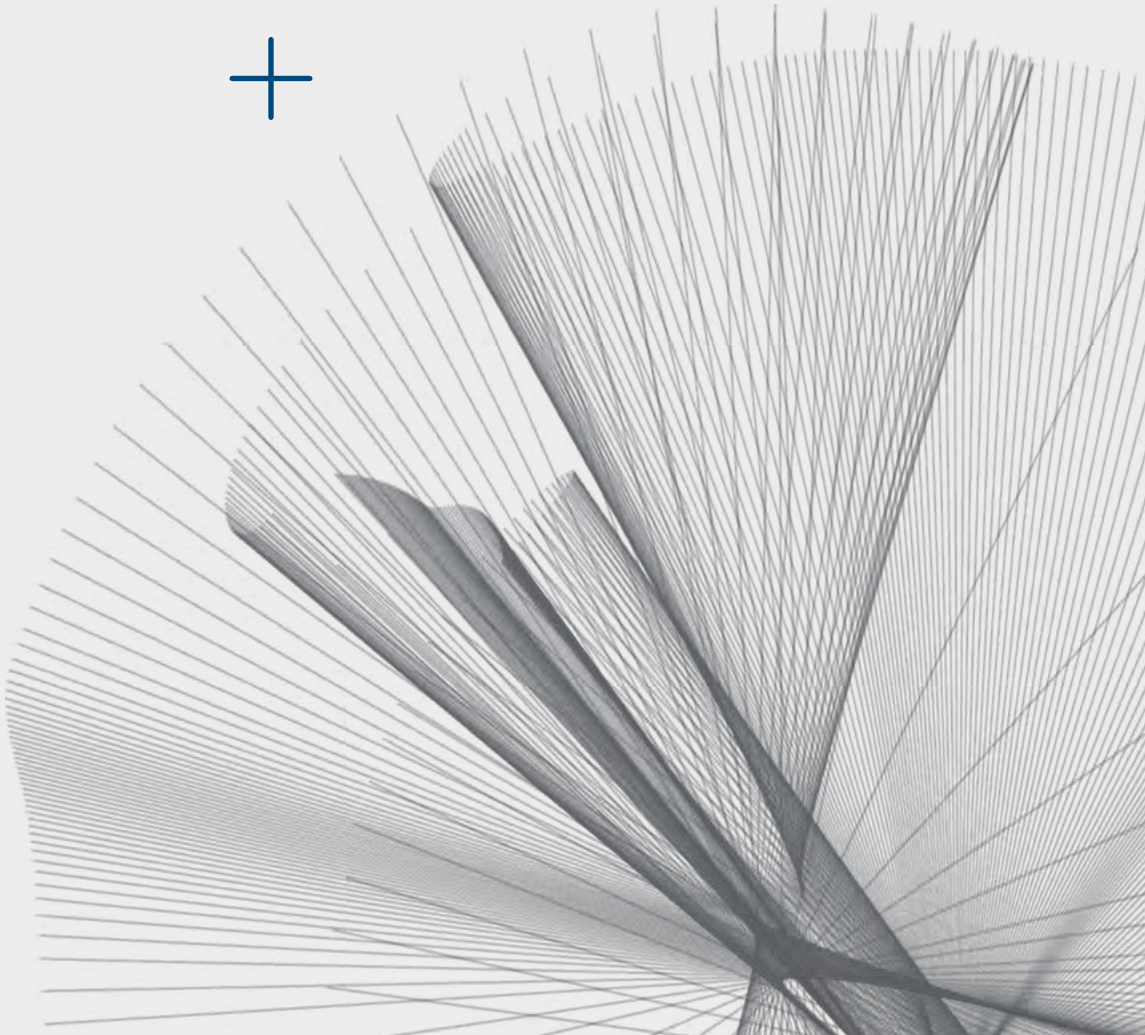
IQVIA INSTITUTE FOR HUMAN DATA SCIENCE

Assessing the Biosimilar Void

ACHIEVING SUSTAINABLE LEVELS OF BIOSIMILAR COMPETITION IN EUROPE



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Introduction

While biosimilar competition in Europe has played a vital role in achieving significant healthcare savings and expanding patient access to key medicines, the changing nature of future loss of exclusivity (LoE) events means that competition, and by extension savings, is not always guaranteed.

This report explores the nuances of biosimilar development, specifically market segments that are likely to have biosimilar competition or are not able to support a biosimilar. Currently available information on the biosimilar void points to a minimum of €15Bn in missed opportunity for cost savings, with implications for overall treatment cost efficiency gains and medicine availability.

The findings challenge the perception that all biologics facing LoE will automatically receive competition from biosimilar medicines, and expectations for the classical lifecycle curve for pharmaceuticals in the future. These dynamics will shape the biosimilar landscape and have implications for healthcare savings, commercial organisations, and ultimately, patient access.

By providing a valuable and timely understanding of biologic LoE events, the biosimilar pipeline, and competitive dynamics, this report guides healthcare stakeholders in making informed decisions to prepare for the future and maximise the opportunity ahead.

Biosimilar medicine use and competition plays a vital role in the overall economic sustainability of health systems in Europe. In the past, opportunities for cost savings have attracted numerous development programs. As the biologic pipeline evolves, biosimilar manufacturers face unprecedented development and commercial challenges.

This report provides a timely view of the factors underlying the changing level of biologic pipeline activity in Europe, highlighting classes of biologics that are at risk of failing to attract biosimilar competition, a concept called “the biosimilar void.” This report also aims to quantify the potential impact of the biosimilar void on healthcare system budgets. Drawing on a wide range of IQVIA proprietary data and engagement with individual stakeholders, the report examines the cohort of biologic medicines that will lose protection over the next 10 years. The period for assessment (2023–2032) has been chosen to reflect the average development timeline for new biosimilar candidates (~7-10 years) and intrinsic limitations with forecasting data beyond 2032. Due to the evolving nature of the IP landscape in Europe, legal and IP barriers are not discussed in the present study.

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Executive Director
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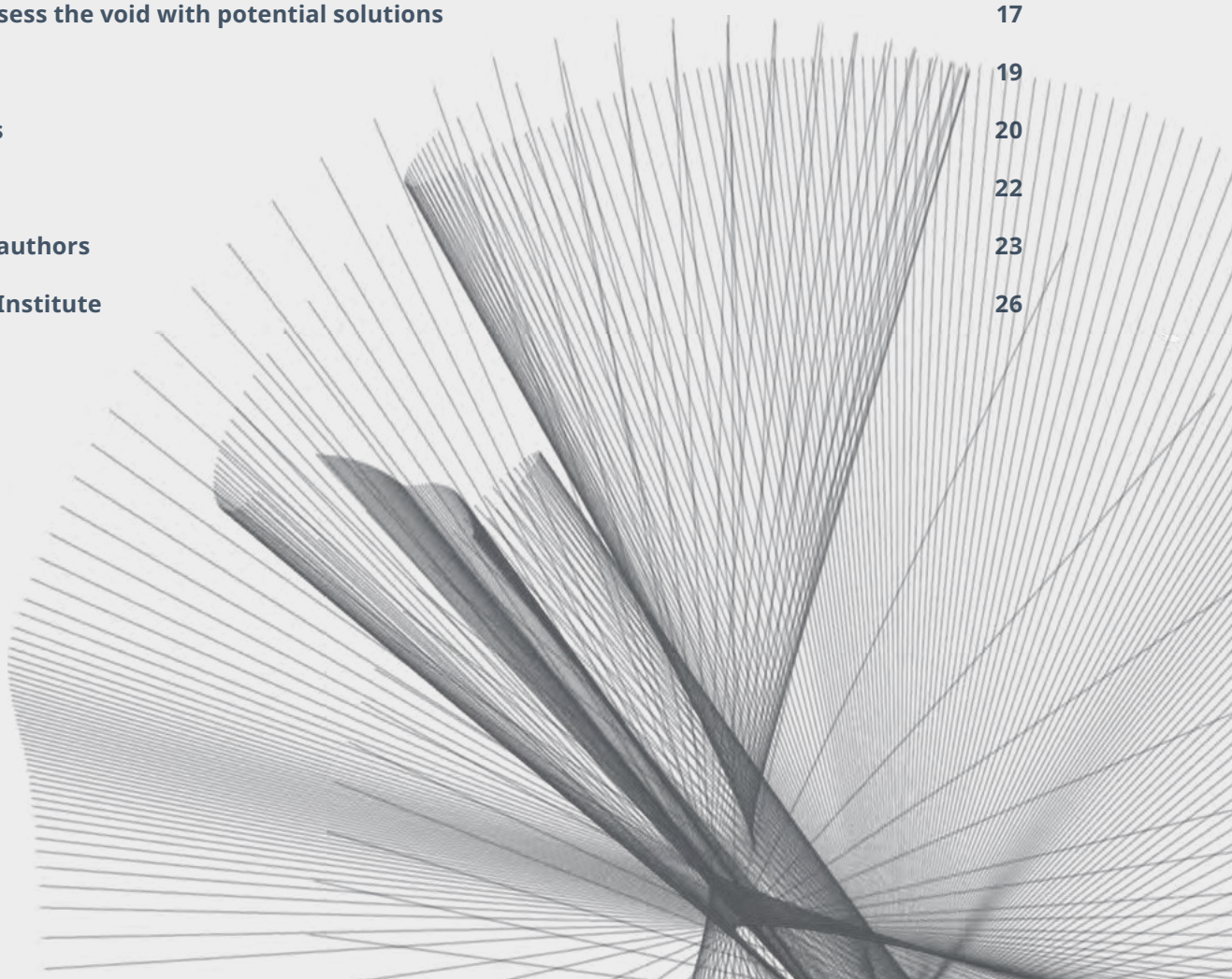


Overview

Over the last 20 years, biologics have transformed the therapeutic landscape, demonstrating remarkable efficacy in treating patients with various conditions, ranging from diabetes to cancer to immune disorders. Despite these successes, biologics are among the most expensive medicines on the market and their contribution to the total pharmaceutical expenditure continues to rise. In the face of inflationary pressures and rising economic volatility, their escalating contribution to overall medicine costs underscores the pressing need to find strategies to contain expenses while ensuring that patients continue to have access to innovative treatments.

With savings reaching €30Bn in 2022, biosimilars – defined as medicines resembling an already approved biological medicine ('reference medicine') after its exclusivity has lapsed – have shown considerable potential to secure cost savings for healthcare systems while broadening access to biologics. The benefits associated with biosimilars have led to the widespread belief that savings from these medicines are guaranteed and that manufacturers will always be able to apply competitive pressure on reference biologic medicines through new launches. Recent reports, however, have highlighted a high degree of variability in competitive dynamics, which can impact the availability of these cost-efficient medicines in the European market. Past research has shown that up to 55% of biologic medicines with loss of exclusivity (LoE) between 2023 and 2027 do not have a biosimilar in development, showing that competition, and by extension savings, is not always guaranteed.

