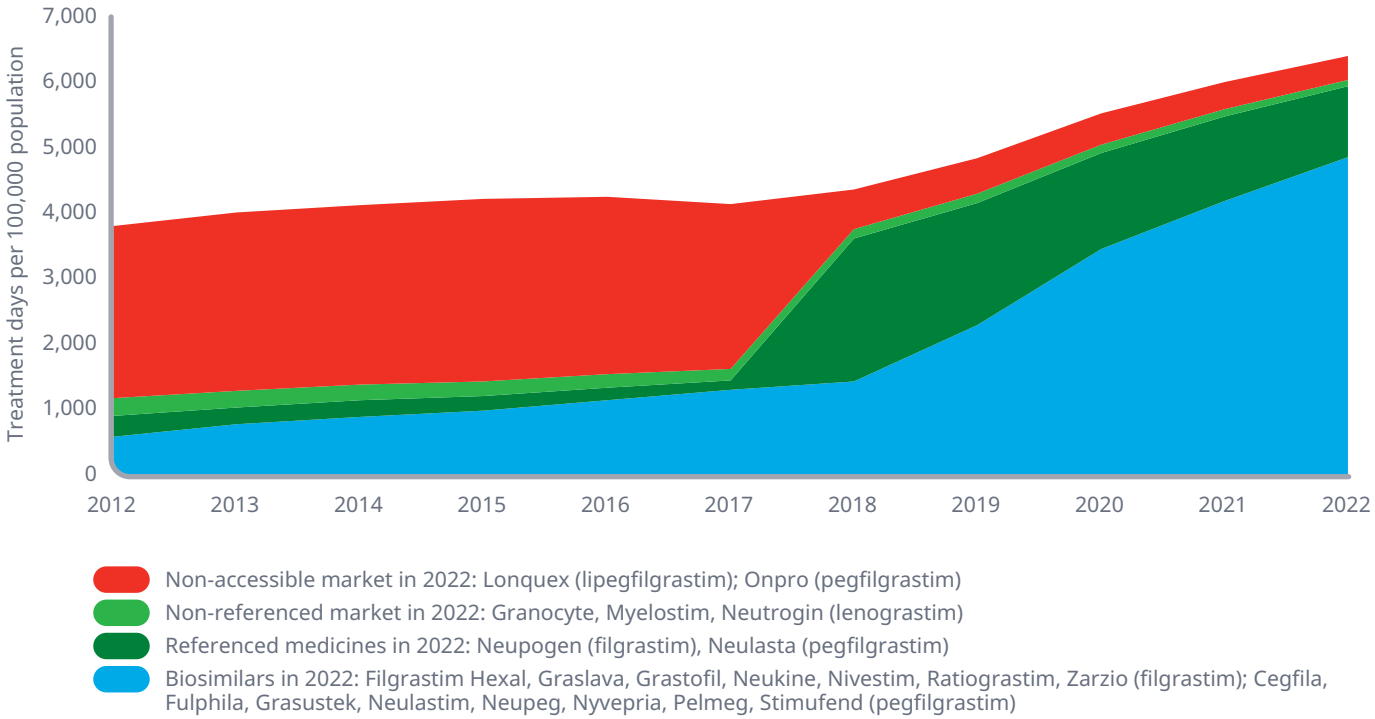
Granulocyte-colony stimulating factor (GCSF)

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 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 72hrs 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					
MOLECULE	PRODUCT	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2222	CYTOTOXIC CHEMOTERAPY ASSOCIATED WITH FEBRILE INDUCED NEUTROPENIA	NEUTROPENIA INDUCED BY ACUTE MYELOID LEUKEMIA	BONE MARROW TRANSPLANTATION FOR NON MYELOID MALIGNANCY INDUCED NEUTROPENIA	MOBILISATION OF PERIPHERAL BLOOD PROGENITOR CELLS (PBPCS)	SEVERE CHRONIC NEUTROPENIA (SCN) WITH DIAGNOIS OF CONGENITAL, CYCLIC, OR IDIOPATHIC NEUTROPENIA	NEUTROPENIA PREVENTION AND TREATMENT IN PATIENTS WITH HIV
FILGRASTIM	GRANULOKINE GRASALVA GRASTOFIL NEUKINE NEUPOGEN NIVESTIM RATIOGRASTIM ZARZIO FILGRASTIM HEXAL	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●	● ● ● ● ● ● ● ● ● ●	● ● ●	● ● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ● ●	● ● ● ● ● ● ● ● ● ●
LENOGRASTIM	GRANOCYTE MYELOSTIM NEUTROGIN	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●		● ● ●	● ● ●		
LIPEGFILGRASTIM	LONQUEX				●	●	●	●	●	●	●	●	●	●					
PEGFILGRASTIM	NEULASTA ONPRO NEULASTIM NEUPEG PELMEG FULPHILA CEGFILA GRASUSTEK NYVEPRIA STIMUFEND	●	●	●	●	●	●	●	● ●	● ●	● ●	● ●	● ●	● ● ● ● ● ● ● ● ● ●					

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

Notes: Tevagrastim = Grasalva in IQVIA MIDAS; Accofil = Neukine in IQVIA MIDAS; Ziextenzo = Neulastim in IQVIA MIDAS; Pelgraz is Neupeg in 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 (2022)	Biosimilar vs Referenced product	62%	54%	74%	99%	100%	73%	83%	61%	98%	100%	18%	91%	92%	98%	100%	97%	95%	96%	45%	95%	98%	63%	86%	82%
	Biosimilar vs Accessible market	62%	54%	74%	99%	100%	73%	80%	60%	98%	100%	18%	91%	92%	98%	100%	96%	95%	96%	45%	95%	98%	63%	84%	80%
	Biosimilar vs Total market	54%	38%	51%	87%	100%	63%	79%	54%	97%	100%	16%	84%	87%	98%	100%	96%	95%	80%	41%	94%	98%	63%	83%	75%
PRICE PER TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-79%	-70%	-90%	-85%	-64%	-82%	-75%	-73%	-74%	-88%	-73%	-57%	-73%	-61%	-93%	-98%	-72%	-89%	-87%	-52%	-76%	-59%	-26%	-73%
	Biosimilar accessible market	-79%	-70%	-90%	-85%	-64%	-82%	-73%	-72%	-74%	-88%	-72%	-57%	-73%	-61%	-93%	-98%	-72%	-89%	-87%	-52%	-76%	-59%	-24%	-72%
	Total market	-67%	-56%	-86%	-79%	-38%	-71%	-57%	-60%	-59%	-84%	-47%	-37%	-54%	-36%	-92%	-92%	-71%	-82%	-80%	-42%	-66%	-34%	-11%	-61%
VOLUME TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	839%	1343%	4487%	2500%	1341%	1209%	2309%	883%	5234%	698%	1107%	472%	1328%	3099%	1073%	659%	1950%	2880%	1414%	117%	833%	555%	659%	933%
	Biosimilar accessible market	839%	1343%	4487%	2500%	1344%	1209%	2406%	903%	5235%	698%	1120%	477%	1328%	3099%	1073%	662%	1950%	2880%	1414%	118%	833%	555%	678%	949%
	Total market	120%	152%	3977%	1024%	131%	118%	121%	155%	-26%	85%	102%	21%	20%	246%	387%	-13%	1840%	1025%	400%	-27%	138%	92%	160%	115%
	TD per capita	0.11	0.11	0.08	0.05	0.09	0.12	0.11	0.06	0.01	0.07	0.10	0.04	0.04	0.09	0.08	0.03	0.07	0.10	0.09	0.03	0.05	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

Anti-tumour necrosis factor (Anti-TNF)

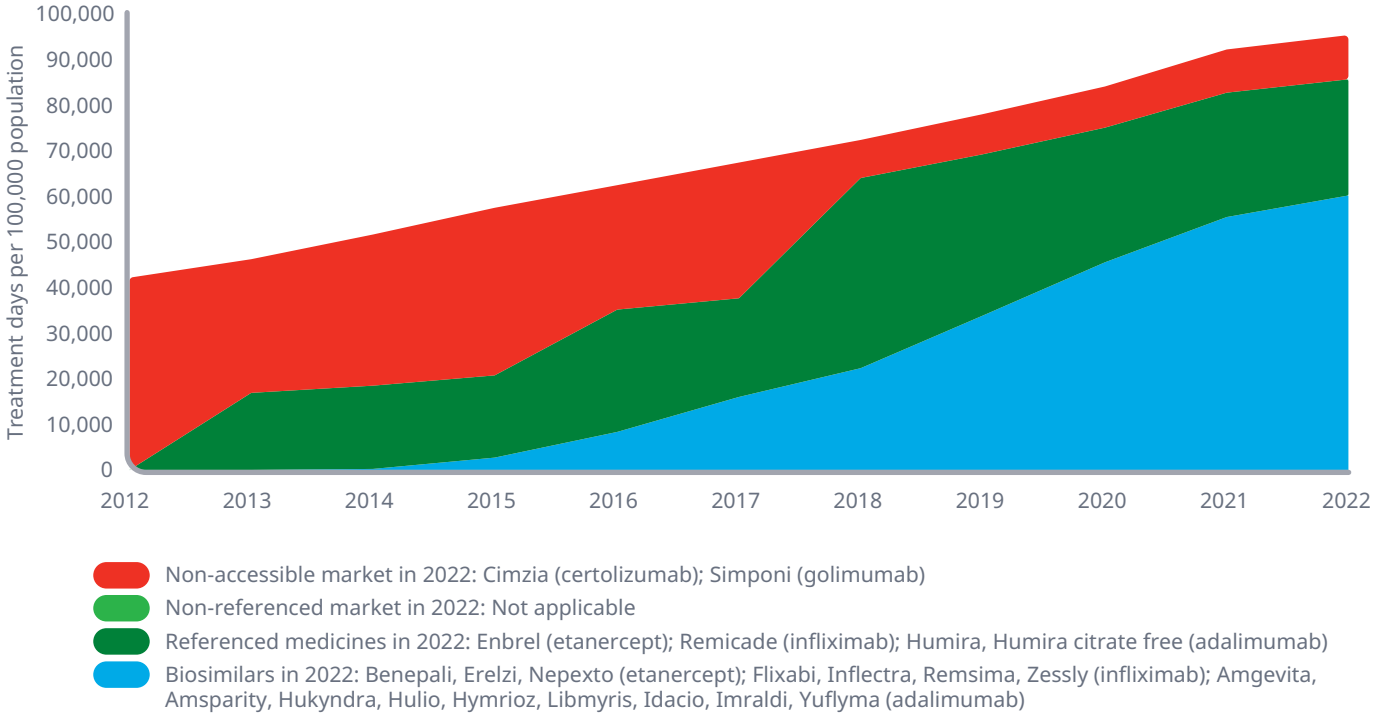
Anti-TNF drugs are a class of drugs that are used to treat inflammatory conditions such as Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, Juvenile Arthritis, Crohn's Disease, Ulcerative Colitis, Psoriasis and Hidradinitis Suppurativa. These drugs are able to reduce inflammation and 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	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	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	N
	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

