Solving the *Biosimilar Void* in Europe

—

Empowering the Patients through Sustainable Access

C_EU_202506_006_250708

Table of Contents

C_EU_202506_006_250708

01.

Executive Summary

Biosimilars are an important part of the European healthcare system and play a significant role in improving patient outcomes. Biosimilars have already delivered €56 billion in cumulative biologic treatment cost reductions across Europe (approximately €6 billion in 2024 alone), demonstrating their massive contribution to healthcare systems.[1] The entry of biosimilars generates competition with the reference medicines and other biologics in the same class, which drives value for the healthcare system and across three broad areas.

Biosimilar competition is integral to creating stronger and more resilient healthcare systems and enhance the ability to improve patient access and outcomes through gains in :

(1) **efficiency** by generating cost savings which facilitates redistribution of healthcare budgets and frees resources to improve access to innovative medicines

(2) **patient access** through broader and earlier access to biologics including biosimilars where innovative products were previously unavailable or increase access in earlier lines of treatment and

(3) **supply security** by diversification of suppliers for biologic medicines protecting against the risk of shortages.

These are all critical value elements for European markets facing increasing pressure on pharmaceutical spending, delays in patient access and an escalating challenge with supply security as highlighted in multiple EU-level and national policy agendas.

However, the current policy environment in Europe, particularly the post-launch pathways need improvements to better reflect the value recognition of biosimilars and ultimately support a more sustainable market. Biosimilars face challenges from launch with restrictive and misaligned tailored Health Technology Assessment (HTA) and pricing and reimbursement (P&R) processes. These are further exacerbated by tendering and cost-containment policies that lead to continuous price erosion throughout the biosimilars lifecycle. Finally, inadequate policies hinder sufficient uptake, as the lack of incentives and ongoing efforts in awareness prevents the manufacturers from consistently providing high quality biosimilars, thereby limiting the potential value that can be realized.

As a result of this policy environment, many biosimilar manufacturers are forced to reduce their participation in the market, meaning that many biologics facing loss of exclusivity (LoE) in the coming years do not currently have biosimilars candidates in development and will not experience biosimilar competition, an outcome called the “biosimilar void”. Looking solely at the savings generated from biosimilar competition, European markets stand to lose a total of €4.4 billion of savings as a result of the biosimilar void.

If healthcare systems wish to continue benefiting from biosimilars and improving patient outcomes, then targeted and considered policy reform is required. Reforms must reflect market dynamics to create a sustainable biosimilar environment, where the business of developing and supplying high-quality, safe, and effective biosimilars is appropriately supported. By establishing policies that facilitate collaboration and mutual understanding among stakeholders, healthcare systems can unlock the full value of biosimilars, both now and in the future. To achieve this, optimizing key areas—outlined in the accompanying table—will be instrumental in driving progress and ensuring long-term success for all involved.

Table 1. Policy Recommendations to Create a Sustainable Biosimilar Environment

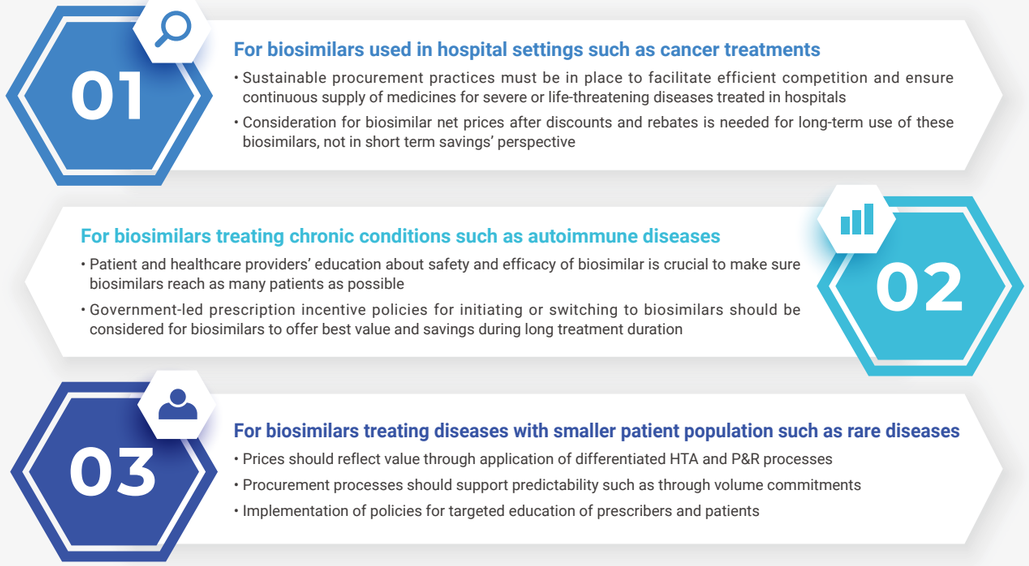
Policy Recommendations to Ensure Biosimilar Value is Fairly Reflected in Access and Pricing Decisions at Launch	
HTA	A streamlined HTA for timely access: e.g., HTA waivers, indication extrapolation and accelerated mechanisms
	Develop a tailored HTA process for biosimilars that offer additional benefit or where the reference biologic is not reimbursed. e.g., easing certain evidence requirements or ensuring timely access via temporary reimbursement until final decisions are reached
P&R	Avoid arbitrary price controls for biosimilars at launch such as unjustified mandatory discount
	Introduce free pricing for biosimilars at launch when the reference medicine is available on the market, and allow for price discounts to be naturally achieved by market dynamics and increased competition
	Where the reference biologic is not available, pricing decisions to be linked to the updated HTA process to reflect the differentiated and broader value