Understanding the changing nature of future loss of exclusivity (LoE) events is an important part of ensuing a sustainable competitive market.

Understanding the changing nature of future loss of exclusivity (LoE) events is an important part of ensuing a sustainable competitive market. In the next 10 years, a total of 110 biological medicines are anticipated to lose exclusivity in Europe. Although biologics with more than €500Mn in annual European sales at the time of expiry have historically attracted high levels of competition, new trends 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. This represents ~€8Bn in missed opportunity for payers.

In the long-term (2027 and beyond), the average number of biosimilars in development is expected to decrease from 2.19 per molecule to 0.43. This trend is driven in large part by a decrease in the average number of biosimilar candidates in development for oncology where the costs and time required to take a biosimilar medicine to market are increasingly constraining the ability of sponsors to develop and launch new products. 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. These products represent 76% of the biological medicines exposed to LoE in the next 10 years, but only 7% of them are expected to receive competition from biosimilars.

As the share of orphan biologics facing LoE continues to increase, it is also important to assess the sustainability of the biosimilar market for rare diseases. Available data indicate that only one orphan biologic has so far attracted biosimilar development, corresponding to less than 3% of the entire cohort. Increasing complexity and low reimbursement rates are identified as key challenges surrounding the feasibility of orphan biosimilar launches in Europe.

Opportunity forecast for biosimilar competition in Europe

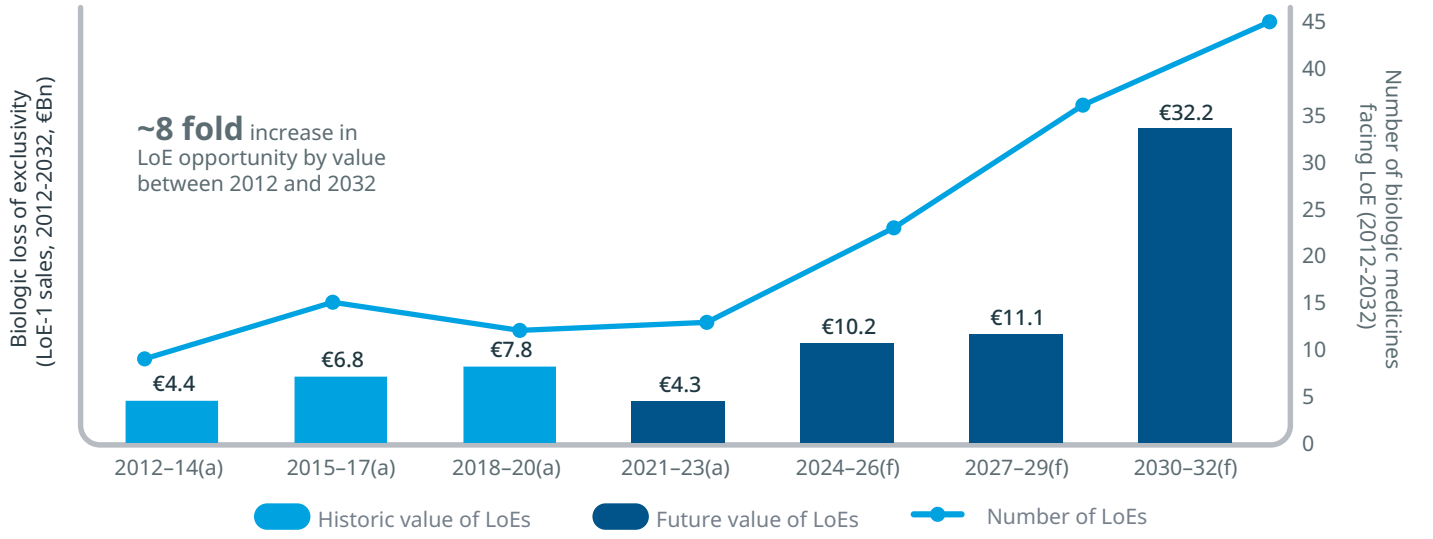
+ **Biosimilar competition is not necessarily guaranteed, and emerging dynamics pose a risk to conventional notions of medicine lifecycles. Forecasting the impact and addressing the specific hurdles will be necessary for healthcare systems to reap the benefits that biosimilar competition has brought in the past.**

By the end of 2022, the cumulative savings at list prices from the impact of biosimilar competition in Europe reached more than €30Bn (Exhibit 1),[1] which corresponds to approximately 10% of the annual expenditure on pharmaceuticals in Europe. The recognition of the large impact of biosimilar medicines competition on healthcare savings, biologic treatment cost efficiency gains, and average increase in the number of eligible patients treated has shaped the belief that these treatments will become a permanent and integral part of the healthcare landscape.

However, in 2020 a study was published on the prospects for biosimilar medicine of orphan originators[2] as the market matured, citing high development costs and limited commercial opportunity among the reasons behind the contraction in development activity. In 2021, a report detailed the emergence of other classes that failed to attract competition from a biosimilar several years after loss of exclusivity (LoE).[3] More recently, a 2022 report confirmed the trend by showing that up to 55% of biologic medicines with LoE between 2023 and 2027 do not have a biosimilar in development. Few studies exist on the topic and therefore the present report represents the first attempt to comprehensively assess and forecast the status of biosimilar competition in the coming years.

Following several years of growth in the number and value of LoE events for biologic medicines, fewer opportunities have emerged between 2021 and 2023.

Exhibit 1: Opportunity forecast for biosimilar competition in Europe



Source: IQVIA Ark Intelligence; IQVIA Forecast Link; IQVIA MIDAS Q4 2022.
Notes: (a) represents actual sales and (f) represents forecast sales. The IP profile of individual biologics is subject to change as new patents and/or patent extensions become available during a product lifecycle. The data shown in this chart is accurate as of July 2023.

During this time, €4.3Bn of biologics have faced off-patent competition (down 45% compared to the previous three years). Potential savings opportunities, however, are expected to increase rapidly in the short term. 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 (Exhibit 1).

The eight-fold increase in value compared to the 2012–14 period is driven in large part by major LoE events, such as pembrolizumab (Keytruda), daratumumab (Darzalex) and nivolumab (Opdivo). The number and type of biologics losing exclusivity creates unprecedented opportunities for payers, biosimilar developers, and patients. This report explores current and future challenges that may prevent healthcare systems from unlocking the potential of off-patent biologic therapies in ensuring accessibility and affordability for European patients.

The importance of assessing the biosimilar development pipeline

+ **With record numbers of biologic medicines reaching protection expiry in Europe in the next 10 years (to 2032), assessing which medicines are likely to face competition, or those that are at risk of not generating competition provides valuable insights for all healthcare stakeholders in evaluating the possible impact it may have on biologic therapy affordability and accessibility.**

Given the rapidly evolving biosimilar landscape, perceptions around the sustainability of the European biosimilar market must be examined to develop a deeper understanding of the current state of the market and identify evidence-based, actionable solutions. An IQVIA analysis of available literature on biosimilar medicines points to five key perceptions around the projected levels of competition in Europe. A summary of the results is shown in Table 1.

Table 1: Overview of common perceptions around biosimilar market sustainability

Perception	Assessment
Competition will always be present for commercially valuable (high sales) products because of the large commercial opportunity offered by the originator product.	This is not always the case, as molecules are increasingly complex and new barriers to entry are starting to emerge in major therapeutic areas like oncology.
The European sales of a biologic are not always an equivalent proportion of the global sales and therefore not representative of the attractiveness of the biologic for developers due to the sales in ex-EU markets, mainly U.S.	The opposite is true as a linear correlation exist between European and global sales of biologics on the market, with few exceptions.
Limited market size (lower sales forecasts in the year before LoE) is the main driver behind the low levels of biosimilar development, which include some orphan medicines.	This is partially true, as exceptions exist where medicines with only moderate sales in Europe attract high levels of biosimilar development due to high commercial returns in other markets.
The cycle of investment in biosimilars is affected by the rapid pace of innovation and new treatment options increase uncertainty for biosimilar developers and reduce market entry.	This statement is true, as new treatment options and delivery methods limit the potential for direct competition by biosimilar medicines.
The savings from high value molecules will be signficant, and the value of savings from other lower value biologics will not have an impact on the savings potential	The total missed opportunity amounts to at least ~15bn, approximately half of which comes from biologics with low forecast sales.

The most common perception is the belief that competition will always be present for products referencing originator molecules with large commercial opportunities. The large market size of certain biologic medicines is perceived to stimulate investment decisions, based on the assumption that the economic return will always be sufficient to offset upfront investments towards biosimilar development programs.

Other perceptions concern the impact of the evolving standard of care on biosimilar medicines development and launch. Building on this and other perceptions, the next sections characterise the complexities of the 'biosimilar void,' which is defined as 'the molecules, or clusters of molecules with similar characteristics, for which the development of a biosimilar is challenging and consequently unlikely.'

Commercial value does not always predict pipeline availability

+ **A common assumption is that the number of biosimilar candidates increases with the commercial value of the reference biologic. While this theory might have been true in the past, current data suggests that in the future, regulatory hurdles, therapeutic class, and disease indication are likely to play a larger role on the attractiveness of biosimilar development and launch.**

Previous data from IQVIA showed that 55% of all biologics facing LoE events between 2023 and 2027 do not have a biosimilar in development. Since development costs and net present values (NPV) are the main metrics of commercial assessment in the biosimilar market, this report employs a more nuanced methodology to determine if biosimilar development varies according to the commercial value of the originator product.

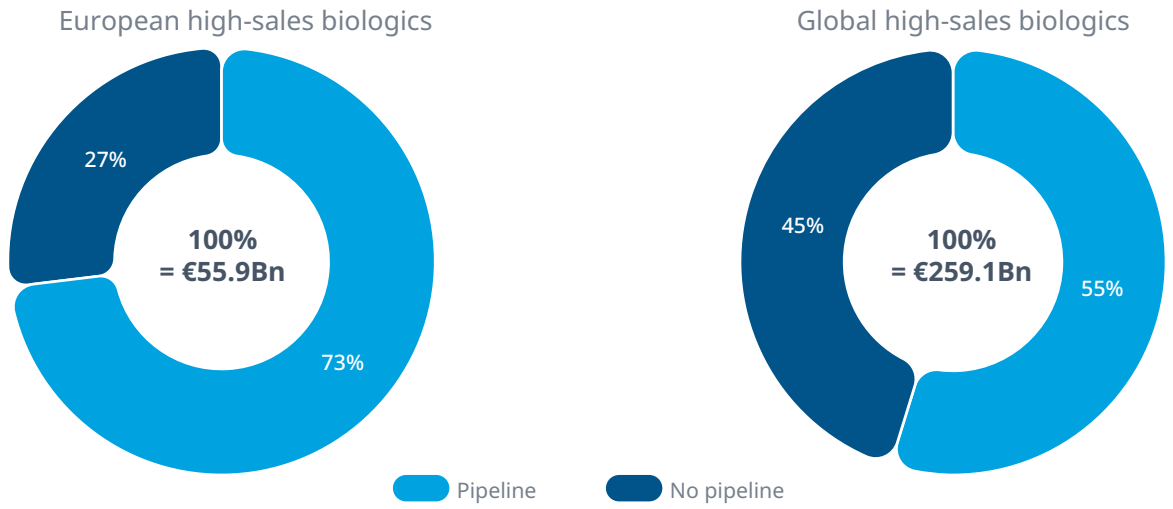
Exhibit 2 shows that biologics with European annual sales exceeding €500Mn ('high-sales') at the time of LoE appear to attract high levels of biosimilar development.