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

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

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

		AT	BE	BU*	CZ	DK	FI	FR	DE	GR**	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD (2022)	Biosimilar vs Referenced product	41%	55%	15%	59%	98%	79%	63%	78%	65%	89%	76%	84%	75%	94%	96%	75%	38%	21%	53%	69%	89%	35%	89%	71%
	Biosimilar vs Accessible market	41%	55%	15%	59%	98%	79%	63%	78%	65%	89%	76%	84%	75%	94%	96%	75%	38%	21%	53%	69%	89%	35%	89%	71%
	Biosimilar vs Total market	34%	49%	13%	53%	91%	68%	55%	69%	51%	78%	70%	72%	72%	90%	79%	70%	34%	20%	48%	63%	85%	28%	84%	64%
PRICE PER TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-43%	-23%	-32%		3%		-31%	-5%	-40%	4%	-8%	36%	-20%		-72%	-57%	-8%	-41%	-52%	-14%	-52%	4%	30%	-16%
	Biosimilar accessible market	-43%	-23%	-32%		3%		-31%	-5%	-40%	4%	-8%	36%	-20%		-72%	-57%	-8%	-41%	-52%	-14%	-52%	4%	30%	-16%
	Total market	-45%	-40%	-44%	-42%	-30%	-48%	-47%	-44%	-34%	-24%	-35%	-17%	-43%	-15%	-75%	-70%	-38%	-53%	-60%	-36%	-65%	-24%	-8%	-43%
VOLUME TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	890%	174%	>1Mn%		401%		296%	441%	146%	274%	887%	326%	313%		1400%	514%	192%	227%	383%	384%	438%	203%	544%	390%
	Biosimilar accessible market	890%	174%	>1Mn%		401%		296%	441%	146%	274%	887%	326%	313%		1400%	514%	192%	227%	383%	384%	438%	203%	544%	390%
	Total market	703%	36%	384%	259%	123%	184%	92%	89%	94%	49%	176%	48%	68%	167%	280%	169%	31%	80%	87%	102%	112%	68%	100%	96%
	TD per capita	0.44	0.61	0.07	0.45	1.79	1.21	0.65	0.63	0.01	0.38	1.75	0.40	1.15	2.47	0.13	0.55	0.09	0.17	0.41	0.71	1.58	0.37	1.01	0.58
	TD/capita (Yr before BS entrance)	0.17	0.95	0.10	0.24	0.92	0.65	0.62	0.50	0.01	0.32	1.00	0.36	1.00	1.12	0.04	0.29	0.20	0.49	0.47	0.57	0.95	0.84	0.62	0.47
	First recorded sales of biosimilars	2015	2015	2014	2013	2015	2013	2015	2015	2019	2014	2014	2015	2015	2013	2014	2014	2014	2014	2015	2015	2015	2016	2015	2013

* The significant volume increase in Bulgaria is due to no sales of Remicade prior to biosimilar entry in 2014
** Only retail panel data is available for Greece
Note: Gaps in price and volume per TD are due to there being no 'Non-referenced' or 'Referenced' products in the year before biosimilar entry

Fertility (follitropin alfa)

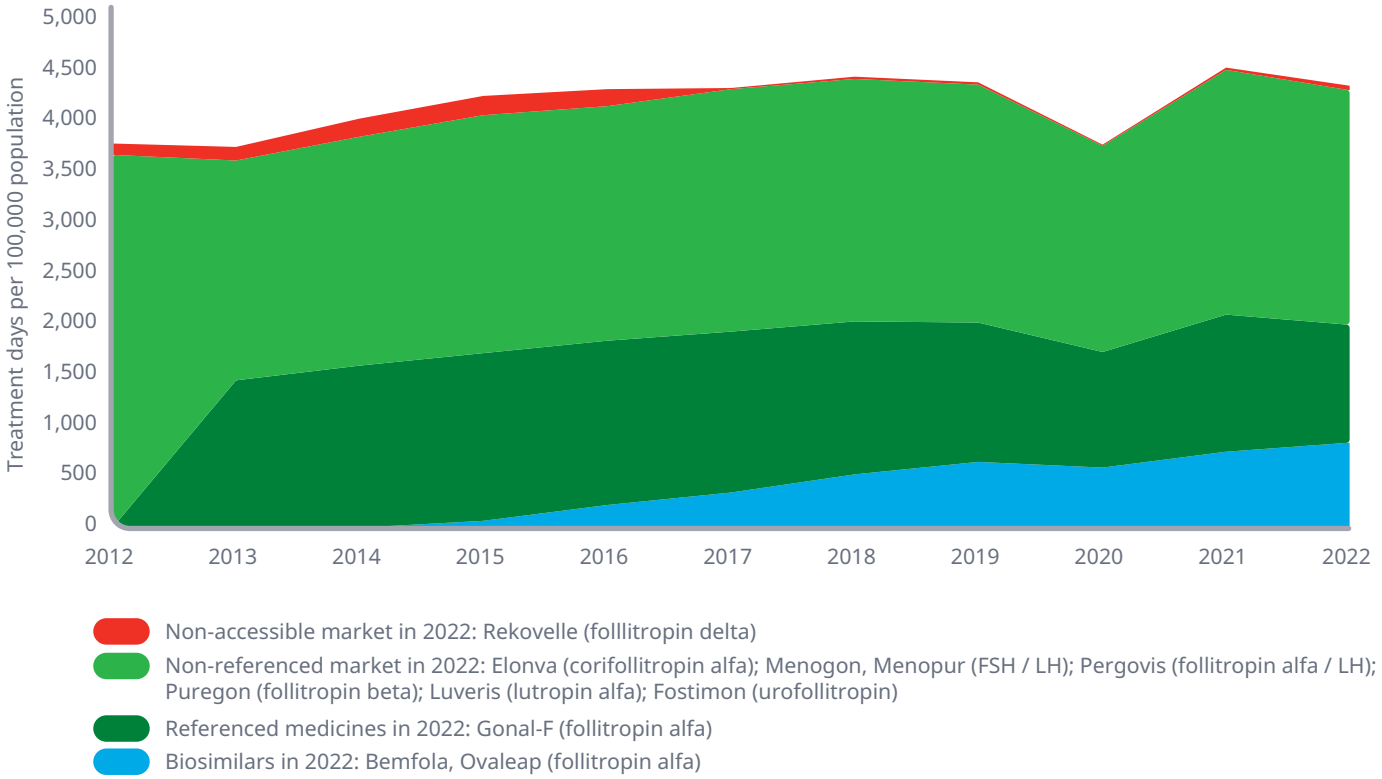
Gonadotropin preparations are drugs that mimic the physiological effects of gonadotropins, used therapeutically primarily as fertility medication for ovarian hyperstimulation and reversal of an ovulation. For the purpose of this report, only Follicle-Stimulating Hormones (FSH) and Luteinizing Hormone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

FERTILITY MARKET DEVELOPMENT

A significant decline in treatment volume in 2020 is not a trend break in reporting, but the impact of the COVID-19 pandemic on prescriptions in this area and is therefore an accurate assessment of the market dynamics. The market has since recovered to pre-pandemic levels in 2022.