C_EU_202506_006_250708

Policy Recommendations to Facilitate Continued and Sustainable Access of Biosimilars Through Competition	
Lifecycle Management	Provide exemptions or apply differentiated approach to biosimilars from cost-containment measures (e.g., clawbacks/paybacks/rebates), so they do not suffer double price erosions
	Negotiate a minimum price boundary line, at which biosimilar price is protected from any further erosion and continued procurement is guaranteed
	Introduce broader recognition on the role of biosimilars in achieving cost efficiencies and ability to redistribute spending in policy agendas by payers and national authorities
Tenders	National, regional and local tenders should support diversification of supply and fair competition through multi-winner tenders with contract volume shares, transparent and periodic tender opening and a broad set of value criteria considerations
	Implementation of security of supply in tender criteria to incentivize manufacturers to make strategic investments in more robust supply chains
	Active communication of stakeholders to increase demand predictability- procurement authority to provide demand volume estimates and manufacturers to provide supply commitment
	Tender designs should reflect types of products depending on chracteristics. e.g., Using Most Economically Advantageous Tender (MEAT) criteria, enabling switch between products with different administration, length of contract depending on treatment duration
Policy Recommendations to Promote Greater Biosimilar Uptake and Appropriate Use	
Prescribing & Dispensing	Prescribing and dispensing decision should be guided by physician and patient's shared decision making (rather than automatic switches based on price) to support communication and preserve physician autonomy to achieve best outcomes
Incentives	Formal prescription incentives such as gain/benefit sharing should be sustainable and introduced to stimulate biosimilar uptake while preserving competition and autonomy
Education & Guidelines	Official authorities to implement targeted education programs and awareness campaigns for physicians, pharmacists and patients on the benefits and features of biosimilars, especially focusing on countries where there is limited biologic use or where biosimilars are introduced for the first time
	Introduce infrastructure and programs for monitoring biosimilar uptake across specific biosimilars, patients and regions. Data from monitoring tools can be used to support devising targeted educational programs and adapt future policies
	Updated guidelines in conjunction with European and National Societies, alongside input from Patient Advocacy Groups (PAGs)

While the table outlines broad policy interventions essential for biosimilar sustainability, it also underscores that biosimilars are not a one-size-fits-all product. It will be vital to tailor and prioritize key solutions that address the unique challenges faced by each product type, which differ based on their characteristics (Figure 1). It is particularly important to create the right market conditions for existing products but also to signal the willingness to create a sustainable and adapted market which in turn shapes the incentives to continue investment in expanding the range of biosimilars available in the future. A summary of priority solutions by biosimilar types is provided below.

Figure 1: Policy Priorities for a Sustainable Market by Biosimilar Types



02.

Introduction

Samsung Bioepis is a biopharmaceutical company that develops and manufactures high-quality biosimilars to accelerate patient access to biologic medicines. Samsung Bioepis is a world-leader in the development of biosimilars, and the current portfolio and pipeline include a diverse and expansive range of biosimilars, including 9 available products in Europe as of June 2025. Samsung Bioepis believes that increasing access to biosimilars more broadly supports healthcare systems and creates headroom for innovation by increasing healthcare spending efficiency, increasing patient access to biologics (both biosimilars and reference medicines) and addressing supply shortages by offering alternative treatments. However, the current biosimilar environment in Europe is not optimized to recognize these values, which leads to an unsustainable market for manufacturers to continue to develop high-quality biosimilars. Samsung Bioepis commitment to ensuring continued supply of high-quality biosimilars should be matched by the required policy reforms to create a more sustainable environment and ensure healthcare systems capture the value biosimilars can offer, in both the short- and long-term.

The objective of this report is, therefore, to identify key policy gaps for recognizing the value of biosimilars in Europe and propose solutions to bridge these gaps, which will sustain biosimilar's value in the future.

Background

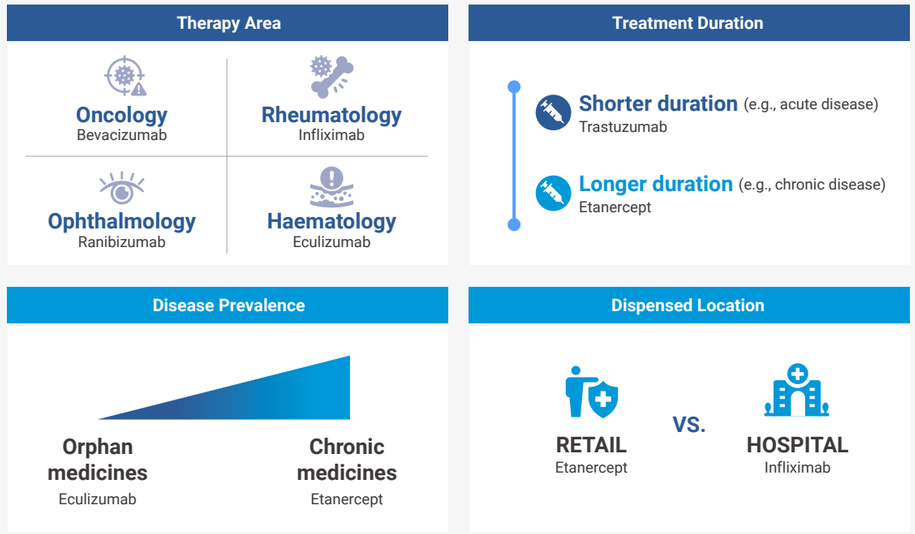
Biological medicines contain active substances originating from a biological source (e.g., living cells) and play a vital role in the disease prevention and treatment of patients across a wide range of therapeutic areas, including oncology and immunology. **A biosimilar** is a biological medicine which is highly similar to another, already-approved reference biological medicine, in terms of the medicine's structure, biological activity, efficacy, safety and immunogenicity profile.[2] At the same time, a biosimilar is not regarded as a "generic" of a biological medicine. This is mostly because the natural variability and complex manufacturing of biological medicines do not allow an exact replication of the molecular micro-heterogeneity. Despite this heterogeneity, biosimilars that are approved according to the same quality, safety, and efficacy standards to their reference medicine, can be considered interchangeable with the reference medicine.[3,4]