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. This represents ~€8Bn in missed opportunity for payers. In contrast, more than 100 biosimilars are in development for the remaining products, which could give rise to a highly competitive off-patent market. Exhibit 2 also distinguishes between European and global sales. This is particularly relevant as biosimilar medicines developers typically focus on global opportunities, beyond Europe. This distinction also allows investigation of instances where the innovator achieves commercial success in markets other than Europe, and therefore gives a more complete picture of the molecules' attractiveness. Under these circumstances, there are a few rare instances where a biologic medicine may generate more than €500Mn in sales globally, despite only limited commercial value in Europe (categorised as 'low-sales').

While pipeline availability is often assumed to predate biosimilar market entry, attrition means that not all biosimilar candidates will make it to market. Although attrition rates for biosimilar candidates remain low, there are instances where changing feasibility from early development to manufacturing or revised commercial opportunity estimates may delay or halt development programs. Although Exhibit 2 indicates that a biosimilar development program exists for approximately three in four high-sales biologics, greater granularity is needed to assess the robustness of pipeline activity.

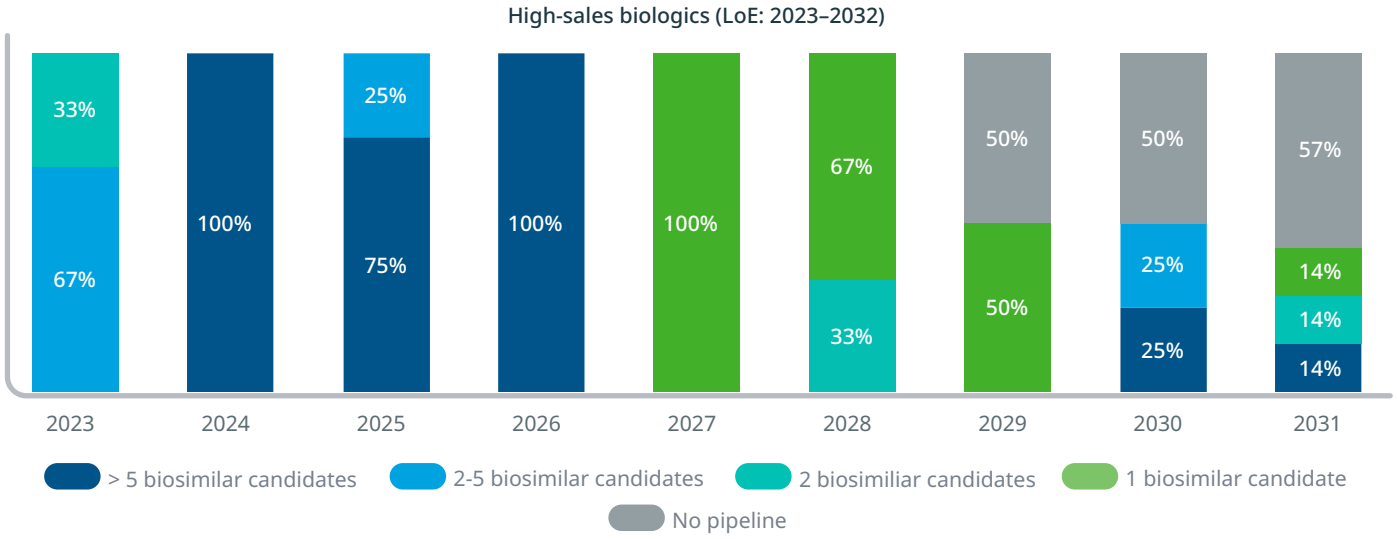
Biosimilar pipeline analysis shows that large variations exist in the number of candidates per molecule, typically in the range of 1 to 5 (Exhibit 3). In a few instances, the number of candidates exceeds five, notably for products with protection expiry occurring between 2024 and 2026.

Exhibit 2: Biosimilar pipeline based on European and global forecast sales data (LoE: 2023–2032)



Source: IQVIA MIDAS; IQVIA Ark Intelligence; IQVIA Forecast Link.
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 €500Mn in European sales before LoE (LoE-1).

Exhibit 3: Biosimilar pipeline for high-sales biologics by LoE date



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).

The trend is explained by major LoE events during this period, when high-sales products aflibercept (Eylea) and ustekinumab (Stelara) are expected to lose IP protection in Europe. Looking further ahead, a total of nine high-sales products with cumulative forecast European sales exceeding the €15Bn mark are expected to face LoE between 2029 and 2031. However, current data suggests lower development activity, perhaps as a result of development constraints (see next section) or long development timelines.

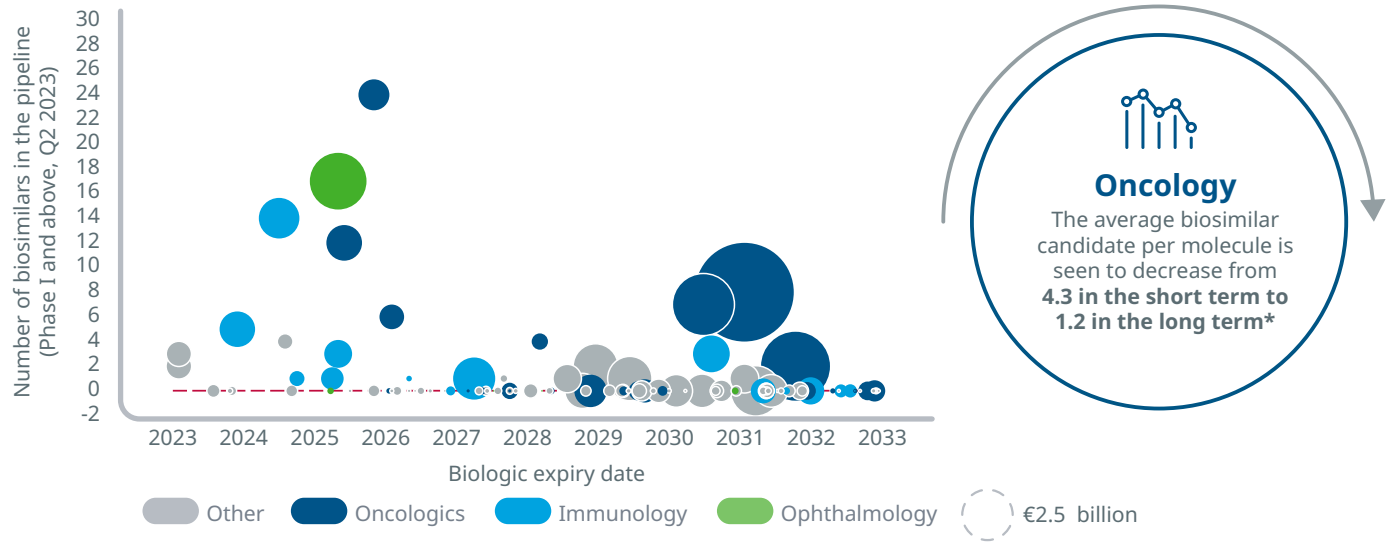
ONCOLOGY ATTRACTS HIGH LEVELS OF BIOSIMILAR DEVELOPMENT BUT CHALLENGES ARE STARTING TO EMERGE

Over the next 10 years, the majority of biologic LoEs will be oncology biologics (24%), followed by biologics to treat immune system (11%) and blood disorders (10%) (see Appendix 1), reflecting the wave of innovation of the last decade. Although the future LoE cohort spans nearly 30 therapeutic areas, biosimilar development programs are largely mirroring the innovative pipeline focus and are currently concentrated across three therapeutic areas: oncology, immunology and ophthalmology (Exhibit 4). In absolute numbers, these three areas account for 41% of all originator products facing LoE by 2032 in Europe and have attracted 91% of the entire biosimilar pipeline.

In the short-term (next five years, by 2027), oncology accounts for the largest share of biosimilar development programs: 44% of all biosimilars candidates in early to late development for LoE events occurring between 2023 and 2027 are directed at oncology products. Immunology and ophthalmology account for a further 45%, although competition in the ophthalmology segment is entirely driven by one molecule only, aflibercept, a vascular endothelial growth factor (VEGF) inhibitor. In contrast to the combined interest in oncology, immunology and ophthalmology, other therapeutic areas have notably fewer biosimilar assets in development (Appendix 1): together they account for less than 10% of the global biosimilar pipeline in the short term.

While the high concentration of biosimilar development activity appears to suggest that major therapeutic areas will always attract biosimilar competition, the opposite is true. In the long-term (2027 onward), the average number of biosimilars in development is seen to decrease from 2.19 per molecule to 0.43. This trend is driven in large part by a large decrease in the average number of biosimilar candidates in development for oncology, which is seen to decrease from 4.3 (short term, 2023-2027) to 1.2 (long term, 2028–2032).

Exhibit 4: Top 3 therapeutic areas by number of biosimilars in the pipeline



Source: IQVIA MIDAS; IQVIA Forecast Link; IQVIA Ark Intelligence; IQVIA Forecast Link.
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. *Short term defined as 2023 to 2027 and long term defined as 2028 to 2032.

Although the sharp decrease could be attributable to the assessment period of the present study, it is important to highlight that the cost and time required to take a biosimilar medicine to market are increasingly constraining the ability of sponsors to develop and launch new products. Critically, these constraints do not only apply to products with a limited commercial opportunity. While there is a perception that oncology biologics will invariably attract competition owing to their higher economic returns, increasing market competition coupled with high development costs are expected to decelerate onco-biosimilar development.

One of the main drivers of development costs for the onco-biosimilar category are comparative efficacy studies (Exhibit 5). The high purchasing costs of the relevant reference comparator biologic products and the large patient samples required to meet the designated clinical endpoints within the current European and global regulatory frameworks constrain the ability of manufacturers to developing new biosimilar medicines, while ensuring that the market remains commercially viable. Previous research has shown that oncology biosimilar efficacy studies often have larger sample sizes and are subject to more double-blind RCTs than the originator's Phase III studies.[4] Furthermore, some challenges are specific to new treatment classes and are likely to increase with time. For instance, the immune mediated adverse reactions associated with PD-L1/PD-1 inhibitors pose a significant practical challenge in terms of conducting the pharmacokinetic (PK) and efficacy equivalence studies for the relevant biosimilar candidates. These factors are expected to decelerate future development activity, increasing the time required for the production and approval of oncology biosimilar medicines in the long term.