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

Fertility market development



Fertility approved indications

NAMING		CLASSIFICATION												INDICATIONS					DOSING/ADMINISTRATION	
MOLECULE	PRODUCT	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	INFERTILITY	HYPOGONADISM	ANOVULATION	OVULATION INDUCTION	REPRODUCTIVE TECHNIQUES, ASSISTED	ROUTE (SUBQ/IV/IM)	FREQUENCY
CORIFOLLITROPIN ALFA	ELONVA	●	●	●	●	●	●	●	●	●	●	●	●	●					SC	Patient specific
FOLLICLE-STIMULATING HORMONE / LUTEINISING HORMONE	MENOGON MENOPUR	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ●		●		● ●	SC/IM SC	Daily Daily
FOLLITROPIN ALFA	GONAL-F BEMFOLA OVALEAP	●	●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ●	● ●		● ●	All All All	Daily Daily Daily
FOLLITROPIN ALFA / LUTEINISING HORMONE	PERGOVERIS	●	●	●	●	●	●	●	●	●	●	●	●	●					All	Daily
FOLLITROPIN BETA	PUREGON	●	●	●	●	●	●	●	●	●	●	●	●	●	●				SC	Patient specific
FOLLITROPIN DELTA	REKOVELLE	●	●	●	●	●	●	●	●	●	●	●	●	●			●	●	SC	Daily
LUTROPIN ALFA	LUVERIS	●	●	●	●	●	●	●	●	●	●	●	●	●			●		All	Daily
UROFOLLITROPIN	FOSTIMON	●	●	●	●	●	●	●	●	●	●	●	●	●			●		IM	Daily

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

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

		AT	BE	BU	CZ	DK	FI	FR	DE	GR*	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD (2022)	Biosimilar vs Referenced product	30%	53%	1%	47%	40%	22%	46%	52%	42%	95%	1%	38%	0%	29%	59%	45%	9%	65%	27%	52%	27%	25%	38%	43%
	Biosimilar vs Accessible market	6%	18%	0%	22%	18%	11%	25%	22%	18%	57%	0%	14%	0%	14%	24%	17%	4%	32%	19%	22%	16%	9%	18%	20%
	Biosimilar vs Total market	6%	18%	0%	22%	18%	11%	25%	22%	18%	55%	0%	13%	0%	14%	23%	17%	4%	32%	18%	21%	16%	9%	18%	20%
PRICE PER TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-30%	-8%	-22%	-23%	-29%	-34%	-32%	-12%	-27%	-25%	-20%	-9%	-16%	-2%	-1%	-25%	-14%	-21%	-23%	-26%	-19%	-22%	17%	-23%
	Biosimilar accessible market	-8%	19%	6%	-2%	-6%	-18%	-16%	1%	6%	8%	1%	0%	-3%	11%	-9%	9%	10%	27%	-1%	-4%	-14%	-13%	11%	-5%
	Total market	-7%	9%	-8%	-2%	-11%	-23%	-17%	-1%	2%	11%	2%	-3%	2%	9%	-1%	3%	10%	27%	-4%	-10%	-14%	-12%	12%	-7%
VOLUME TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	136%	65%	168%	53%	70%	126%	45%	35%	91%	57%	87%	-34%	1%	142%	94%	95%	86%	95%	85%	25%	96%	28%	-2%	27%
	Biosimilar accessible market	29%	30%	-58%	59%	39%	26%	16%	19%	36%	27%	66%	-9%	-11%	50%	40%	72%	64%	-6%	2%	11%	29%	3%	-11%	15%
	Total market	31%	30%	-58%	61%	33%	21%	13%	12%	35%	22%	68%	-12%	-9%	51%	41%	69%	65%	-4%	3%	1%	30%	3%	-11%	11%
	TD per capita	0.01	0.05	0.00	0.07	0.09	0.04	0.08	0.03	0.02	0.06	0.11	0.05	0.05	0.07	0.02	0.04	0.02	0.02	0.05	0.06	0.07	0.05	0.01	0.05
	TD/capita (Yr before BS entrance)	0.01	0.04	0.01	0.05	0.07	0.03	0.07	0.03	0.02	0.05	0.07	0.06	0.06	0.05	0.01	0.02	0.01	0.02	0.05	0.06	0.06	0.05	0.01	0.04
	First recorded sales of biosimilars	2014	2015	2016	2015	2014	2014	2015	2014	2016	2015	2016	2015	2016	2014	2015	2015	2017	2016	2015	2015	2014	2018	2015	2014

* Only retail panel data is available for Greece

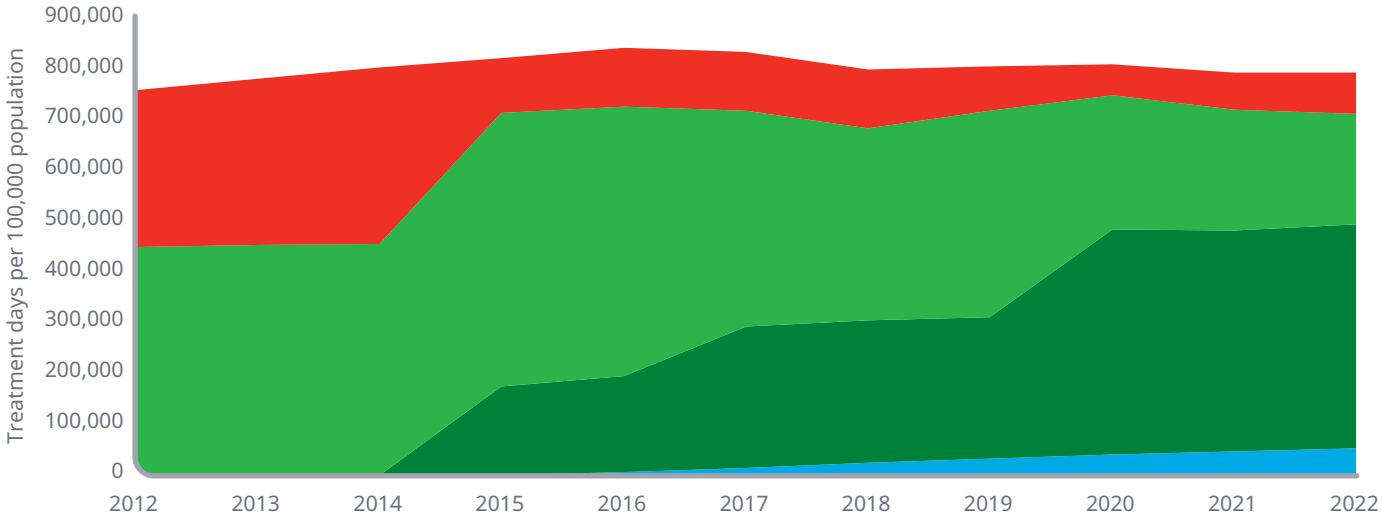
Insulins

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 2022: Ryzodeg (insulin aspart / insulin degludec); Tresiba (insulin degludec); Xultophy (insulin degludec / liraglutide); Toujeo (insulin glargine); Soliqua (insulin glargine / lixisenatide)
- Non-referenced market in 2022: 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 2022: Novorapid (insulin aspart), Lantus (insulin glargine); Humalog / Liprolog (insulin lispro)
- Biosimilars in 2022: Insulin aspart SNFI, Kirsty (insulin aspart); Truvelog Mix 30 (insulin aspart / protamine); Abasaglar, Semglee (insulin glargine); Ademlog / insulin lispro SNFI (insulin lispro)

ADDITIONAL INFORMATION ABOUT INSULIN MEDICINES

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

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

Insulin approved indications

NAMING		CLASSIFICATION												INDICATIONS	DOSING/ADMINISTRATION	
MOLECULE	PRODUCT	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	DIABETES MELLITUS	FREQUENCY	MODE OF ACTION
INSULIN ASPART	NOVORAPID INSULIN ASPART SANOFI KIRSTY	●	●	●	●	●	●	●	●	●	● ●	● ●	● ●	● ● ●	before every meal	Fast-acting
INSULIN ASPART#INSULIN ASPART PROTAMINE	NOVOMIX TRUVELOG MIX 30	●	●	●	●	●	●	●	●	●	●	●	● ●	● ●	before every meal	Fast-acting
INSULIN ASPART#INSULIN DEGLUDEC	RYZODEG			●	●	●	●	●	●	●	●	●	●	●	daily	Fast-acting
INSULIN DEGLUDEC	TRESIBA			●	●	●	●	●	●	●	●	●	●	●	daily	Long-acting
INSULIN DEGLUDEC / LIRAGLUTIDE	XULTOPHY				●	●	●	●	●	●	●	●	●	●	daily	Long-acting
INSULIN DETEMIR	LEVEMIR	●	●	●	●	●	●	●	●	●	●	●	●	●	twice a day	Long-acting
INSULIN GLARGINE	LANTUS TOUJEO ABASAGLAR SEMGLEE	●	●	●	●	● ● ●	● ● ●	● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	daily daily daily daily	Long-acting Long-acting Long-acting Long-acting
INSULIN GLARGINE / LIXISENATIDE	SOLIQUA							●	●	●	●	●	●	●	daily	Long-acting
INSULIN GLULISINE	APIDRA	●	●	●	●	●	●	●	●	●	●	●	●	●	before every meal	Fast-acting
INSULIN HUMAN*	ACTRAPID HUMULIN PROTAPHANE	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	before every meal once/twice a day once/twice a day	Short-acting Short-acting Intermediate-acting
INSULIN LISPRO	HUMALOG/LIPROLOG ADEMLOG/ INSULIN LISPRO SANOFI	●	●	●	●	●	●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	before every meal before every meal	Fast-acting Fast-acting
INSULIN LISPRO#INSULIN LISPRO PROTAMINE	HUMALOG /LIPROLOG MIX	●	●	●	●	●	●	●	●	●	●	●	●	●	determined by physician	Fast-acting

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

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

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

		AT	BE	BU	CZ	DK	FI	FR	DE	GR*	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD (2022)	Biosimilar vs Referenced product	5%	1%	3%	4%	16%	5%	14%	8%	10%	3%	0%	10%	34%	5%	22%	13%	4%	17%	4%	12%	25%	0%	5%	12%
	Biosimilar vs Accessible market	3%	1%	1%	2%	14%	5%	12%	6%	8%	1%	0%	9%	26%	4%	9%	8%	3%	9%	2%	9%	18%	0%	3%	8%
	Biosimilar vs Total market	3%	1%	1%	2%	10%	4%	10%	5%	6%	1%	0%	7%	23%	3%	9%	7%	2%	8%	2%	9%	17%	0%	3%	8%
PRICE PER TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-32%	-38%					-37%		-23%		-37%	-28%				-27%	-15%		-44%					-24%
	Biosimilar accessible market	1%	-13%	5%	27%	-22%	3%	-18%	23%	-4%	28%	-14%	-6%	3%	36%	7%	3%	15%	21%	-13%	19%	17%	1%	13%	6%
	Total market	3%	-7%	24%	31%	-22%	-22%	-7%	8%	25%	59%	-10%	22%	-9%	53%	1%	2%	25%	29%	13%	-7%	5%	5%	-1%	5%
VOLUME TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	414%	221%					151%		114%		259%	172%				156%	164%		350%					542%
	Biosimilar accessible market	-4%	9%	-76%	47%	63%	159%	23%	23%	0%	11%	32%	2%	84%	31%	22%	21%	29%	55%	-6%	150%	63%	78%	110%	25%
	Total market	-4%	10%	-84%	31%	4%	-4%	20%	-8%	10%	-2%	23%	-4%	-5%	16%	4%	16%	34%	9%	-4%	2%	2%	7%	19%	-4%
	TD per capita	5.12	7.09	6.37	10.07	6.63	10.95	7.33	10.41	7.76	9.09	5.43	5.61	8.63	7.70	6.99	6.30	7.15	7.10	8.03	7.11	9.52	4.68	8.31	7.78
	TD/capita (Yr before BS entrance)	5.50	6.69	35.34	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	8.15
	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

* 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

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.