The European Medicines Agency (EMA) has approved 92 biosimilars since 2006, when the first biosimilar received approval, to November 2024.[5] These biosimilars span across product classes such as monoclonal antibodies, human growth hormones and tumour-necrosis factor (TNF)-inhibitors.[6] They have become an important part of the healthcare system and offer the opportunity to improve patient outcomes across Europe. However, introduction of biosimilars also presented challenges to policymakers, with differentiated policies needed to govern their development, regulation, manufacturing, pricing, and access. Together, these policies must cultivate a sustainable biosimilar environment which supports the realization of their potential value by patients.

The policy environment for biosimilars can be split in pre- and post-launch policy areas. Led by the EMA, the EU has pioneered regulatory frameworks so that Europe now has the most extensive experience with biosimilars worldwide. However, post-launch policy advances in harnessing the potential of biosimilars have lagged behind, and many barriers remain. Policies governing the post-launch steps fall within the remit of each individual Member State, resulting in fragmented market policies and substantial disparities in biosimilar pricing, availability, uptake, and education across Europe.[7] Therefore, comparative perspectives across each European nation when considering the best policies for optimizing the biosimilar environment is crucial. This white paper will focus largely on the post-launch process when examining the biosimilar policy environment and providing potential policy solutions.

Due to the highly differentiated nature and usage, biosimilars can be grouped according to their intended treatment duration, eligible patient population or dispensing location (Figure 2). These features in part dictate the policy requirements needed for pricing, access and use, and a tailored approach to policy solutions is crucial.

Figure 2: Biosimilar Categorisation Based on Different Features



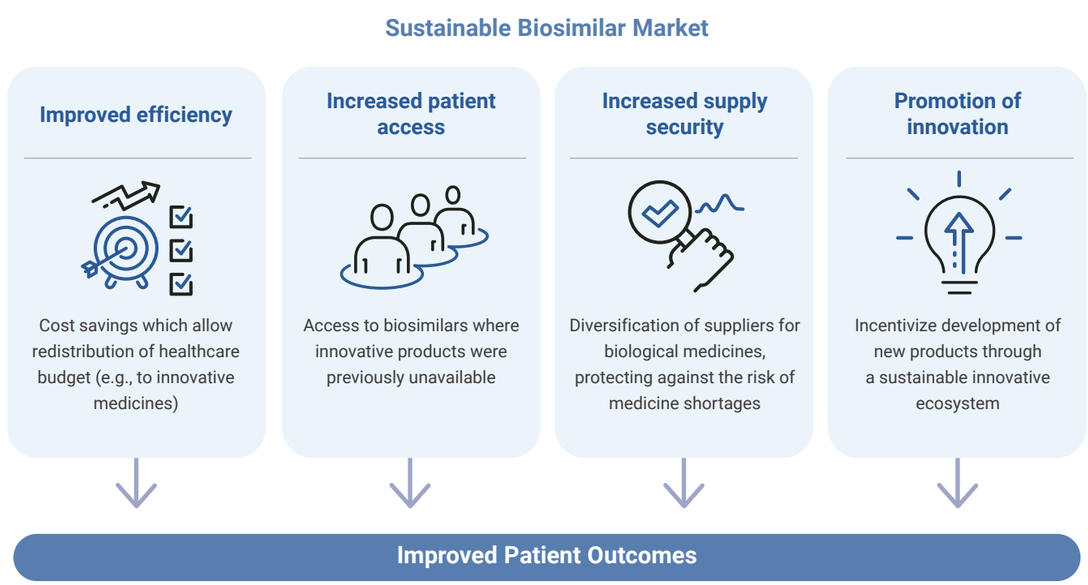
C_EU_202506_006_250708

03.

The Value of Biosimilars in European Markets

Since their introduction in 2006, biosimilars have developed to become integral parts of the European healthcare system. Upon entering the market, biosimilars stimulate competition to the more costly reference medicines, which drives a broader value realized when there is a sustainable biosimilar dynamic present on the market (Figure 3).