The cost and time required to take a biosimilar medicine to market are increasingly constraining the ability of sponsors to develop and launch new products.

Exhibit 5: Current and future challenges in the development of onco-biosimilars

THE CHALLENGE IS MOST ACUTE FOR PRODUCTS WITH LIMITED COMMERCIAL SUCCESS IN EUROPE

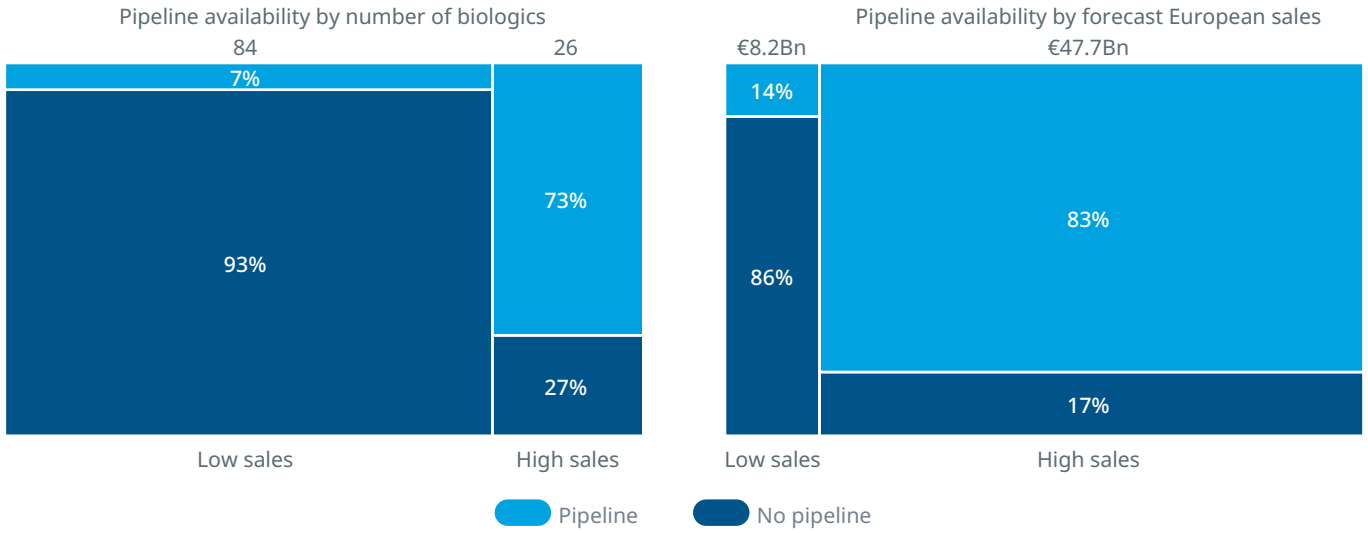
The large majority of LoE events for biologic medicines in the next 10 years (by end of 2032) are composed of products anticipated to achieve less than €500Mn in annual sales in Europe at the time of expiry ('low-sales' category). Due to the limited commercial opportunity, these products are expected to attract low levels of biosimilar development. In absolute numbers, 76% (84) of the biologics reaching protection expiry in Europe fit the definition of 'low-sales.' Only 7% of them are expected to receive competition in the next 10 years (Exhibit 6). Based on the forecast annual sales value of low-sales products with no biosimilar candidates in the pipeline, the missed opportunity for this segment amounts to ~€7Bn. Therefore, currently available information suggests that the biosimilar void could cost a minimum of ~€15Bn in lost savings, approximately 25% of the total LoE opportunity by 2032.

This data suggests that low-sales products represent nearly 50% of the total missed opportunity in Europe.

Despite the challenging outlook, a few exceptions do exist where low commercial returns in Europe do not affect development feasibility or market attractiveness for biosimilar developers. Technological and manufacturing know-how, platforms and market access excellence may allow for some developers to achieve niche development. In addition, some products with annual forecast sales lower than €500Mn in Europe before LoE may have achieved blockbuster status elsewhere.

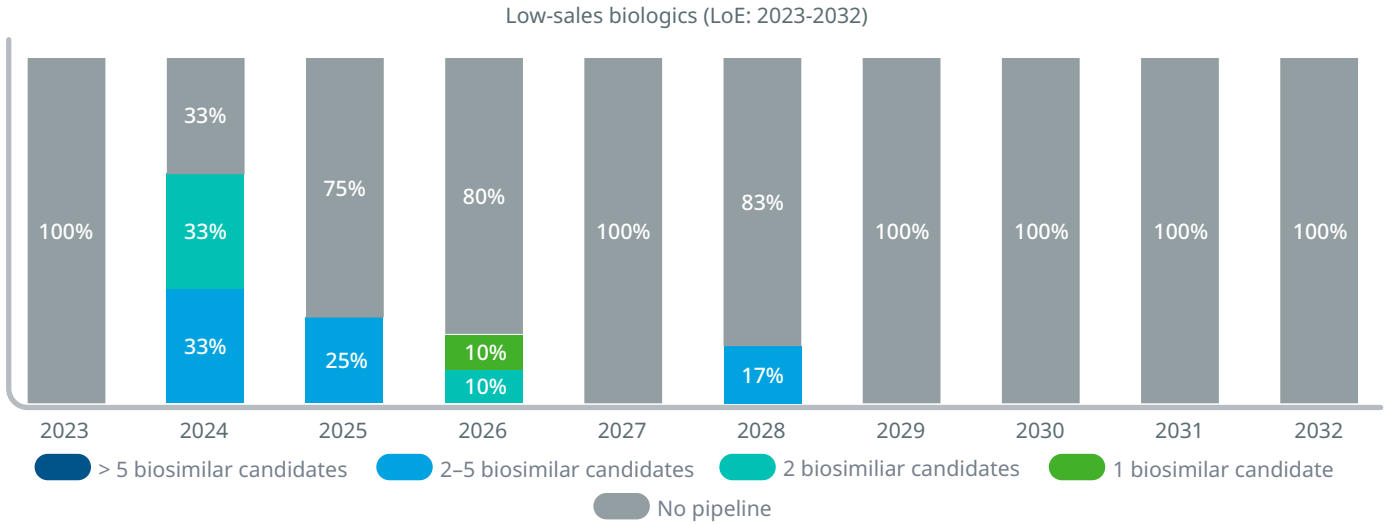
Under such circumstances, biosimilar developers may still be incentivised to compete with the originator post protection expiry. This situation is exemplified by two products, certolizumab pegol (Cimzia) and romiplostim (Nplate), where a biosimilar pipeline exists despite only moderate sales performance in Europe. Given the timeframe considered for this analysis, it could be assumed that biologics with low European sales could still attract biosimilar competition in the long term. Current data suggests that in 2024, 67% of such biologics will attract biosimilar entry, before this figure

Exhibit 6: 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.
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 €500Mn in European sales before LoE (LoE-1).; Low sales= biologics with less than €500Mn in European sales before LoE (LoE-1).

Exhibit 7: Biosimilar pipeline for low-sales biologics by LoE date



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).; Low sales= biologics with less than €500m in European sales before LoE (LoE-1).

declines to 20% in 2026 and 17% in 2028 (Exhibit 7). Although this decline could be due to a lack of predictability or incomplete pipeline visibility for the low-sales segment, it is important to note that, by contrast, all high-sales products reaching expiry by 2030 have a biosimilar in development.

Secondly, variable uptake of biologic medicines that lack strong clinical differentiation can also influence the amount of competition for no-longer-protected products. Biosimilar success requires the originator to be present in the market, to be reimbursed and available to physicians. For those low-sales biologics for which no biosimilar pipeline has been identified, the average reimbursement rate in Europe is 51%. This figure is approximately 30% lower than the reimbursement rate identified for low-sales products for which a biosimilar candidate has been identified and for which reimbursement data is available. These products include two oncology therapies, ramucirumab (Cyramza) and pegaspargase (Oncaspar). Of all low-sales biologics included in the analysis, 15% have been launched in fewer than 10 European countries. Of these, no product was launched in all EU4 + UK markets.

Finally, factors other than sales or reimbursement may affect manufacturers' launch plans. For instance, it is important to consider that manufacturers of originator biologics often use life-cycle management strategies to strengthen market positioning and delay biosimilar market entry. While beyond the scope of this report, intellectual property surrounding the originator biologic is often perceived as an obstacle to biosimilar medicine market entry, a topic reviewed in other studies.[5]

The biosimilar void could cost a minimum of ~€15Bn in lost savings, approximately 25% of the total LoE opportunity by 2032.

Orphan biologics face little to no biosimilar development

+ **While the number of orphan biologic approvals has steadily increased in Europe over the past decade, limited market size and variable uptake across member states makes the future of orphan biosimilar medicines uncertain.**

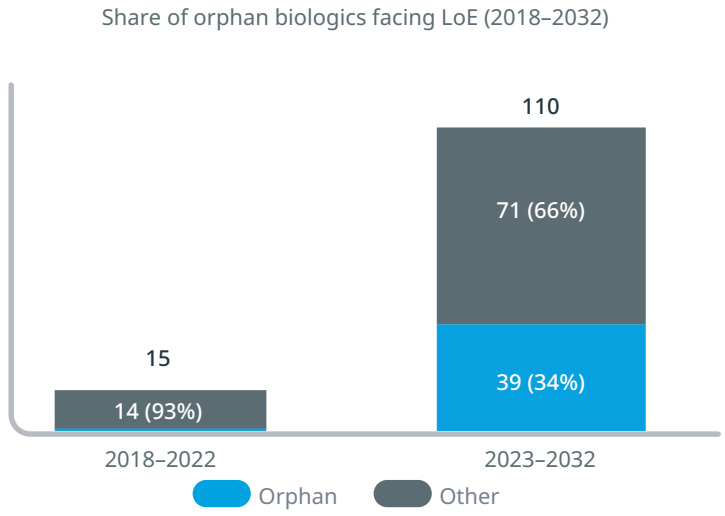
Orphan medicines face biosimilar pipeline availability and development challenges. According to the EMA, orphan medicine is defined as 'A medicine for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition that is rare (affecting not more than five in 10,000 people in the European Union) or where the medicine is unlikely to generate sufficient profit to justify research and development costs.'