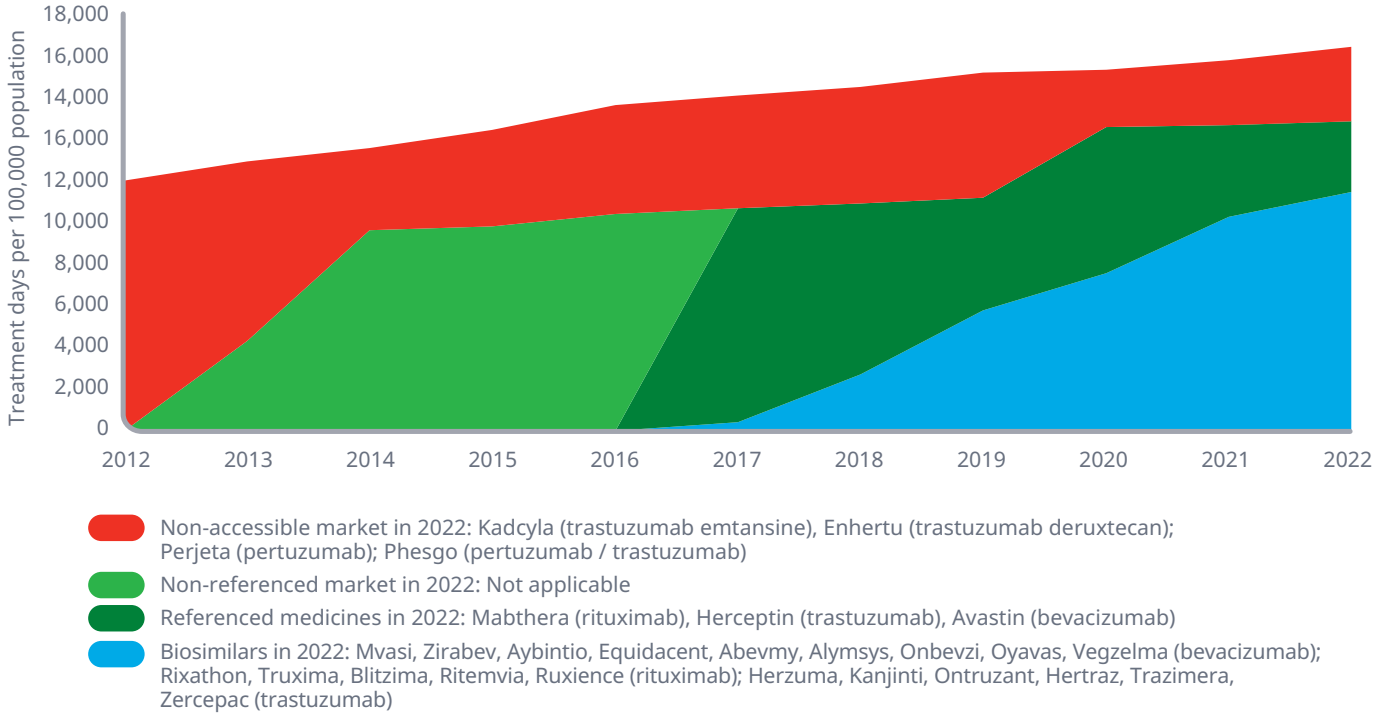
In this market the non-accessible products are classified by identifying products which have a similar mechanism of action, and are used for similar indications to rituximab. There are both IV and SC forms of Mabthera available, but because the biosimilar is only available in IV form, Mabthera IV is 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	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	FL, DLBC (NON-GL)	CLL	MC	BC	METASTATIC GC	RCC	NSCLC	EOC	PPC	ROUTE (SUBQ / IV)	FREQUENCY
BEVACIZUMAB	AVASTIN MVASI ZIRABEV AYBINTIO EQUIDACENT ABEVMY ALYMSYS ONBEVZI OYAVAS VEGZELMA	●	●	●	●	●	●	●	●	●	●	●	●			●	●		●	●	●	●	IV IV IV IV IV IV IV IV IV IV	2 – 3 week cycles (indication/ combination dependant)
RITUXIMAB*	MABTHERA RIXATHON TRUXIMA BLITZIMA RITEMVIA RUXIENCE	●	●	●	●	●	●	●	●	●	●	●	●	●	●								SC/IV IV IV IV IV IV	3 week cycles
TRASTUZUMAB**	HERCEPTIN HERZUMA KANJINTI ONTRUZANT HERTRAZ TRAZIMERA ZERCEPAC	●	●	●	●	●	●	●	●	●	●	●	●				●	●					SC/IV IV IV IV IV IV IV	3 week cycles
TRASTUZUMAB EMTANSINE	KADCYLA			●	●	●	●	●	●	●	●	●	●				●						IV	3 week cycles
TRASTUZUMAB DERUXTECAN	ENHERTU										●	●	●				●						IV	3 week cycles
PERTUZUMAB	PERJETA			●	●	●	●	●	●	●	●	●	●				●						IV	3 week cycles
ERTUZUMAB-#TRASTUZUMAB	PHESGO										●	●	●				●						SC	3 week cycles

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

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

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

		AT	BE	BU	CZ	DK	FI	FR	DE	GR*	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD (2022)	Biosimilar vs Referenced product	92%	53%	41%	49%	96%	77%	78%	88%	0%	86%	55%	85%	91%	93%	63%	61%	78%	70%	59%	76%	88%	39%	62%	79%
	Biosimilar vs Accessible market	92%	53%	41%	49%	96%	77%	78%	88%	0%	86%	55%	85%	91%	93%	63%	61%	78%	70%	59%	76%	88%	39%	62%	79%
	Biosimilar vs Total market	74%	42%	33%	42%	84%	66%	65%	71%	0%	75%	46%	67%	75%	79%	48%	49%	60%	62%	43%	64%	75%	31%	44%	65%
PRICE PER TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	0%	-25%	-33%	-34%		-22%			0%	-26%					-66%		5%	-39%	-42%		-6%	-20%		-21%
	Biosimilar accessible market	0%	-25%	-33%	-34%	-12%	-22%	-36%	-35%	0%	-26%	-30%	-13%	-27%	14%	-66%	-45%	5%	-39%	-42%	-26%	-6%	-20%	1%	-29%
	Total market	11%	-22%	-21%	-20%	-3%	-7%	-14%	-23%	0%	-20%	-22%	-3%	-20%	20%	-30%	-22%	20%	-30%	-12%	-13%	15%	-11%	47%	-14%
VOLUME TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	57%	42%	120%	32%		34%			0%	83%					17%		115%	86%	3%		12%	28%		573%
	Biosimilar accessible market	57%	42%	120%	32%	45%	34%	111%	48%	0%	83%	39%	16%	32%	73%	17%	68%	115%	86%	3%	67%	12%	28%	-24%	55%
	Total market	8%	17%	47%	9%	12%	11%	48%	7%	0%	17%	20%	-2%	14%	57%	27%	56%	45%	18%	11%	43%	1%	9%	-6%	21%
	TD per capita	0.19	0.19	0.17	0.12	0.18	0.18	0.25	0.19	0.00	0.14	0.19	0.15	0.15	0.20	0.08	0.15	0.08	0.13	0.14	0.19	0.14	0.19	0.11	0.17
	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	0.05	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

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

Low-molecular-weight heparin (LMWH)