Figure 3: Biosimilar Value Elements

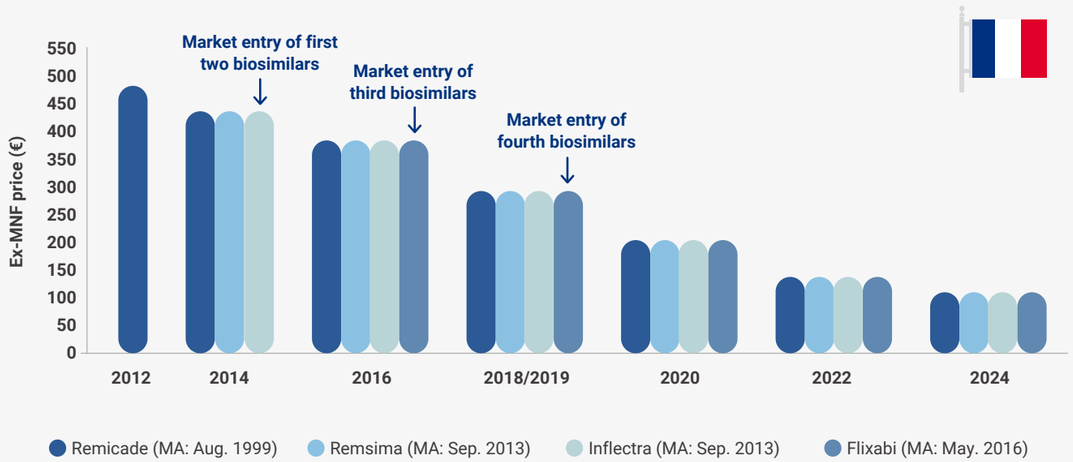


Spending Efficiency and Reinvesting in Innovation

Biological medicines are some of the most expensive medicines, and in 2024 accounted for 41% of all pharmaceutical expenditure in Europe.[8] This high expenditure on biologics comes at a time of increasing financial pressure for healthcare systems across Europe, with the challenging global economic climate, high rates of inflation, aging population and long-term impacts of COVID-19 all contributing to a limited budget for pharmaceutical expenditure.[9]

Biosimilars offer an opportunity for healthcare systems to generate cost-savings. Biosimilars market entry sparks competition and leads to lower prices of reference medicine. The first large-molecule to have multiple biosimilars approved was Janssen's Remicade (infliximab), which achieved marketing authorization (MA) from the EMA in 1999. Following infliximab biosimilars market entry (initially Remsima and Inflectra in 2015, closely followed by Flixabi in 2016), healthcare systems across Europe were able to generate savings due to the increased competition. (See Figure 4).

Figure 4: The Price Evolution of Infliximab Biologics in France



Source: codage[10]

These cost-savings are especially critical in disease areas with high-cost therapies and limited options. For example, upon approval in 2011, Soliris (eculizumab) was the most expensive drug in Europe and the only drug that could treat paroxysmal nocturnal haemoglobinuria (PNH), a rare blood disorder. In the UK, it was estimated that the cost of treating a patient for one year with Soliris was close to £350,000.[10] The approvals of Bekemv and Epysqli, two eculizumab biosimilars, in 2023, have been vital in generating competition and subsequent cost-savings, with spending on Soliris estimated to have fallen by 70% from the $805 million in Europe in 2022.[11] These shifts result in significant cumulative savings for healthcare systems. From 2012 to 2024, it is estimated that biosimilar competition resulted in €56 billion in savings across Europe.[12] These savings are more common in Western European countries, such as in EU4 (including France, Germany, Italy and Spain) and the United Kingdom (UK)[13] where there is historically high use of biologics. Looking specifically at the anti-TNF biosimilars

C.EU.202506.006.250708

infliximab, etanercept and adalimumab in 2023, the EU4+UK countries had an average biosimilar penetration rate of 80%, whereas the average penetration in the remaining EU countries was 67%.[14] High penetration, can lead to significant savings.

Cost-savings generated from biosimilar competition enable redistribution of budgets, so that more patients can be treated, at a higher standard, within the constraints of a country's healthcare budget and create headroom to invest in innovation. This can be seen explicitly in some regions of Italy, where 50% of savings generated from biosimilar use are reallocated to augment the innovative medicines budget by 20%. In England, €474 million in savings from prescribing adalimumab biosimilars partially enabled €808 million in funding for access to innovative medicines through the Innovative Medicines Fund.[15,16]

Increased Patient Access and Earlier Treatment

The increased competition from biosimilars entering the market can also allow health systems to provide patient access to biological medicines earlier in a treatment paradigm, at points where they would have previously been unavailable. The availability of biosimilars decrease delays in access to efficacious medicines, which consequently improves patient outcomes.[17,18]

This can be a critical value aspect of biosimilars in some Central and Eastern European (CEE), where more limited pharmaceutical budgets and less developed frameworks for Health Technology Assessment (HTA) and pricing and reimbursement (P&R) frameworks often result in delayed or no access to biological medicines.[19,20] Biosimilars work to close this gap. For example access to the anti-TNF inhibitor infliximab increased by an average of 88.9% across Europe following biosimilar market entry, with the most pronounced increase in access seen in Poland (246% increase)[21] Similarly, treatment of erythropoietin increased by over 250% in Romania, Bulgaria and Czech Republic, after biosimilar launch.[22]

Biosimilar market entry can also reshape the treatment landscape and improve patient's treatment. For example, biosimilars can increase access to combination therapies that include both innovative and biosimilar components. In 2019, the combination of pertuzumab and trastuzumab for the treatment of HER2-early stage breast cancer was recommended by NICE as a cost-effective method, and subsequently made available through the NHS, following the market entry of trastuzumab biosimilars in the UK.[23,24] While in Germany, the introduction of biosimilars for the treatment of rheumatoid arthritis has drastically decreased the average patient wait time for treatment with a biologic medicine from 7.4 years to 0.3 years.[25] Biosimilars are more than 'alternative treatment options', they can enhance a patient's healthcare quality.