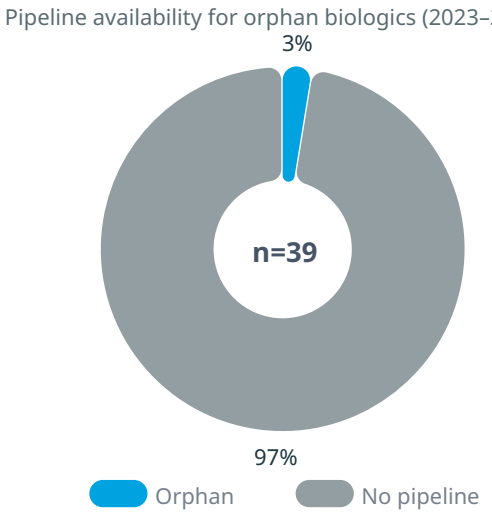
Of the total number of medicines with an active orphan medicine status approved in 2022 in Europe, 63% were biologic medicines, up from 53% in 2021 (Appendix 1). This figure reflects a growing trend. Between 2018 and 2022, less than 10% of all biologics reaching protection expiry in Europe carried an orphan designation. In the next 10 years (by end of 2032), the share of orphan biologics losing exclusivity is expected to reach 34% as innovators continue to invest in orphan medicines (Exhibit 8).

Despite the fast-growing opportunity for orphan biosimilar medicines, very few are in development. Only one orphan biologic (eculizumab) has so far attracted biosimilar development, corresponding to less than 3% of the entire cohort. Two biosimilar medicines referencing this molecule (Bekmev and Epysqli) have already been granted EMA approval this year for the treatment of paroxysmal nocturnal hemoglobinuria (PNH).[6] In total, four more candidates are currently in development referencing the same product.

Beyond Soliris (eculizumab), no other orphan biologic is expected to face off-patent biosimilar competition. This is mostly because the commercial opportunity for biosimilar medicines to enter the market and achieve a sufficient economic return is too small under current development paradigms. Of the 39 orphan biologics facing LoE by 2032, 74% had sales of less than €100Mn in 2022, with the average annual orphan biologic sales being €105Mn. The corresponding figure for non-orphan biologics included in the LoE cohort was €582Mn, several multiples higher than the figure obtained for orphan biologics.

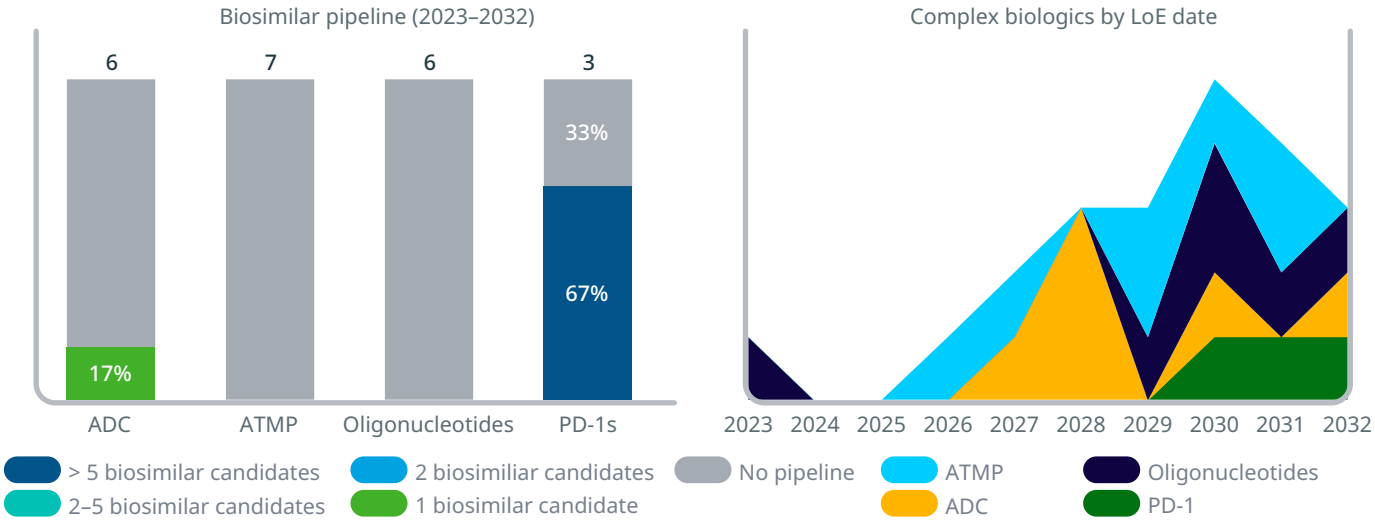
Exhibit 8: Share of orphan biologics facing LoE and associated biosimilar pipeline





Source: IQVIA Ark Intelligence; IQVIA Global Biosimilar Database. The cohort includes currently designated orphan biologics and excludes withdrawals.
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: All biosimilar pipeline data is based on publicly available information only.

Exhibit 9: Biosimilar pipeline and expected LoE dates for complex biologics



Source: IQVIA Ark Intelligence; IQVIA Forecast Link.; IQVIA Global Bioisimilar Database.
Notes: ATMP: advanced therapy medicinal products (includes cell and gene therapies); Oligonucleotides include antisense oligonucleotides and siRNA therapies.

LIMITED MARKET SIZE IS NOT THE CORE ISSUE FOR ALL ORPHAN BIOLOGICS

The incentive to develop a biosimilar medicine is based on a number of factors, some of which are not limited to its market size, as shown in Exhibit 5. Research identified two other factors beyond return on investment that affect the development and launch of new biosimilars for orphan biologics.

First, compared to early versions (e.g., filgrastim), biologics are becoming more complex, incorporating intricate structures and unique logistical requirements. An assessment of all biologics approved to date in Europe reveals three distinct 'waves' of innovation, characterised by rising levels of manufacturing, clinical testing and logistical complexity (Appendix 2). Of these, the latest wave, or Wave 3, includes biological products facing LoE events by 2032 at risk of little or no biosimilar competition. This cohort comprises antibody-drug-conjugates (ADC), cell and gene therapies (or Advanced Therapy Medicinal Products; ATMPs), oligonucleotides and PD-1 inhibitors. Although the manufacturing complexity of PD-1 inhibitors does not differ significantly from other classes of monoclonal antibodies, these products were included in this category because of the unique clinical testing requirements (e.g., large patient samples and high reference product purchasing costs). Although not all of these products target rare diseases, a rising share of them do. Of the 22 Wave 3 biologics facing protection expiry by 2032, 63% of them have an orphan designation.

There are large commercial opportunities associated with some of these Wave 3 biologics. However, with the exceptions of PD-1 inhibitors, the introduction of biosimilar versions is anticipated to be limited. Compared to the development of traditional biosimilar medicines, these products require higher upfront investments and greater effort required for analytical and clinical testing. ADCs, for instance, require greater manufacturing capabilities due to additional safety and analytical requirements conferred by conjugation of the biologic to the active cytotoxic component. On the other hand, the shortage of long-term outcomes data and complexities around analytical characterization pose challenges to the development of biosimilars for ATMPs.

As a result, these products have so far failed to attract biosimilar competition as no biosimilar candidate is currently in the pipeline for any of these complex orphan

biologics. However, 16 candidates exist for non-orphan, Wave 3 biologics. These non-orphan, Wave 3 candidates include an early asset (Phase I) referencing trastuzumab emtansine, eight biosimilar candidates for pembolizumab and seven for nivolumab (Exhibit 9). As highlighted above, considering the challenges to development and feasibility, not all candidates can be expected to progress to clinical trials or enter the European market following the expiry of patents and other exclusivity rights. At the time of writing, only 25% of the candidates in development for non-orphan. Wave 3 biologics are being investigated by companies headquartered in Europe.

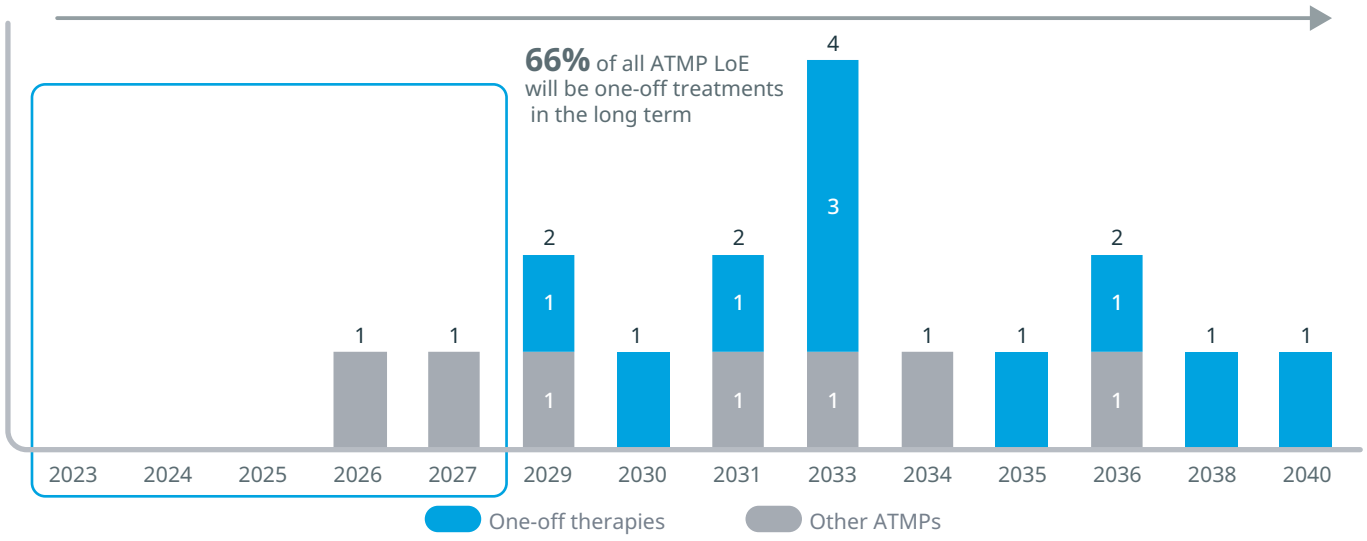
Although the European Union has a common regulatory system for approving new medicines, differences in reimbursement policies and incentives as well as variations in clinical standards often result in variable clinical use and uptake levels across member states. This issue creates notable challenges for biosimilar developers seeking to reference biologics characterised by low reimbursement rates in Europe. These challenges are largely amplified when considering orphan biosimilar development.

ONE-OFF THERAPIES PRESENT LONG-TERM CHALLENGES FOR MANUFACTURERS

The field of cell and gene therapies (or ATMPs) has witnessed remarkable advancements in recent years, leading to the development of an increasing number of orphan, one-off therapies targeting various genetic disorders. These therapies offer transformative treatment options for patients with previously uncurable conditions. The landscape of orphan, one-off therapies is expected to undergo a significant shift in the coming years, as an increasing number of therapies reach the end of their protection lifecycle.