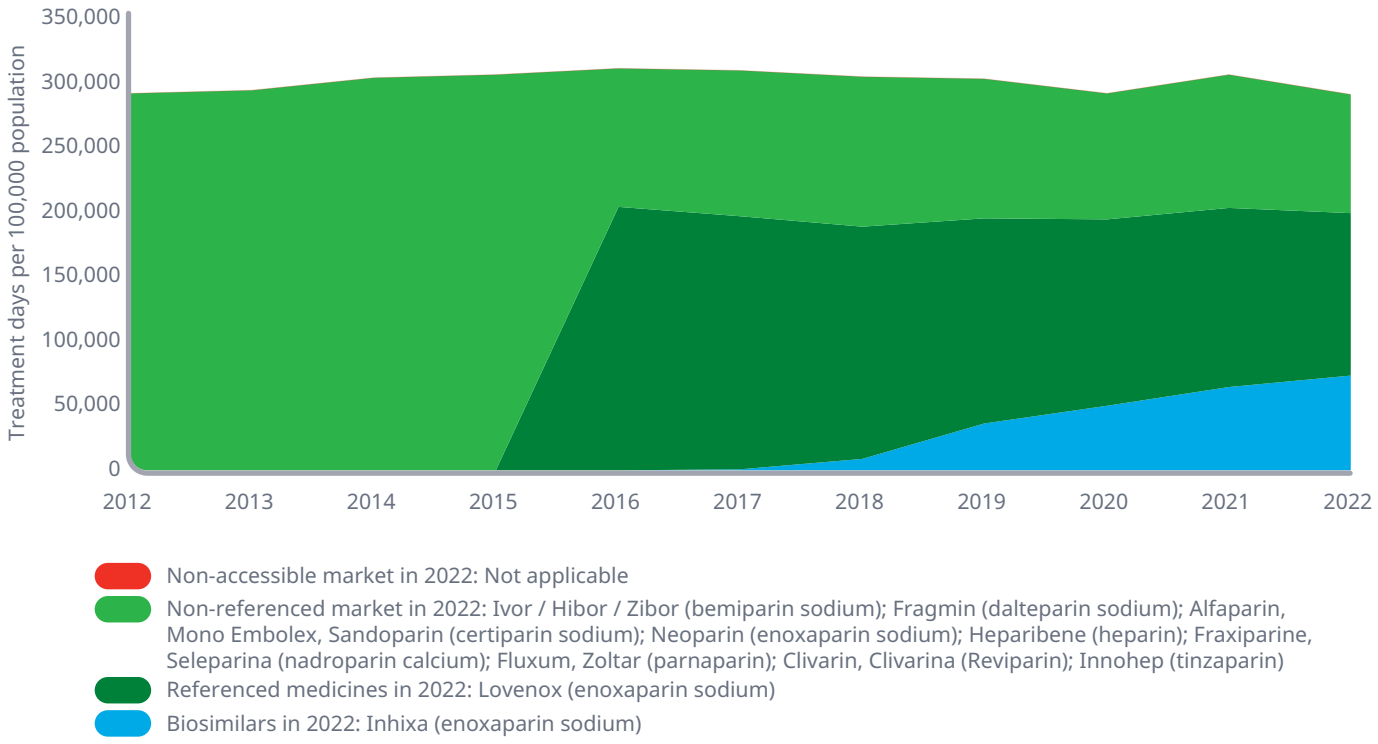
Low-Molecular-Weight Heparin (LMWH) is a class of anticoagulant medications. They are used in the prevention of blood clots, treatment of venous thromboembolism (deep vein thrombosis and pulmonary embolism) and in the treatment of myocardial infarction. LMWH is obtained by fractionation of polymeric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

Two enoxaparin sodium biosimilars (Inhixa and Thorinane) were authorised by the EMA in 09/2016, however Thorinane is now withdrawn meaning that Inhixa is the only remaining biosimilar in 2021.

LMWH MARKET DEVELOPMENT

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

LMWH market development



LMWH approved indications

NAMING		CLASSIFICATION												INDICATIONS			
MOLECULE	PRODUCT	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	DEEP VEIN THROMBOSIS TREATMENT AND PROPHYLAXIS	PULMONARY EMBOLISM	ATRIAL THROMBUS	BRIDGING THERAPY PRIOR TO STARTING WARFARIN
BEMIPARIN SODIUM	IVOR/HIBOR/ZIBOR	●	●	●	●	●	●	●	●	●	●	●	●	●	●		
CERTOPARIN SODIUM	ALFAPARIN MONO EMBOLEX SANDOPARIN	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●		
DALTEPARIN SODIUM	FRAGMIN	●	●	●	●	●	●	●	●	●	●	●	●	●			
ENOXAPARIN SODIUM	LOVENOX NEOPARIN INHIXA	●	●	●	●	●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●			● ● ●
HEPARIN	HEPARIBENE	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
NADROPARIN CALCIUM	FRAXIPARINE SELEPARINA	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●		
PARNAPARIN	FLUXUM ZOLTAR	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●		
REVIPARIN	CLIVARIN CLIVARINA	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●		
TINZAPARIN	INNOHEP	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●

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

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

		AT	BE	BU	CZ	DK	FI	FR	DE	GR*	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK	EU
MARKET SHARE TD (2022)	Biosimilar vs Referenced product	59%	4%	0%	12%	101%	97%	8%	31%	0%	0%	0%	77%	36%	0%	0%	57%	0%	0%	0%	50%	0%	2%	66%	35%
	Biosimilar vs Accessible market	48%	3%	0%	8%	1%	58%	6%	21%	0%	0%	0%	71%	0%	0%	0%	55%	0%	0%	0%	40%	0%	1%	38%	24%
	Biosimilar vs Total market	48%	3%	0%	8%	1%	58%	6%	21%	0%	0%	0%	71%	0%	0%	0%	55%	0%	0%	0%	40%	0%	1%	38%	24%
PRICE PER TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-22%	-3%		38%	37%	-9%	-11%	4%				-7%	-3%		20%	-17%				-22%	32%	6%	-1%	-8%
	Biosimilar accessible market	-20%	-3%		41%	0%	9%	-8%	5%				-8%	-4%		14%	-17%				-15%	33%	13%	-3%	-5%
	Total market	-20%	-3%		41%	0%	9%	-8%	5%				-8%	-4%		14%	-17%				-15%	33%	13%	-3%	-5%
VOLUME TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	-24%	1%		43%	-64%	-21%	9%	-35%				7%	-100%		61%	-4%				16%	-2%	9%	23%	10%
	Biosimilar accessible market	-23%	0%		2%	-5%	-2%	0%	-27%				-8%	-12%		1%	-6%				9%	-7%	2%	3%	4%
	Total market	-23%	0%		2%	-5%	-2%	0%	-27%				-8%	-12%		1%	-6%				9%	-7%	2%	3%	4%
	TD per capita	3.82	2.90	0.99	3.84	1.26	2.44	2.64	3.02	2.73	5.27	1.78	3.35	0.95	1.73	3.57	1.75	1.70	5.31	2.65	3.66	1.72	2.09	2.08	2.95
	TD/capita (Yr before BS entrance)	5.08	2.93		3.72	1.36	2.50	2.70	4.20				3.55	1.10		3.51	1.88				3.43	1.90	2.09	2.07	2.85
	First recorded sales of biosimilars	2018	2021		2020	2019	2020	2018	2017				2017	2021		2019	2019				2018	2020	2020	2017	2017

* Only retail panel data is available for Greece

Note: Gaps in price and volume per TD are due to there being no 'Non-referenced' or 'Referenced' products in the year before biosimilar entry

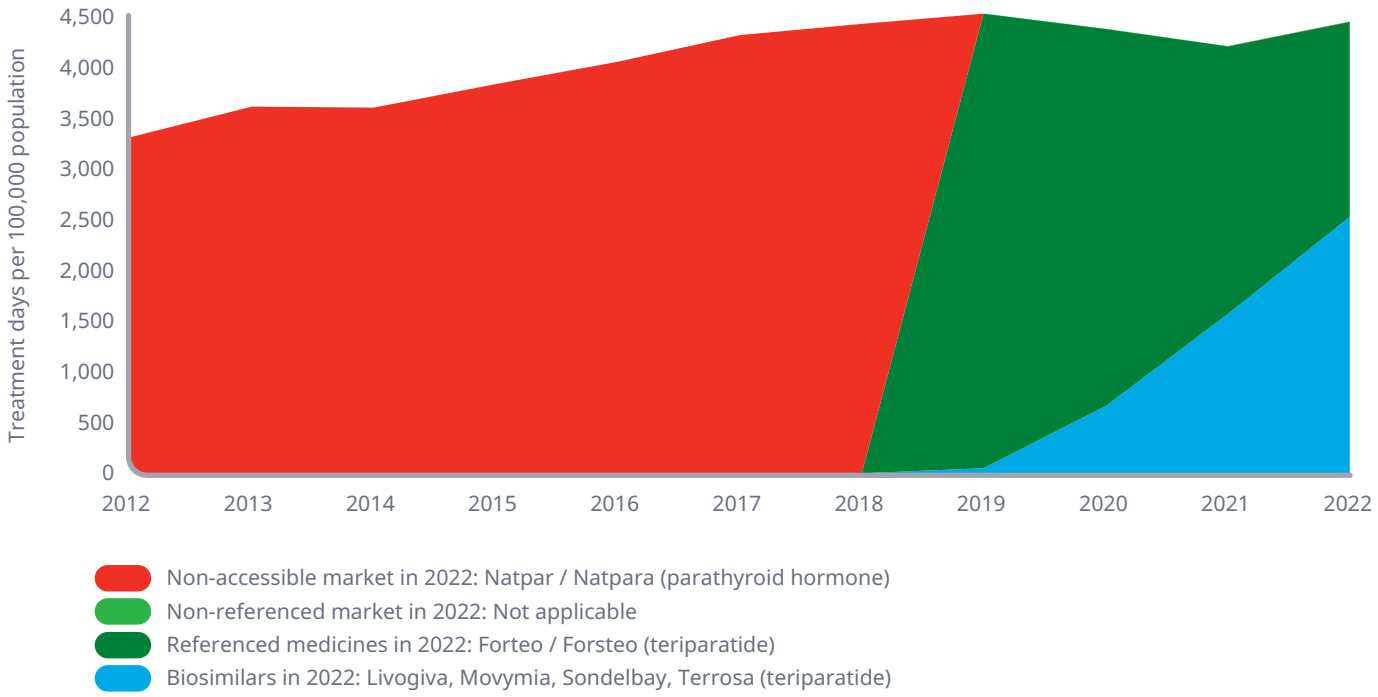
Parathyroid hormones

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

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	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	OSTEOPEROSIS (IN POST MENOPAUSAL WMOEN AND MEN AT INCREASED RISK OF FRACTURE	HYPOPARATHYROIDISM
TERIPARATIDE*	FORTEO MOVYMIA TERROSA LIVOGIVA SONDELBAY	●	●	●	●	●	●	●●●	●●●	●●●	●●●●	●●●●	●●●●●	●●●●●	
PARATHYROID HORMONE	PREOTACT NATPAR/NATPARA	●	●	●				●	●	●	●	●	●	●	●