Finally, biosimilars can also enhance patient access to products that provide added value beyond the reference medicine. By leveraging advances in technology, biosimilar manufacturers can introduce innovation such as more environmentally sustainable products, reduced injection volumes to minimize discomfort, or more convenient storage options.[26] For example, in Europe, 90% of reference adalimumab has been replaced by the citrate-free, low-volume biosimilar.[27] Similarly, research into cell lines during development of biosimilar trastuzumab has optimized monoclonal antibody (mAb) production, resulting in a more stable medicine capable of remaining stable for up to 28 days at room temperature, compared to only 24 hours for the reference medicine when stored at 2-8°C.[28]

Improve Supply Security and Address Shortages

The ongoing reform of the EU Pharmaceutical Legislation sets out as a key priority to address shortages of medicines and ensure security of supply.[29] This comes amid growing concern over shortages in Europe, with 28 out of 30 countries in the European Economic Area (EAA) reporting shortages in 2022.[30] This priority has been reinforced as multiple initiatives have launched in recent year such as the Critical Medicines Alliance (CMA) (which may be subsequently followed by the Critical Medicines Act).[31]

In a 2023 survey of European hospital pharmacists, 55% indicated they had experienced more than 10 shortages in 2022 of a medicine that was supplied by a single manufacturer.[32] Therefore, a biosimilar market with multiple marketed alternatives for the same active substance could play a role in increasing supply security, reducing the number of drug shortages and drastically improving patient outcomes.[33] This is particularly critical in life-threatening diseases, such as oncology, where shortages of treatment drugs could have devastating results for patients. Wider recognition of the opportunity for biosimilars to shore up the supply chain and prevent future shortages could ensure patient access to life-saving medications.[34]

Despite this, neither the EU Pharmaceutical Legislation, nor the CMA reference the role of biosimilars in increasing supply security. This lack of recognition could contribute to an underappreciation of the true value of biosimilars in supporting countries to achieve supply security.

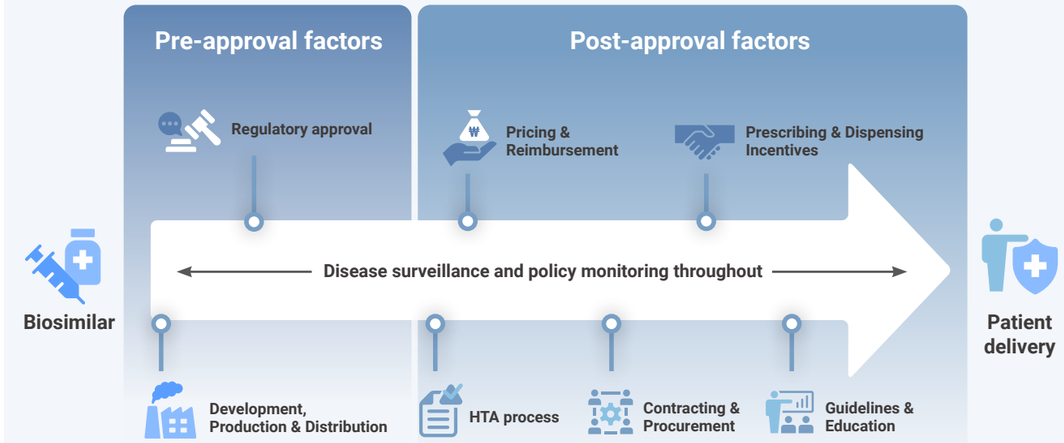
C_EU_202506_006_250708

04.

The Unsustainable Biosimilar Environment in Europe and the Biosimilar Void

It is clear that biosimilar medicines offer inherent values to healthcare systems in Europe and have proven to improve patient access. However, the extent to which this value is realized is driven by the policies that act along the biosimilar pathway, from development to patient delivery (Figure 5).

Figure 5: Biosimilar Pathways to Patient Delivery



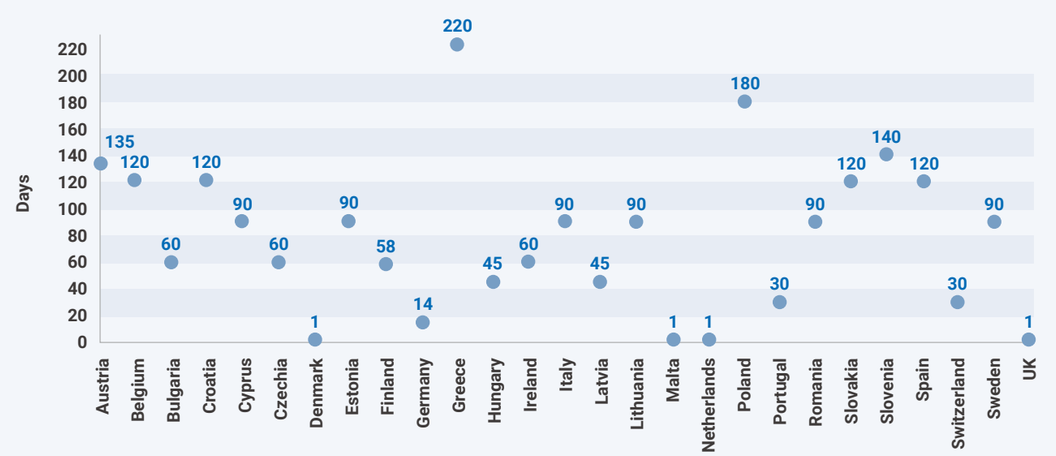
The current post-launch policy framework in Europe presents structural challenges that threaten market sustainability. These policies restrict manufacturers' capacity to consistently supply high-quality, cost-effective biosimilars and may limit a comprehensive recognition of the clinical and economic benefits these products offer.