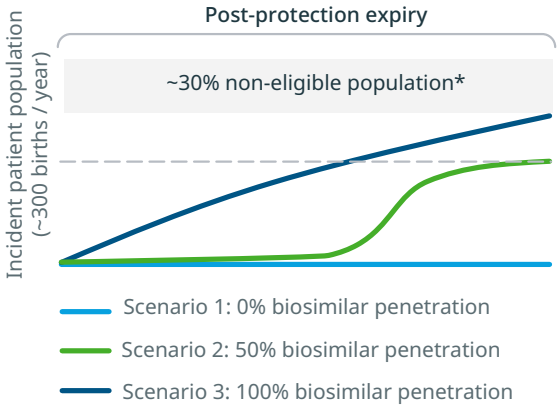
In Europe, the number of LoE events is anticipated to be relatively modest in the short term as many orphan, one-off therapies are in the early stages of their exclusivity period. In the next five years, no one-off therapy is expected to lose exclusivity in Europe. However, the forecast suggests that the share of one-off therapies among ATMPs will rise from 0% to 66% by 2040 when 10 orphan, one-off therapies will come off protection (Exhibit 10).

Exhibit 10: Anticipated LoE dates for EMA approved ATMPs



Source: IQVIA Ark Intelligence.
Notes: It should be noted that these are estimates and that patent extensions or other IP mechanisms may modify the forecast LoE dates of the products included in this analysis. Future EMA appprovals and/or withdrawals may also alter the IP landscape for ATMPs in the long term.

Exhibit 11: Scenario modelling for one-off biosimilar treatments



Caveats:
- Share of non-eligible patients represents an estimate
- Modelling fails to capture the effect of peer competition
- Reimbursement delays may affect market penetration timelines

Case study: Spinal muscular atrophy (~300 new births each year)

		+0 months	+ 6 months	+ 12 months	+24 months
0% biosimilar penetration	Alternative biologic	210 (70%)	210 (70%)	210 (70%)	210 (70%) Worst case
	Biosimilar	-	-	-	-
50% biosimilar penetration	Alternative biologic	210 (70%)	210 (70%)	105 (35%)	105 (35%)
	Biosimilar	-	-	105 (35%)	105 (35%)
100% biosimilar penetration	Alternative biologic	210 (70%)	105 (35%)	- Best case	-
	Biosimilar	-	105 (35%)	210 (70%)	210 (70%)

Months after LoE

Source: EMA (2020).

Notes: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed on the basis of data from the European Union, Iceland, Liechtenstein, Norway and the United Kingdom. This represents a population of 519,200,000 (Eurostat 2020). *Estimate only: based on real-world safety and efficacy data for commercially available gene therapies.

Despite the increasing market opportunity, biosimilar developers looking to enter this market will face unprecedented challenges. These therapies often involve new technology platforms and manufacturing processes, as well as customised delivery systems. In addition, the regulatory framework is still evolving for originator medicines assessment and so far, the off-patent regulatory landscape remains unexplored, contributing to overall unpredictability. As an example, the commercial opportunity for a one-off biosimilar looking to enter the spinal muscular atrophy (SMA) market is very limited, even when one assumes 100% biosimilar penetration. Although this condition affects approximately 300 newborns in Europe each year, the addressable patient population consists of only a fraction of that cohort. By the time the biosimilar reaches the market, assuming first-to-market advantage and strong uptake, the market may only consist of ~200 patients for which an alternative biologic treatment is not available (Exhibit 11). Furthermore, for a vast number of one-off therapies, payer policy entails specific contracting processes, such as Managed Entry Agreements (MEA) or Value Based Agreements. These potentially constitute market pockets outside of traditional off-patent markets, contributing to a lack of commercial predictability for developers. Brand loyalty, safety risks, competitive dynamics and significant logistical demand may further reduce the commercial opportunity.

The feasibility challenges and high costs of developing and distributing advanced therapies mean that biosimilar developers may not be able to amortize initial investments, leaving this category of biologics at high risk of falling into the 'biosimilar void.' At the time of writing, no biosimilar pipeline could be identified for any of the one-off therapies for which exclusivity data is available.

The share of one-off therapies among ATMPs will rise from 0% to 66% by 2040.

New treatment options can reduce the incentive for development

+ **Cycles of investment rely on predictable regulatory frameworks and market dynamics. In some cases, a change in formulation or delivery of the originator (e.g., subcutaneous trastuzumab) may leave a new biosimilar medicine – and the original molecule - with a substantially smaller market with implications on biosimilar market sustainability.**

A shifting standard of care, which describes the impact of a rapidly evolving therapeutic landscape in multiple scenarios, is impacting biosimilar development.

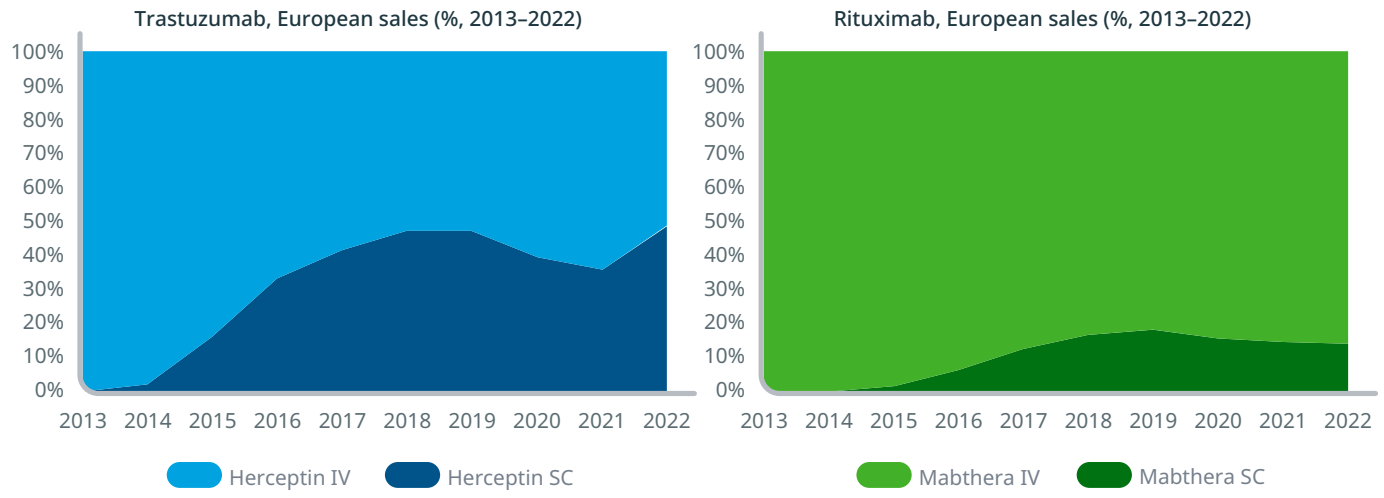
Shifting standards of care mean that the reference biologic's market may not be the same as when the biosimilar development program started. Biosimilar manufacturers operating in this space face smaller revenue potential because of competition from biosimilar and innovative manufacturers. This class includes a relatively small number of high-sales biologics where an improvement on the original formulation or route of administration confers additional protection against biosimilar competition, thereby attracting low biosimilar development activity (Exhibit 12).

A change in formulation or delivery of the originator brings new treatment options that often deliver more value to patients than the original molecule for which biosimilar medicines are available. As Exhibit 12 shows, the experience of trastuzumab and rituximab in Europe exemplify this concept. Both products were originally approved as intravenous (IV) formulations but have since been developed for subcutaneous (SC) administration. Studies comparing IV with SC trastuzumab indicate that these formulations offer comparable pharmacological and clinical profiles,[7] leading to strong uptake of the SC formulation in Europe.

+

Combination therapies that combine two or more biologic medicines present additional barriers to entry for biosimilar developers

Exhibit 12: Intravenous (IV) to subcutaneous (SC) shift in Herceptin and Mabthera



Source: IQVIA MIDAS MAT Q4, 2022.
Notes: IV=intravenous; SC=subcutaneous.

Exhibit 13: Evolving treatment landscape of breast cancer

Source: IQVIA analysis of EMA approvals (EPAR assessment list).

THE EVOLVING STANDARD OF CARE POSES RISKS TO BIOSIMILAR DEVELOPERS

In other cases, notably within oncology, several second-generation products have been developed since the introduction of biosimilar medicines, leaving the original molecule and its biosimilar medicines with a potentially smaller market. As shown in Exhibit 13, perceived improved benefits to breast cancer patients means that the new subcutaneous form of trastuzumab has rapidly captured a substantial share of this market segment in Europe. However, the overall breast cancer market has also benefited from large availability of second-generation products, such as trastuzumab emtansine and trastuzumab deruxetan, which were introduced in 2013 and 2021, respectively.

NEW COMBINATION THERAPIES COMPOUND DEVELOPMENT CHALLENGES

As mentioned above, the increasing complexity of different classes of biologics presents significant challenges to biosimilar development. In the future, combination therapies may further compound these challenges. In the past, most combinations were made between a novel biologic and a small molecule. However, current combinations involve the simultaneous use of multiple biologics due to their synergistic effects and improved patient outcomes. For instance, chemotherapy agents in addition to trastuzumab are widely viewed as the standard of care for HER-2 breast cancer.[8]

Despite the notable therapeutic advantages, combination therapies that combine two or more biologic medicines present additional barriers to entry for biosimilar developers. One notable challenge arises from the inclusion of high-value biologics, such as certain monoclonal antibodies, in these combinations. Monoclonal antibodies are highly specific and targeted therapies often used in oncology; however, the high costs and development challenges associated with a subset of these therapies, such as PD-1 inhibitors (reviewed above), makes them especially expensive for biosimilar manufacturers to develop due to the feasibility challenges and unpredictable commercial opportunity discussed earlier. Of particular importance, the current EMA guidelines require that the clinical study is sufficiently powered to show equivalence of the add-on effect of the biotherapeutic in this combination, which is often rather small. This requirement significantly increases the size of the study population, and the reference product costs.

The U.S. FDA's recent approval of enfortumab vedotin in combination with pembrolizumab highlights these challenges. Enfortumab vedotin is an ADC indicated for patients with urothelial cancer. As for other recently approved ADCs, their development presents Wave 3 manufacturing challenges and the inclusion of pembrolizumab in the combination therapy further heightens barriers to entry for biosimilar developers by significantly increasing the costs of the clinical similarity studies.

Ways to assess the void with potential solutions

+ **The familiarity of medical practitioners and patients with biosimilar medicines is increasing and, in certain cases, the extent of biosimilar competition has led to biologic treatment cost efficiency gains and to an average increase in the number of eligible patients treated.**

This research highlights potential concerns for the European biosimilar market. This final section explores which solutions may be considered to overcome the challenges highlighted in the report.