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

* TETRIDAR has been excluded as it is not approved via EMA biosimilars pathway

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 (2022)	Biosimilar vs Referenced product	78%	0%	100%	78%	32%	7%	48%	44%	0%	94%	14%	72%	76%	69%	0%	38%	74%	100%	73%	52%	80%	36%	90%	55%
	Biosimilar vs Accessible market	78%	0%	100%	78%	32%	7%	48%	44%	0%	94%	14%	72%	76%	69%	0%	38%	74%	100%	73%	52%	80%	36%	90%	55%
	Biosimilar vs Total market	78%	0%	100%	78%	32%	7%	48%	44%	0%	94%	14%	72%	76%	69%	0%	38%	74%	100%	73%	52%	80%	36%	90%	55%
PRICE PER TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product			-68%			-15%			-7%				-8%	-19%		8%	-27%							-3%
	Biosimilar accessible market			-68%			-15%			-7%				-8%	-19%		8%	-27%							-3%
	Total market	-60%		-68%	-47%	-38%	-7%	-34%	64%	-4%	-33%	-34%	-36%	-8%	10%		8%	-24%	-48%	-52%	-25%	-23%	-20%	5%	-3%
VOLUME TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product						-24%			0%				-66%	48%		4%	33%							807%
	Biosimilar accessible market			84%			-24%			0%				-66%	48%		4%	33%							807%
	Total market	80%		84%	82%	-22%	-24%	6%	12%	0%	35%	7%	-23%	-66%	48%		4%	33%	-9%	29%	9%	46%	22%	18%	-14%
	TD per capita	0.11	0.00	0.01	0.02	0.06	0.02	0.05	0.02	0.07	0.04	0.08	0.07	0.01	0.08	0.00	0.02	0.03	0.01	0.03	0.14	0.02	0.09	0.02	0.05
	TD/capita (Yr before BS entrance)	0.06		0.00	0.01	0.07	0.02	0.05	0.02	0.09	0.03	0.08	0.08	0.04	0.06		0.02	0.02	0.02	0.03	0.13	0.02	0.07	0.02	0.05
	First recorded sales of biosimilars	2019		2021	2019	2019	2020	2019	2019	2022	2019	2019	2019	2020	2020		2020	2020	2019	2019	2019	2019	2019	2019	2019

* Only retail panel data is available for Greece

Note: Gaps in price and volume per TD are due to there being no 'Non-referenced' or 'Referenced' products in the year before biosimilar entry

Ophthalmology

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

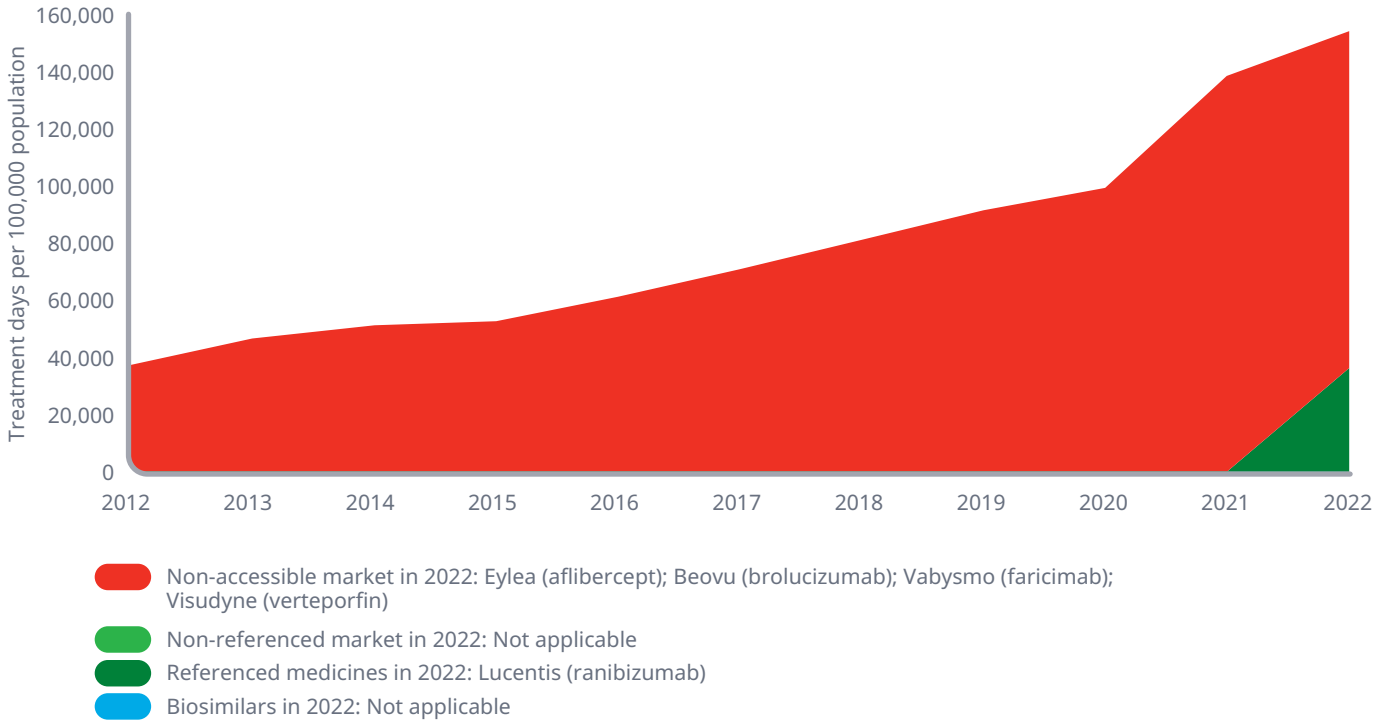
Eylea (aflibercept) and Lucentis (ranibizumab) are anti-VEGF agents used to treat several ocular inflammatory conditions, including wet age-related macular degeneration (AMD), macular edema, and diabetic retinopathy. They work by preventing the growth of abnormal blood vessels in the eye caused by the 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 and is therefore classified as 'referenced' from 2022 onwards. Despite biosimilar approvals in 2022, there are as of yet no biosimilar sales. This therapy area will be included in subsequent reports to track the impact of biosimilar entry in this newly accessible market.

Ophthalmology market development



Ophthalmology approved indications

NAMING		CLASSIFICATION												INDICATIONS								DOSING	
MOLECULE	PRODUCT	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	NEOVASCULAR (WET) AGE-RELATED MACULAR DEGENERATION (AMD)	VISUAL IMPAIRMENT DUE TO MACULAR OEDEMA SECONDARY TO RETINAL VEIN OCCLUSION (BRANCH RVO OR CENTRAL RVO)	VISUAL IMPAIRMENT DUE TO DIABETIC MACULAR OEDEMA (DME)	VISUAL IMPAIRMENT DUE TO MYOPIC CHOROIDAL NEOVASCULARISATION (MYOPIC CNV)	PROLIFERATIVE DIABETIC RETINOPATHY (PDR)	RETINOPATHY OF PREMATURITY (ROP) WITH ZONE I (STAGE 1+, 2+, 3 OR 3+), ZONE II (STAGE 3+) OR AP-ROP (AGGRESSIVE POSTERIOR ROP) DISEASE	EXUDATIVE (WET) AGE-RELATED MACULAR DEGENERATION (AMD) WITH PREDOMINANTLY CLASSIC SUBFOVEAL CHOROIDAL NEOVASCULARISATION (CNV)	SUBFOVEAL CHOROIDAL NEOVASCULARISATION SECONDARY TO PATHOLOGICAL MYOPIA	ROUTE	FREQUENCY
AFLIBERCEPT	EYLEA		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●					Intravitreal	Every 8 wks
BROLUCIZUMAB	BEOVU										●	●	●	●		●						Intravitreal	Every 8 wks
FARICIMAB	VABYSMO												●	●		●						Intravitreal	Every 4 wks
PEGAPTANIB	MACUGEN	●												●								Intravitreal	Every 6 wks
RANIBIZUMAB*	LUCENTIS** BYOOVIZ RANIVISIO XIMLUCI	●	●	●	●	●	●	●	●	●	●	●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	● ● ● ●	●			Intravitreal	Every 4 wks
VERTEPORFIN	VISUDYNE	●	●	●	●	●	●	●	●	●	●	●	●							●	●	UV + light activation	Every 12 wks

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

* ONGAVIA (ranibizumab) is approved in UK by MHRA but not by EMA;

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 (2022)	Biosimilar vs Referenced product	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	Biosimilar vs Accessible market	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	Biosimilar vs Total market	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
PRICE PER TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	Biosimilar accessible market	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	Total market	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
VOLUME TD (2022/YR BEFORE BS ENTRY)	Biosimilar and Referenced product	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	Biosimilar accessible market	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	Total market	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	TD per capita	0.32	1.69	0.31	0.97	2.20	0.86	2.17	1.25	0.01	0.16	0.83	0.56	11.84	0.76	0.40	0.47	0.35	1.06	1.85	1.25	1.53	1.95	1.63	1.53
	TD/capita (Yr before BS entrance)																								
	First recorded sales of biosimilars																								

* Only retail panel data is available for Greece

Appendix

EMA list of approved Biosimilars (November 2023)