Biosimilars Face Delays in HTA and Price Pressures During the P&R Process which Create Barriers to Market Entry

Health Technology Assessment (HTA) is a multidisciplinary process that evaluates the properties, effects, and impacts of health technologies. It aims to provide evidence-based information to inform decision-making in healthcare, particularly regarding the adoption and use of new technologies, and that includes biologics (and biosimilars). In some countries, HTA for biosimilars has been shortened or simplified with a consideration that biosimilarity has been demonstrated through regulatory assessment, but this has often led to adverse consequences, where reimbursement decisions are simply based on price comparison. And the HTA processes and requirements vary significantly among European countries, and these disparities within European countries are demonstrated in the time for a biosimilar to receive P&R approval following submission, average time ranging from 1 day to 220 days (Figure 6). Misaligned HTA requirements slow down biosimilar entry and prevent timely access, limiting the speed at which biosimilars can reach patients.

Furthermore, in conditions where the reference product is not reimbursed, or biosimilars make added-value claims different from the reference product (e.g., indication, pharmaceutical forms, routes of administration, etc.), HTA is still relevant but with limited guidance on biosimilar value assessment.[35]

Figure 6: Average Time for a Biosimilar Medicine to Receive Its P&R Approval from the Point of Application across Europe



Source: Medicines for Europe[36]

The steps immediately following HTA, defined by P&R policies, can be overly restrictive and focus on achieving the lowest possible prices for biosimilars via reductive mechanisms such as price linkage and reference pricing.[37] For example, of 28 European countries, 12 countries use external reference pricing methods, and 17 countries mandate arbitrary discounts on biosimilars' prices at an average of 28% below reference product, creating an unlevel playing field.[36] This discount gap is even wider at net price levels driven down further by competition and leading to a gap of 80% or above. This approach disregards the holistic value a biosimilar can

C_EU_202506_006_250708

bring to the healthcare system, and instead utilizes biosimilar launches to drive decreases in the price of the reference product.

Additional Price Erosion from Cost-containment and Tendering Policies Reduces a Biosimilar's Market Viability Further

Tendering is widely used in the procurement of biologic medicines in the hospital setting and can be organized at national or sub-national levels.[38] However, these tenders often rely on price as the primary criterion while often overlooking broader qualitative factors such as supply stability or quality. They tend to favour single-winner, or are not re-opened in time with a new biosimilar market entry, and in multi-winner tenders, there is a lack of transparency in demanded volume. (Figure 7)

In addition to tendering, biosimilars are subject to wider cost-containment policies, such as rebates and clawbacks, which are intended to act as healthcare budget control mechanisms. On top of that, some countries regulate drug prices by including mandatory discounts once a biosimilar has been on the market for several years. Collectively, these policies create a dynamic of 'race-to-the-bottom price erosion' which can lead to market prioritisation, potentially endangering supply security.

Figure 7: Tender Profiles of European Countries

Tender Properties	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czechia	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	UK
Criterion beyond only-price?	✖	○	✖	✖	○	✖	○	✖	✖	○	N/A	○	✖	✖	✖	✖	✖	○	✖	○	✖	✖	✖	✖	○	N/A	○	○
Multi-winner at hospital level?	✖	✖	✖	✖	✖	✖	○	✖	✖	✖	N/A	○	✖	✖	○	✖	✖	✖	✖	✖	✖	✖	✖	○	○	N/A	✖	○
Re-opened after biosimilar market entry?	○	✖	✖	○	✖	✖	✖	✖	○	✖	N/A	✖	✖	✖	○	✖	✖	✖	✖	✖	○	✖	✖	✖	✖	N/A	✖	✖
Minimum or maximum volume guarantee?	✖	✖	○ Max	✖	○ Max	✖	✖	✖	✖	N/A	N/A	○ Min	○ Min	✖	✖	○ Min	○ Max	○ Max	✖	○ Max	○ Max	N/A	✖	✖	✖	N/A	✖	✖

○ Positive for biosimilars ✖ Negative for biosimilars

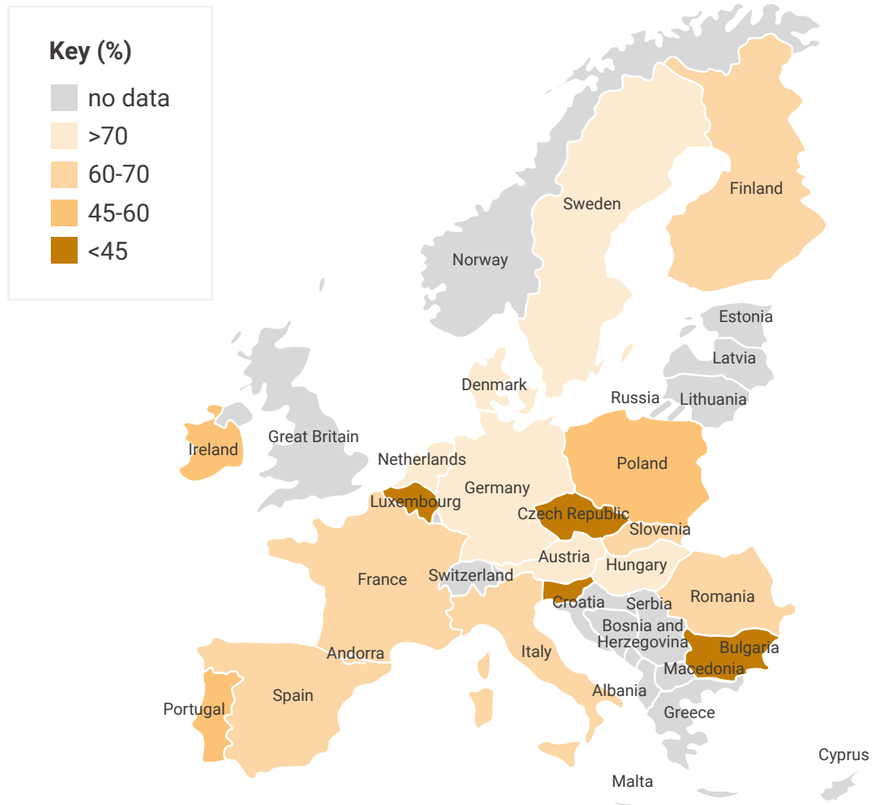
Source: Medicines for Europe[39]