The present report indicates that a complex set of challenges threatens to constrain the broad availability of biosimilar medicines in Europe in the coming years. As the number of biologic medicines losing exclusivity continues to increase, achieving sustainable levels of off-patent competition will require a careful rebalancing and consideration. Potential solutions to the areas at risk of a biosimilar void may be explored and are discussed below:

1. **Horizon scanning to anticipate and prevent the biosimilar void**

The data presented in this study highlight the need to identify, anticipate and prevent contractions in biosimilar development activity to maximise the cost saving potential of this class of medicines. One option to achieve this goal is the systematic use of horizon scanning systems to identify the upcoming loss of exclusivity of biologic reference products, estimate the data of availability of new biosimilars, and monitor the number of competitors in Europe. Regulators and payers could use the findings from the systematic use of horizon scanning techniques to anticipate and prepare for biosimilar market entry when the system is well-functioning. However, when biosimilar development activity declines, the tool could be used to decide what levels of demand-side incentives could be introduced to stimulate the supply of new biosimilar medicines.

2. **Streamlining clinical studies to accelerate biosimilar development and reduce costs**

A major finding of this report is that the large majority of biologics facing LoE in Europe have forecast sales below €500Mn annually in Europe and do not support multiple competitors effectively in the current framework. High development costs and low reimbursement rates mean that biosimilar developers face significant uncertainty when engaging in the development and production of biosimilar medicines for this segment. Orphan biosimilar medicines face additional challenges, including significant reference comparator medicine cost, access to a limited patient population, and brand loyalty. Of the 84 low-sales biologics that do not have a biosimilar in development, approximately half (46%) are orphan biologics. Across Europe, the uptake of these medicines has been historically variable due to multiple factors including low levels of clinician awareness and lack of diagnostic infrastructure. To unlock the full potential of orphan biosimilar medicines, stakeholders could explore the potential for a default waiver of comparative efficacy studies, streamlining development without compromising the demonstration of biosimilarity.

Cost savings from the introduction of biosimilar medicines referencing high-sales products, such as oncology products, risk being tempered by the fact that high development costs and regulatory barriers disincentivise investments. Under the current global framework, the global development of biosimilar medicines remains grounded in the comparison of a proposed biosimilar candidate with a multitude of locally-licensed reference products, with the final stage consisting of a clinical biosimilarity exercise in a sensitive study population. These trials are designed to confirm comparable clinical outcomes between the biosimilar and the originator biologic, but often require clinical samples that are larger than the originator Phase III trials[4]. In addition, retrospective analyses suggest the efficacy endpoints in comparative efficacy studies add limited scientific value to successful biosimilar development programs,[9] despite high financial costs.

Recent scientific advancements and increased experience of biosimilar medicines by regulators offer the opportunity for streamlining development to simplify the review process, reduce costs, and shorten development timelines. Such expediting could change the biosimilar landscape and significantly reduce the void in Europe, especially if coordinated globally (see next section).

3. Convergence of biosimilar guidelines to expedite the entry of biosimilar medicines

Global convergence of development requirements is needed to support a sustainable biosimilar market in Europe. Regulatory guidance on the requirements for biosimilar development and marketing authorisation remains local to each jurisdiction, even if elements of guidance derive from internationally agreed upon guidelines (e.g., ICH Q5E) and are similar in practice.[10] This issue is exemplified by the requirement for bridging studies that consider differences between local and foreign versions of the reference product, even when development data supports comparability with all reference products.[11] Bridging studies can significantly expand the cost of regulatory approval. Past estimates suggest that around 50–100 subjects are expected for each comparative PK or PD clinical bridging study for a biosimilar product in a jurisdiction, with the cost estimated between $5-10Mn.[12]

Where existing data and information are sufficient to establish the necessary bridge, similar studies could be avoided. International guidance on the suitable qualification of a global comparator as well as progress on a single global biosimilar development would contribute to the necessary regulatory convergence to maximise biosimilar medicines approvals in Europe and in more jurisdictions globally. In addition, an efficient EU biosimilar regulatory framework, backed up by collaborative and reliance frameworks (e.g., WHO), could have a material impact on investment decisions, with the ultimate effect of increasing the type and number of biosimilar medicines available to the European and global markets.

4. Market conditions and procurement process improvements could facilitate greater availability, affordability, and plurality of supply

In addition to regulatory frameworks, market conditions could also be optimised to improve the feasibility of biosimilar development programs. With the aim of stimulating biosimilar uptake levels and clinical use, physicians may be appropriately incentivized, which may require combining benefit-share incentives with a prescription target or introducing a biosimilar market share quota.

Procurement procedures that are challenging to sustain represent another challenge that needs to be addressed. Winner takes all, price-only tenders remain the most common form of tenders in Europe despite rising evidence of market impoverishment.[13] In order to realise the competition potential of biosimilars, European countries could pursue market plurality by favouring multi-winner tenders. An example of good practice in this area includes NHS England's procurement of adalimumab, where multiple winners were guaranteed different volumes, ensuring competition and sustainability in the market.[14] Beyond this criteria, tenders have the ability to reward investment in new product features, green production, and resilient supply to improve purchasing practices. Changes to procurement structures could have the immediate effect of easing potential pricing pressures on biosimilar manufacturers, increasing biosimilar availability, and decreasing the risk of medicine shortages.

5. Clear regulatory pathways could incentivise development of next-generation biosimilar medicines

Given the complex technological features of cell and gene therapies and the potential for 'one-off' treatments to discourage biosimilar entry, clear regulatory pathways for the approval of biosimilars are beneficial to achieve competition and future cost savings. Regulatory uncertainty continues to surround the commercialisation and uptake of these therapies in Europe. Single-arm, non-randomised studies do not meet the safety criteria

established by the EUnetHTA-21 consortium's joint clinical assessment (JCA) which is due to apply from January 2025.[15]

Cell and gene therapies are often unsuitable for randomised clinical trials, which may affect positive reimbursement decisions by members states in Europe. Due to non-favourable benefit ratings, single-arm studies may also decrease the chance of obtaining favourable reimbursement prices in negotiations for therapies with limited clinical data,[16] which reduces the attractiveness of developing biosimilar medicines for this class of biologics. Delivery methods represent another layer of complexity for regulatory agencies as current systems, including viral vectors and nanoparticles, pose severe safety risks and, in addition to safety, ethical concerns around the use of some genome editing agents, which have also attracted careful scrutiny by regulators.[17]

In summary, ongoing regulatory uncertainty threatens to affect investments in cell and gene therapy biosimilars with important implications on patient access and affordability as these treatments typically come with a high cost, even after rebates and discounts (Exhibit 14).

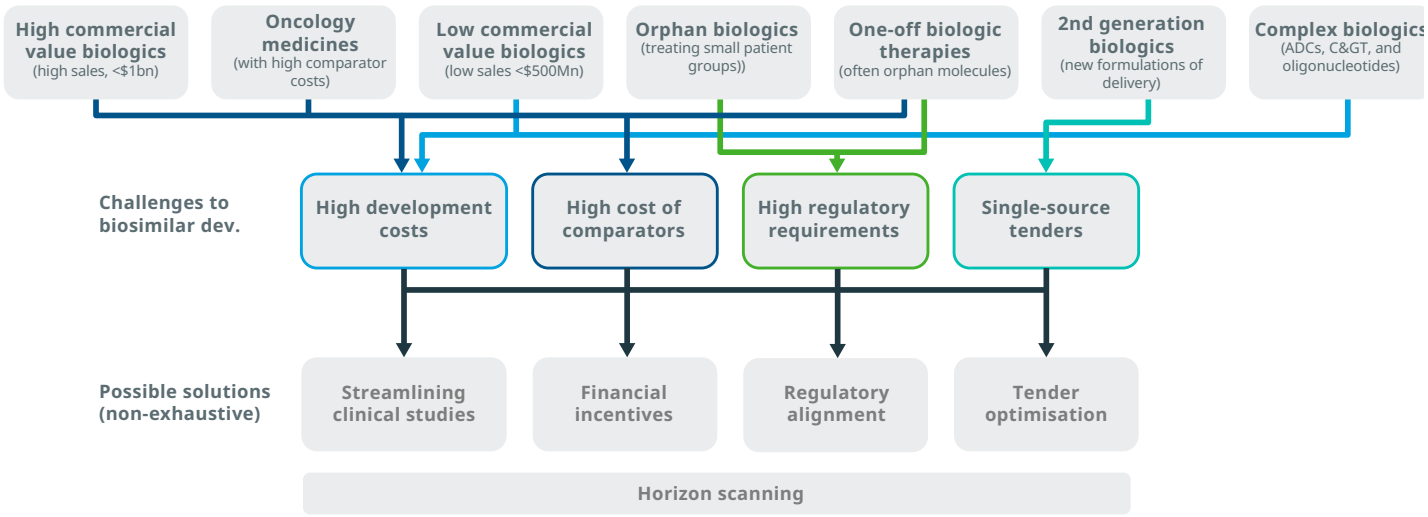
Conclusion

With fewer entrants into the market, competition between the originators and biosimilar medicines could resemble competition between brand-name medicines, with fewer products, and a reduction in price discounts.[18] Failure to address the barriers to biosimilar development is likely to increase the financial burden of European healthcare systems while reducing impact to improve patient access.

The research shows a complex set of challenges that limit the availability of biosimilar medicines in Europe in the coming years, leading to a missed opportunity of at least ~€15Bn in cost savings, with significant implications for biologic treatment cost efficiency gains and average increase in the number of eligible patients treated. A detailed assessment of clusters of biologics at risk of limited or no competition highlights areas for investigation and improvement for global and EU stakeholders.

Progress toward a more sustainable biosimilar market requires re-assessment of current European and global regulatory and market access frameworks to facilitate a more even market penetration of biosimilar medicines across all areas where biologic medicines exist.

Exhibit 14: Clusters assessed for a risk of a biosimilar void



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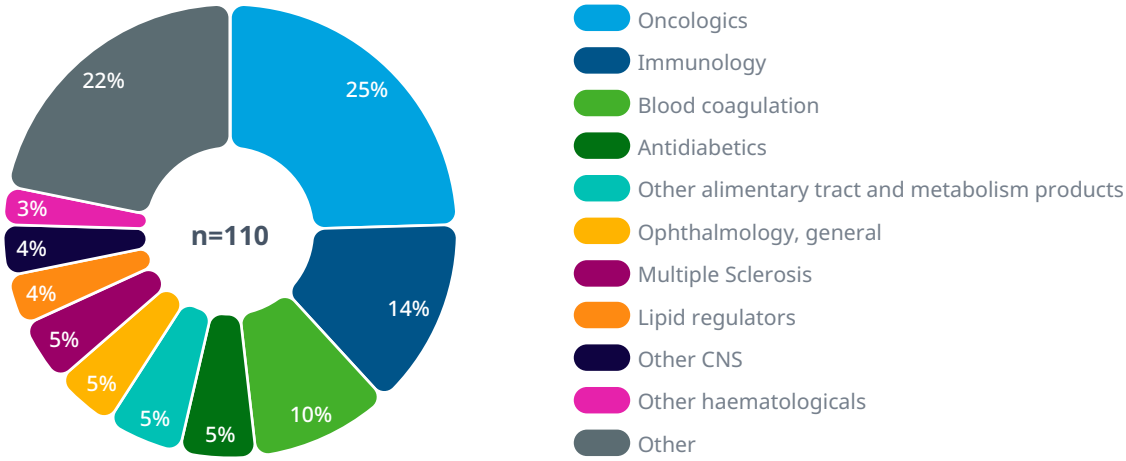
Appendix

Appendix 1: Biologic medicines LoE by therapeutic area (2023–2032)



Source: IQVIA Ark Intelligence; IQVIA Forecast Link; IQVIA MIDAS. Other= therapeutic areas with <3 products.