Table 1: EU list of approved biosimilars source: EMA website, data accessed November 2023
(https://www.ema.europa.eu/en/medicines/download-medicine-data#european-public-assessment-reports-(epar)-section)

MEDICINE NAME	INTERNATIONAL NON-PROPRIETARY NAME (INN) / COMMON NAME	THERAPEUTIC AREA	MARKETING AUTHORISATION DATE	MARKETING AUTHORISATION HOLDER/COMPANY NAME
OMNITROPE	somatropin	Turner Syndrome; Prader-Willi Syndrome; Dwarfism, Pituitary	12/04/2006	Sandoz GmbH
ABSEAMED	epoetin alfa	Anemia; Kidney Failure, Chronic; Cancer	27/08/2007	Medice Arzneimittel Pütter GmbH Co. KG
EPOETIN ALFA HEXAL	epoetin alfa	Anemia; Kidney Failure, Chronic; Cancer	27/08/2007	Hexal AG
BINOCRIT	epoetin alfa	Anemia; Kidney Failure, Chronic	28/08/2007	Sandoz GmbH
RETACRIT	epoetin zeta	Anemia; Blood Transfusion, Autologous; Kidney Failure, Chronic; Cancer	18/12/2007	Pfizer Europe MA EEIG
SILAPO	epoetin zeta	Anemia; Blood Transfusion, Autologous; Cancer; Kidney Failure, Chronic	18/12/2007	Stada Arzneimittel AG
TEVAGRASTIM	filgrastim	Neutropenia; Hematopoietic Stem Cell Transplantation; Cancer	15/09/2008	Teva GmbH
RATIOGRASTIM	filgrastim	Neutropenia; Hematopoietic Stem Cell Transplantation; Cancer	15/09/2008	Ratiopharm GmbH
ZARZIO	filgrastim	Neutropenia; Hematopoietic Stem Cell Transplantation; Cancer	6/02/2009	Sandoz GmbH
FILGRASTIM HEXAL	filgrastim	Neutropenia; Hematopoietic Stem Cell Transplantation; Cancer	6/02/2009	Hexal AG
NIVESTIM	filgrastim	Neutropenia; Hematopoietic Stem Cell Transplantation; Cancer	7/06/2010	Pfizer Europe MA EEIG
REMSIMA	infliximab	Arthritis, Psoriatic; Spondylitis, Ankylosing; Colitis, Ulcerative; Psoriasis; Crohn Disease; Arthritis, Rheumatoid	10/09/2013	Celltrion Healthcare Hungary Kft.
INFLECTRA	infliximab	Arthritis, Psoriatic; Spondylitis, Ankylosing; Colitis, Ulcerative; Psoriasis; Crohn Disease; Arthritis, Rheumatoid	10/09/2013	Pfizer Europe MA EEIG
OVALEAP	follitropin alfa	Anovulation	27/09/2013	Theramex Ireland Limited
GRASTOFIL	filgrastim	Neutropenia	17/10/2013	Accord Healthcare S.L.U.
BEMFOLA	follitropin alfa	Anovulation	26/03/2014	Gedeon Richter Plc.
ABASAGLAR (PREVIOUSLY ABASRIA)	insulin glargine	Diabetes Mellitus	9/09/2014	Eli Lilly Nederland B.V.
ACCOFIL	filgrastim	Neutropenia	17/09/2014	Accord Healthcare S.L.U.
BENEPALI	etanercept	Arthritis, Psoriatic; Arthritis, Rheumatoid; Psoriasis	13/01/2016	Samsung Bioepis NL B.V.
FLIXABI	infliximab	Arthritis, Psoriatic; Spondylitis, Ankylosing; Colitis, Ulcerative; Arthritis, Rheumatoid; Crohn Disease; Psoriasis	26/05/2016	Samsung Bioepis NL B.V.
INHIXA	enoxaparin sodium	Venous Thromboembolism	15/09/2016	Techdow Pharma Netherlands B.V.
TERROSA	teriparatide	Osteoporosis	4/01/2017	Gedeon Richter Plc.
MOVYMIA	teriparatide	Osteoporosis	11/01/2017	STADA Arzneimittel AG
TRUXIMA	rituximab	Lymphoma, Non-Hodgkin; Arthritis, Rheumatoid; Wegener Granulomatosis; Leukemia, Lymphocytic, Chronic, B-Cell; Microscopic Polyangiitis	17/02/2017	Celltrion Healthcare Hungary Kft.
AMGEVITA	adalimumab	Arthritis, Psoriatic; Colitis, Ulcerative; Arthritis, Juvenile Rheumatoid; Spondylitis, Ankylosing; Psoriasis; Crohn Disease; Arthritis, Rheumatoid	21/03/2017	Amgen Europe B.V.

MEDICINE NAME	INTERNATIONAL NON-PROPRIETARY NAME (INN) / COMMON NAME	THERAPEUTIC AREA	MARKETING AUTHORISATION DATE	MARKETING AUTHORISATION HOLDER/COMPANY NAME
RIXATHON	rituximab	Lymphoma, Non-Hodgkin; Arthritis, Rheumatoid; Leukemia, Lymphocytic, Chronic, B-Cell; Wegener Granulomatosis; Microscopic Polyangiitis; Pemphigus	15/06/2017	Sandoz GmbH
RIXIMYO	rituximab	Lymphoma, Non-Hodgkin; Arthritis, Rheumatoid; Microscopic Polyangiitis; Wegener Granulomatosis	15/06/2017	Sandoz GmbH
ERELZI	etanercept	Arthritis, Psoriatic; Psoriasis; Arthritis, Juvenile Rheumatoid; Arthritis, Rheumatoid; Spondylitis, Ankylosing	23/06/2017	Sandoz GmbH
BLITZIMA	rituximab	Lymphoma, Non-Hodgkin; Leukemia, Lymphocytic, Chronic, B-Cell	13/07/2017	Celltrion Healthcare Hungary Kft.
INSULIN LISPRO SANOFI	insulin lispro	Diabetes Mellitus	19/07/2017	Sanofi Winthrop Industrie
IMRALDI	adalimumab	Spondylitis, Ankylosing; Arthritis, Rheumatoid; Uveitis; Colitis, Ulcerative; Psoriasis; Arthritis, Psoriatic; Crohn Disease; Hidradenitis Suppurativa; Arthritis	24/08/2017	Samsung Bioepis NL B.V.
ONTRUZANT	trastuzumab	Stomach Neoplasms; Breast Neoplasms	15/11/2017	Samsung Bioepis NL B.V.
MVASI	bevacizumab	Carcinoma, Renal Cell; Peritoneal Neoplasms; Ovarian Neoplasms; Breast Neoplasms; Carcinoma, Non-Small-Cell Lung; Fallopian Tube Neoplasms	15/01/2018	Amgen Technology (Ireland) UC
HERZUMA	trastuzumab	Stomach Neoplasms; Breast Neoplasms	9/02/2018	Celltrion Healthcare Hungary Kft.
SEMGLEE	insulin glargine	Diabetes Mellitus	23/03/2018	Viatris Limited
KANJINTI	trastuzumab	Stomach Neoplasms; Breast Neoplasms	16/05/2018	Amgen Europe BV
ZESSLY	infliximab	Arthritis, Psoriatic; Psoriasis; Crohn Disease; Arthritis, Rheumatoid; Colitis, Ulcerative; Spondylitis, Ankylosing	18/05/2018	Sandoz GmbH
HEFIYA	adalimumab	Spondylitis, Ankylosing; Hidradenitis Suppurativa; Psoriasis; Arthritis, Juvenile Rheumatoid; Uveitis	26/07/2018	Sandoz GmbH
HYRIMOZ	adalimumab	Arthritis, Rheumatoid; Arthritis, Psoriatic; Spondylitis, Ankylosing; Uveitis; Hidradenitis Suppurativa; Colitis, Ulcerative; Arthritis, Juvenile Rheumatoid; Crohn Disease; Skin Diseases, Papulosquamous	26/07/2018	Sandoz GmbH
TRAZIMERA	trastuzumab	Stomach Neoplasms; Breast Neoplasms	26/07/2018	Pfizer Europe MA EEIG
HULIO	adalimumab	Hidradenitis Suppurativa; Psoriasis; Uveitis; Arthritis, Rheumatoid; Spondylitis, Ankylosing; Crohn Disease; Colitis, Ulcerative; Arthritis, Psoriatic	17/09/2018	Biosimilar Collaborations Ireland Limited
PELGRAZ	pegfilgrastim	Neutropenia	21/09/2018	Accord Healthcare S.L.U.
PELMEG	pegfilgrastim	Neutropenia	20/11/2018	Mundipharma Corporation (Ireland) Limited
FULPHILA	pegfilgrastim	Neutropenia	20/11/2018	Viatris Limited
ZIEXTENZO	pegfilgrastim	Neutropenia	22/11/2018	Sandoz GmbH
OGIVRI	trastuzumab	Stomach Neoplasms; Breast Neoplasms	12/12/2018	Biosimilar Collaborations Ireland Limited
ZIRABEV	bevacizumab	Colorectal Neoplasms; Breast Neoplasms; Carcinoma, Non-Small-Cell Lung; Carcinoma, Renal Cell; Uterine Cervical Neoplasms	14/02/2019	Pfizer Europe MA EEIG
IDACIO	adalimumab	Arthritis, Rheumatoid; Arthritis, Psoriatic; Psoriasis; Spondylitis, Ankylosing; Uveitis; Hidradenitis Suppurativa; Colitis, Ulcerative; Crohn Disease; Arthritis, Juvenile Rheumatoid	2/04/2019	Fresenius Kabi Deutschland GmbH
GRASUSTEK	pegfilgrastim	Neutropenia	20/06/2019	Juta Pharma GmbH
CEGFILA (PREVIOUSLY PEGFILGRASTIM MUNDIPHARMA)	pegfilgrastim	Neutropenia	19/12/2019	Mundipharma Corporation (Ireland) Limited