Policies Promoting Biosimilar Uptake are Insufficient and Poorly Implemented, Resulting in Limited Uptake and Unsustainable Market Share

Across European countries, limitations with physician and pharmacist incentives to encourage prescribing and dispensing of biosimilars remain, with significant variance across regions. In some settings, suboptimal confidence in biosimilars among physicians and patients further exacerbates this issue. This lack of confidence is often linked to limited experience with biosimilars in specific therapeutic areas, infrequent updates to treatment guidelines, and insufficient education programs both for physicians and patients.

National policies on uptake result in considerable variation in uptake across Europe (Figure 8). Simultaneously, different implementation of these policies within a Member States can also result in stark regional disparities. For example, in Spain, uptake of biosimilar rituximab and trastuzumab varied between 35.9% and 0%. Similarly, in Italy, biosimilar adoption differs by 21.5% between Northern and Southern regions. Major predictors of lower uptake include a lack of confidence, limited education programs, and low social trust in government.[40,41] Consequently, the biosimilar share in Europe remains below its full potential.

Figure 8: Market Share of Biosimilar Approved in Oncology Indications as a Share of the Total Market



Source: IQVIA[42]

C_EU_202506_006_250708

The Nature and Extent of Policy Challenges Vary Across Biosimilar Types, as There is Limited Consideration and Adaptation to the Distinct Characteristics and Needs of Products

Across the biosimilar pathway there is limited recognition of the unique challenges faced by each biosimilar. Blanket policies are put in place for all different types of biosimilars in a 'one-size-fits all' manner. However, this neglects the difference between each biosimilars according to its types and further exacerbates the unsustainability of the biosimilar environment in Europe.

Box 1: The Different Challenges for Different Biosimilar Types

Biosimilars dispensed at hospital level

Tendering of biosimilars in the hospital setting occurs in 27 out of 28 European countries analysed. Considering the restrictive tendering policies across Europe, this creates significant difficulties for hospital dispensed biosimilars. Since in-patient treatments are administered by healthcare professionals, criteria should evolve to meet their needs. Furthermore, a high price discount applied during hospital procurement and contracting, which is not directly reinvested in the prescribing department or patients, results in further price level decreases for products (often prices approaching the cost of goods sold).

Biosimilars for treatment of chronic and long-term conditions (e.g., autoimmune diseases)

For biosimilars for chronic diseases, patients feel strong attachment to their medications. Frequent medicine switching without adequate education or support can be perceived as disruptive or unsettling. Without a strong physician-pharmacist-patient communication, biosimilar uptake may be hindered. Other challenges include lack of incentive policy for biosimilar prescribing physicians or adequate gain-sharing models for hospitals. As a result, these biosimilars show greater disparities of biosimilar penetration within Europe countries.

Biosimilars for treatment of conditions with small patient population (e.g., rare diseases)

Many HTA authorities across Europe implement modified pathways for orphan drugs due to a recognition of risk in development coupled with smaller eligible patient populations. These modified pathways can include specialized assessment pathways (including reduced evidence requirements or higher cost-effectiveness thresholds) leading to higher prices for innovative orphan medicines. However, these modifications have not yet been extended to orphan biosimilars, resulting in difficulties for achieving timely access at a feasible price. This issue is only expected to grow over the coming years, as the number of orphan biologics losing exclusivity will increase.

Not only do orphan drug biosimilars face delayed entry from longer patent protection, but also application of the same biosimilar P&R regulations such as mandatory price discounts in market entry pose as double challenges where their opportunity for commercial success is limited due to small patient population.

The Biosimilar Void

With aforementioned challenges and high costs of both developing and manufacturing (e.g., due to inflation of raw materials, energy and logistic costs) biosimilars, many biologic medicines will not face biosimilar competition at the point of LoE, a concept introduced from an IQVIA report as "the biosimilar void". Analysis of the current biosimilar pipeline suggests this biosimilar void is already occurring given that: [43]

- The average number of biosimilars in development for each reference biologic product is expected to decrease from 2.19 currently, to 0.43 in 2027 and beyond
- Of the 26 highest cost biologic medicines that will undergo LoE by the end of 2032, only 73% currently have a biosimilar in development

The distinct challenges that different biosimilar types face also lead to specific cases where certain biosimilar types struggle to sustain viability on the market, and manufacturers are likely to stop investment in their development. Despite this, there is limited policy recognition of these challenges, and this is resulting in a greater biosimilar void for certain biologics including:

- Only 7% of the 84 lowest revenue biologic medicines that will undergo LoE by the end of 2032 currently have a biosimilar in development
- From 2028, the average number of biosimilars in development for reference oncology biologic medicines is expected to decrease from 4.3 to 1.2

For biosimilars to be valuable to healthcare systems, there must be consistent biosimilar market entry and high levels of competition with the reference biologic or between biosimilars. The biosimilar void threatens this competition and could prove extremely damaging for the European healthcare system, and especially patient outcomes. Looking solely at the increased efficiency, where savings from biosimilar competition are needed to treat more patients within a restricted pharmaceutical budget, the biosimilar void could cost 4.4 billion in lost savings from competition in 2029-2030 alone.[44] A similar effect will likely be observed across all biosimilar value aspects unless policies are put in place to address the currently unsustainable biosimilar market.