Appendix 2: Assessment framework for complex biologics

	MARKET OVERVIEW		TECHNOLOGICAL COMPLEXITY				CLINICAL COMPLEXITY			LOGISTICS	
TECHNOLOGY	FIRST APPROVAL (YEAR)	FIRST LOE (YEAR)	MOLEC. SIZE (KDA)	CELL SYSTEM	ISOLATION	PURIFICATION	PATIENT RECRUITMENT	CLINICAL SITES	ORIGINATOR COSTS	SOURCING RAW MATERIALS	DISTRIBUTION
Wave I											
1. Hormones	1989	2004	Low	Low	Low	Low	Low	Low	Low	Low	Low
2. Polypeptides	1996	2010	Low	Low	Low	Low	Low	Low	Low	Low	Low
3. Immunoglobulins	2006	2016	Low	Low	Low	Low	Low	Low	Low	Low	Low
Wave II											
1. Fusion proteins	2000	2015	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Low	Low
2. Mono. antibodies	1998	2013	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Low	Low
Wave III											
1. ADC	2012	2027	Medium	High	High	High	High	High	High	Low	Low
2. ATMP	2015	2021	High	High	High	High	High	High	High	High	High
3. Oligonucleotides	2017	2028	High	High	High	High	High	High	High	Low	High
4. PD-1 antibodies*	2015	2028	Medium	Medium	Medium	Medium	High	High	High	Low	Low

Product complexity

Complex biologics

Source: IQVIA Ark Intelligence.
Notes: Hormones: epoetins, follitropins, somatotropins and colony-stimulating factors; Polypeptides: GLP mimetics, somatostatins, insulins; Immunoglobulins: these are plasma-derived therapies used for primary immunodeficiencies, also known as human normal immunoglobulins; *These are monoclonal antibodies, but unique development challenges makes them a category on their own within the 'highly complex' group. ADC=antibody drug conjugates; ATMP: advanced therapy medicinal products (includes cell and gene therapies).

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Murray Aitken is Executive Director, IQVIA Institute for Human Data Science, which provides policy setters and decisionmakers in the global health sector with objective insights into healthcare dynamics. He led the IMS Institute for Healthcare Informatics, now the IQVIA Institute, since its inception in January 2011. Murray previously was Senior Vice President, Healthcare Insight, leading IMS Health's thought leadership initiatives worldwide. Before that, he served as Senior Vice President, Corporate Strategy, from 2004 to 2007. Murray joined IMS Health in 2001 with responsibility for developing the company's consulting and services businesses. Prior to IMS Health, Murray had a 14-year career with McKinsey & Company, where he was a leader in the Pharmaceutical and Medical Products practice from 1997 to 2001. Murray writes and speaks regularly on the challenges facing the healthcare industry. He is editor of Health IQ, a publication focused on the value of information in advancing evidence-based healthcare, and also serves on the editorial advisory board of Pharmaceutical Executive. Murray holds a Master of Commerce degree from the University of Auckland in New Zealand, and received an M.B.A. degree with distinction from Harvard University.

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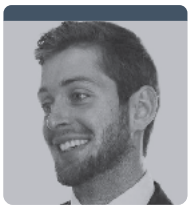

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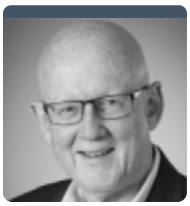
MARCO TRAVAGLIO
Consultant, Global Suppliers and Association Relations, IQVIA

Marco Travaglio is a Consultant in the Global Suppliers and Association Relations' team of IQVIA, based in the London office. He has a strong foundation in pharmaceutical R&D, having previously worked at Eli Lilly and AstraZeneca. Marco supports strategic engagements with global associations, EU bodies and industry groups and holds a MSci degree in Neuroscience from the University of Nottingham and a PhD in Toxicology from the University of Cambridge.



PER TROEIN
VP, Strategic Partners, IQVIA

Per Troein is a global leader at IQVIA, responsible for the relationships with different industry associations, government and EU bodies, wholesalers and pharmacies. His work is focused on policy issues for the pharmaceutical industry and is an expert in pharmaceutical pricing. Per graduated from Lund Institute of Technology (Master in Science) in Sweden and holds an MBA from INSEAD.

About the Institute

The IQVIA Institute for Human Data Science contributes to the advancement of human health globally through timely research, insightful analysis and scientific expertise applied to granular non-identified patient-level data.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved human outcomes. With access to IQVIA's institutional knowledge, advanced analytics, technology and unparalleled data the Institute works in tandem with a broad set of healthcare stakeholders to drive a research agenda focused on Human Data Science including government agencies, academic institutions, the life sciences industry, and payers.

Research agenda

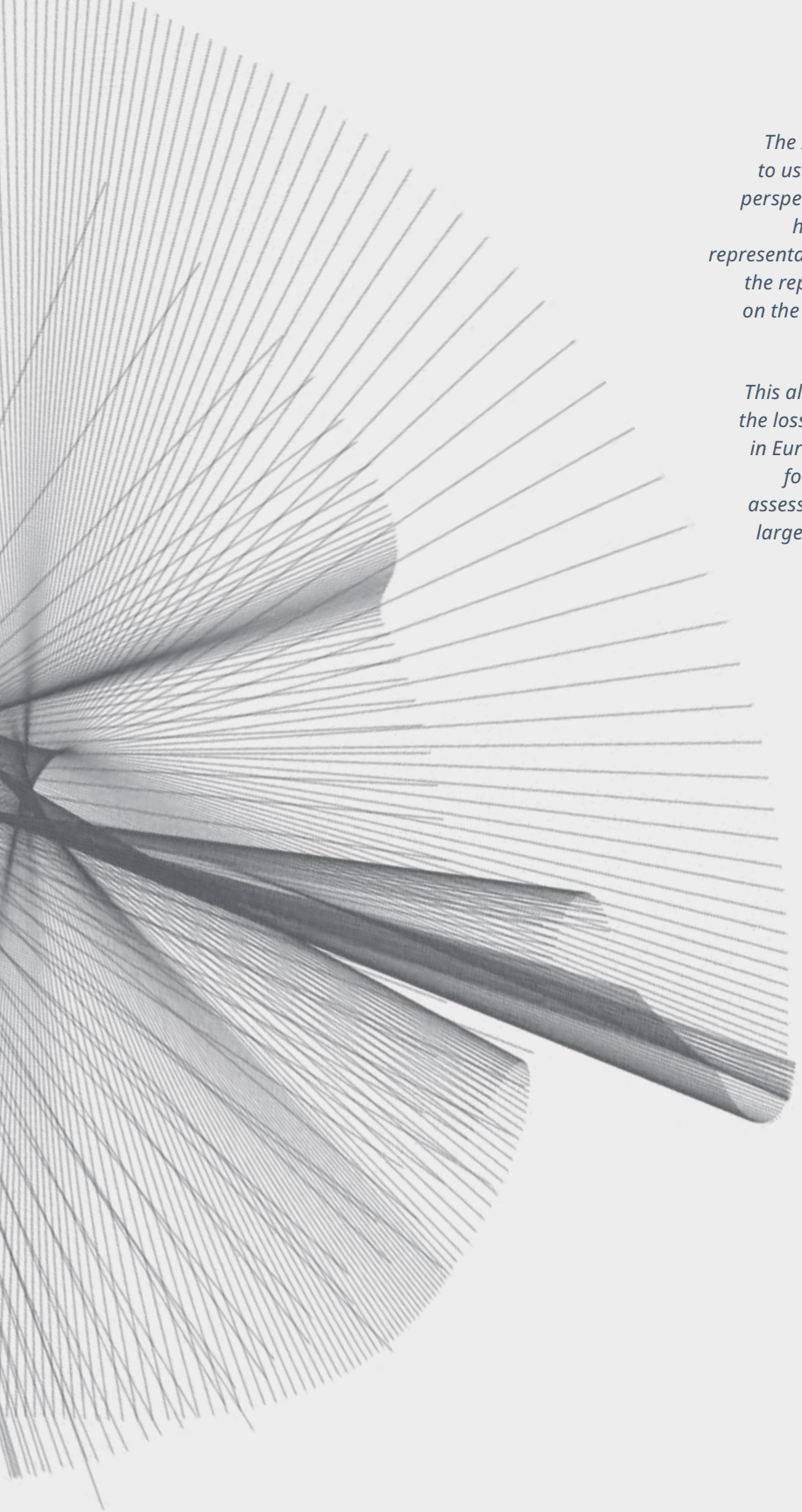
The research agenda for the Institute centers on five areas considered vital to contributing to the advancement of human health globally:

- Improving decision-making across health systems through the effective use of advanced analytics and methodologies applied to timely, relevant data.
- Addressing opportunities to improve clinical development productivity focused on innovative treatments that advance healthcare globally.
- Optimizing the performance of health systems by focusing on patient centricity, precision medicine and better understanding disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.
- Understanding the future role for biopharmaceuticals in human health, market dynamics, and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.
- Researching the role of technology in health system products, processes and delivery systems and the business and policy systems that drive innovation.

Guiding principles

The Institute operates from a set of guiding principles:

- Healthcare solutions of the future require fact based scientific evidence, expert analysis of information, technology, ingenuity and a focus on individuals.
- Rigorous analysis must be applied to vast amounts of timely, high quality and relevant data to provide value and move healthcare forward.
- Collaboration across all stakeholders in the public and private sectors is critical to advancing healthcare solutions.
- Insights gained from information and analysis should be made widely available to healthcare stakeholders.
- Protecting individual privacy is essential, so research will be based on the use of non-identified patient information and provider information will be aggregated.
- Information will be used responsibly to advance research, inform discourse, achieve better healthcare and improve the health of all people.



The IQVIA Institute for Human Data Science is committed to using human data science to provide timely, fact-based perspectives on the dynamics of health systems and human health around the world. The cover artwork is a visual representation of this mission. Using algorithms and data from the report itself, the final image presents a new perspective on the complexity, beauty and mathematics of human data science and the insights within the pages.

This algorithmic art is generated from a dataset combining the loss of exclusivity dates of nearly 100 biologic medicines in Europe in the next 10 years, including orphan medicines for rare diseases. The data supported a comprehensive assessment of the biologic landscape and shed light on the large opportunity for cost savings and improved access in Europe in the short to medium term.

IQVIA INSTITUTE FOR HUMAN DATA SCIENCE

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