MEDICINE NAME	INTERNATIONAL NON-PROPRIETARY NAME (INN) / COMMON NAME	THERAPEUTIC AREA	MARKETING AUTHORISATION DATE	MARKETING AUTHORISATION HOLDER/COMPANY NAME
AMSPARITY	adalimumab	Arthritis, Rheumatoid; Arthritis, Psoriatic; Psoriasis; Spondylitis, Ankylosing; Uveitis; Hidradenitis Suppurativa; Colitis, Ulcerative; Crohn Disease; Arthritis, Juvenile Rheumatoid	13/02/2020	Pfizer Europe MA EEIG
RUXIENCE	rituximab	Leukemia, Lymphocytic, Chronic, B-Cell; Arthritis, Rheumatoid; Microscopic Polyangiitis; Pemphigus	1/04/2020	Pfizer Europe MA EEIG
NEPEXTO	etanercept	Arthritis, Rheumatoid; Arthritis, Juvenile Rheumatoid; Arthritis, Psoriatic; Spondylarthropathies; Spondylitis, Ankylosing; Psoriasis	20/05/2020	Biosimilar Collaborations Ireland Limited
INSULIN ASPART SANOFI	insulin aspart	Diabetes Mellitus	25/06/2020	Sanofi Winthrop Industrie
ZERCEPAC	trastuzumab	Breast Neoplasms; Stomach Neoplasms	27/07/2020	Accord Healthcare S.L.U.
AYBINTIO	bevacizumab	Colorectal Neoplasms; Breast Neoplasms; Ovarian Neoplasms; Fallopian Tube Neoplasms; Peritoneal Neoplasms; Carcinoma, Non-Small-Cell Lung; Carcinoma, Renal Cell; Uterine Cervical Neoplasms	19/08/2020	Samsung Bioepis NL B.V.
LIVOGIVA	teriparatide	Osteoporosis	27/08/2020	Theramex Ireland Limited
NYVEPRIA	pegfilgrastim	Neutropenia	18/11/2020	Pfizer Europe MA EEIG
ONBEVZI	bevacizumab	Colorectal Neoplasms; Breast Neoplasms; Ovarian Neoplasms; Fallopian Tube Neoplasms; Peritoneal Neoplasms; Carcinoma, Non-Small-Cell Lung; Carcinoma, Renal Cell; Uterine Cervical Neoplasms	11/01/2021	Samsung Bioepis NL B.V.
KIRSTY (PREVIOUSLY KIXELLE)	insulin aspart	Diabetes Mellitus	5/02/2021	Biosimilar Collaborations Ireland Limited
YUFLYMA	adalimumab	Arthritis, Rheumatoid; Arthritis, Psoriatic; Psoriasis; Spondylitis, Ankylosing; Uveitis; Hidradenitis Suppurativa; Colitis, Ulcerative; Crohn Disease; Arthritis, Juvenile Rheumatoid	11/02/2021	Celltrion Healthcare Hungary Kft.
OYAVAS	bevacizumab	Colorectal Neoplasms; Breast Neoplasms; Ovarian Neoplasms; Fallopian Tube Neoplasms; Peritoneal Neoplasms; Carcinoma, Non-Small-Cell Lung; Carcinoma, Renal Cell; Uterine Cervical Neoplasms	26/03/2021	STADA Arzneimittel AG
ALYMSYS	bevacizumab	Colorectal Neoplasms; Breast Neoplasms; Ovarian Neoplasms; Peritoneal Neoplasms; Carcinoma, Non-Small-Cell Lung; Carcinoma, Renal Cell; Uterine Cervical Neoplasms	26/03/2021	Mabxience Research SL
ABEVMY	bevacizumab	Colorectal Neoplasms; Breast Neoplasms; Ovarian Neoplasms; Fallopian Tube Neoplasms; Peritoneal Neoplasms; Carcinoma, Non-Small-Cell Lung; Carcinoma, Renal Cell; Uterine Cervical Neoplasms	21/04/2021	Mylan IRE Healthcare Limited
BYOOVIZ	ranibizumab	Wet Macular Degeneration; Macular Edema; Diabetic Retinopathy; Myopia, Degenerative	18/08/2021	Samsung Bioepis NL B.V.
LIBMYRIS	adalimumab	Arthritis, Rheumatoid; Arthritis, Juvenile Rheumatoid; Spondylitis, Ankylosing; Arthritis, Psoriatic; Psoriasis; Hidradenitis Suppurativa; Crohn Disease; Colitis, Ulcerative; Uveitis	12/11/2021	Stada Arzneimittel AG
HUKYNDRA	adalimumab	Arthritis, Psoriatic; Arthritis, Juvenile Rheumatoid; Arthritis, Rheumatoid; Colitis, Ulcerative; Crohn Disease; Hidradenitis Suppurativa; Psoriasis; Spondylitis, Ankylosing; Uveitis	15/11/2021	Stada Arzneimittel AG
SONDELBAY	teriparatide	Osteoporosis	24/03/2022	Accord Healthcare S.L.U.
STIMUFEND	pegfilgrastim	Neutropenia	28/03/2022	Fresenius Kabi Deutschland GmbH
TRUVELOG MIX 30	insulin aspart	Diabetes Mellitus	25/04/2022	Sanofi Winthrop Industrie

MEDICINE NAME	INTERNATIONAL NON-PROPRIETARY NAME (INN) / COMMON NAME	THERAPEUTIC AREA	MARKETING AUTHORISATION DATE	MARKETING AUTHORISATION HOLDER/COMPANY NAME
VEGZELMA	bevacizumab	Colorectal Neoplasms; Breast Neoplasms; Ovarian Neoplasms; Fallopian Tube Neoplasms; Peritoneal Neoplasms; Carcinoma, Non-Small-Cell Lung; Carcinoma, Renal Cell; Uterine Cervical Neoplasms	17/08/2022	Celltrion Healthcare Hungary Kft.
RANIVISIO	ranibizumab	Wet Macular Degeneration; Macular Edema; Diabetic Retinopathy; Diabetes Complications	25/08/2022	Midas Pharma GmbH
XIMLUCI	ranibizumab	Wet Macular Degeneration; Macular Edema; Diabetic Retinopathy; Diabetes Complications	9/11/2022	STADA Arzneimittel AG
KAULIV	teriparatide	Osteoporosis; Osteoporosis, Postmenopausal	12/01/2023	Strides Pharma (Cyprus) Limited
BEKEMV	eculizumab	Hemoglobinuria, Paroxysmal	19/04/2023	Amgen Technology (Ireland) UC
EPYSQLI		Hemoglobinuria, Paroxysmal	26/05/2023	Samsung Bioepis NL B.V.
YESAFILI	aflibercept	Macular Edema; Retinal Vein Occlusion; Diabetic Retinopathy; Myopia, Degenerative; Diabetes Complications	15/09/2023	Viatris Limited
TYENNE	tocilizumab	Arthritis, Rheumatoid; Cytokine Release Syndrome; Arthritis, Juvenile Rheumatoid; COVID-19 virus infection; Giant Cell Arteritis	15/09/2023	Fresenius Kabi Deutschland GmbH
TYRUKO	natalizumab	Multiple Sclerosis, Relapsing-Remitting; Multiple Sclerosis	22/09/2023	Sandoz GmbH

Table 2: Most recent list of Biosimilars under review by EMA (November 2023); Source: EMA, November 2023: report accessed November 2023

(https://www.ema.europa.eu/documents/other/applications-new-human-medicines-under-evaluation-chmp-november-2023_en.xlsx)

INTERNATIONAL NON-PROPRIETARY NAME (INN) / COMMON NAME	THERAPEUTIC AREA (ATC LEVEL 2)	ORPHAN PRODUCT	GENERIC, HYBRID OR BIOSIMILAR	START OF EVALUATION
AFLIBERCEPT	Ophthalmologicals	N	Y	28/09/2023
BEVACIZUMAB	Antineoplastic medicines	N	Y	24/12/2020
DENOSUMAB	Medicines for bone diseases	N	Y	18/05/2023
DENOSUMAB	Medicines for bone diseases	N	Y	19/05/2023
INSULIN ASPART	Medicines used in diabetes	N	Y	28/09/2023
INSULIN GLARGINE	Medicines used in diabetes	N	Y	17/08/2023
INSULIN HUMAN	Medicines used in diabetes	N	Y	26/01/2023
INSULIN LISPRO	Medicines used in diabetes	N	Y	28/09/2023
OMALIZUMAB	Medicines for obstructive airway diseases	N	Y	18/05/2023
RANIBIZUMAB	Ophthalmologicals	N	Y	27/10/2022
RITUXIMAB	Antineoplastic medicines	N	Y	18/05/2023
TERIPARATIDE	Calcium homeostasis	N	Y	13/07/2023
TOCILIZUMAB	Immunosuppressants	N	Y	29/09/2022
TRASTUZUMAB	Antineoplastic medicines	N	Y	17/08/2023
USTEKINUMAB	Immunosuppressants	N	Y	01/12/2022
USTEKINUMAB	Immunosuppressants	N	Y	18/05/2023
USTEKINUMAB	Immunosuppressants	N	Y	18/05/2023
USTEKINUMAB	Immunosuppressants	N	Y	15/06/2023
USTEKINUMAB	Immunosuppressants	N	Y	13/07/2023
USTEKINUMAB	Immunosuppressants	N	Y	15/08/2023
USTEKINUMAB	Immunosuppressants	N	Y	28/09/2023

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