C_EU_202506_006_250708

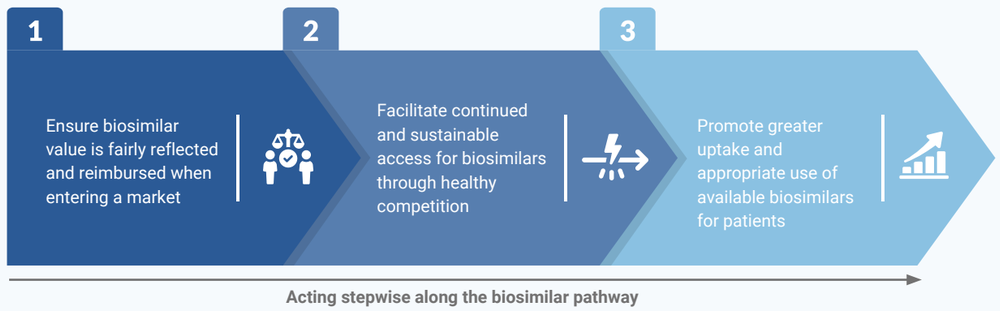
05.

Policy Solutions to Improve the Biosimilar Environment

We can avoid the biosimilar void and reap the benefits through policies that enable a sustainable market post-launch. Such policies should foster competition and ensure biosimilars are appropriately valued, priced, and utilized at launch and beyond, guaranteeing ongoing access. As the most significant challenges to sustainability occur post-launch, our focus is on policies to be implemented at national level. However, increased collaboration and unification in policies across Europe would offer significant advantages for both healthcare systems and manufacturers.

We propose three post-launch policy objectives (see Figure 9), each with specific measures, bolstered by European case studies to emphasise the importance, feasibility and impact.

Figure 9: Policy Objectives for The Biosimilar Landscape



Ensure Biosimilar Value is Fairly Reflected in Access and Pricing Decisions at Launch

Biosimilar's initial assessment and price at launch should adequately recognize their quality, safety and efficacy in line with reference medicines and take into account the wider value to the healthcare system.

Policy Recommendation 1: Simplify and Tailor Health Technology Assessment (HTA) Processes to Support Timely and Value-based Decisions

National policymakers need to update HTA processes for biosimilars to reduce delays and fully recognize their holistic value.

Specific mechanisms to improve HTA processes include:

- Streamlined HTA for timely access:
  - o Introduction of HTA waivers that automatically consider the value of a biosimilar to its reference medicine
  - o Indication extrapolation for approved biosimilars in line with all new indication approvals for the reference medicine
  - o Accelerated access that allows patients to access biosimilars immediately after EMA regulatory approval

In Germany, biosimilars are exempt from the AMNOG (Arzneimittelmarktneuordnungsgesetz) process, meaning they are not required to undergo an HTA for approval in all indications approved for the reference biologic. This enables biosimilars to immediately access the market, without any restrictions to their value. This has led to oncology biosimilars capturing 71% of the total eligible market, compared to an average of 60% elsewhere.[45,46]

- Develop a tailored HTA process for biosimilars that offer additional benefits versus the reference medicine such as expanded indication, innovative formulations, or alternative administration routes or where the reference medicine is not reimbursed or is not the standard of care. These pathways may involve easing certain evidence requirements or providing temporary reimbursement until final decisions are reached, to avoid delays

Policy Recommendation 2: Implement Fair Biosimilar Pricing Rules and Controls at Launch

Policy reforms concerning pricing decisions are critical. Healthcare systems must signal that they are willing to set fair prices for high-quality biosimilars- prices that reflect their holistic value to the healthcare system.

Specific mechanisms to update the pricing mechanisms across Europe include:

- Avoid arbitrary price controls for biosimilars at launch, including unjustified and mandatory price discounts. Such controls often fail to account for the complex development process and significant investment required

C_EU_202506_006_250708

to develop high quality biosimilars thereby undervaluing their broader values

• Introduce free pricing for biosimilars at launch when the reference medicine is available on the market, and allow for price discounts to healthcare systems to be achieved naturally via market dynamics and increased competition

In Germany and the Netherlands, where biosimilars are able to launch at free prices.[47] Biosimilars may launch at a price equal to the reference product, and dynamic price competition leads to adjustments based on efficiency gains and benefits to the healthcare system. For example, in the Netherlands, 82% cost-savings resulted from the entry of 5 different biosimilars from 2015-2022.[48]

• When reference biologics have not undergone P&R in a market, pricing decisions to be linked to the updated HTA process wherever possible. This allows prices to reflect the value of different biosimilar types, and ensure their sustainability given the context

Box 2: Specific Policy Solutions to Support Different Types of Biosimilars at Launch

For orphan biosimilars, implement tailored policies including exemption from mandatory price discounts, to support a sustainable market where there has been no access for the reference medicine or a tailored HTA process that for example supports the consideration of broader value criteria, accounts for disease severity and provides an opportunity for input from patients and other key stakeholders.

Facilitate Continued and Sustainable Access for Biosimilars through Healthy Competition

Patient access for multiple biosimilars must be encouraged and maintained across a biosimilar's lifecycle, with policies in place that prevent price erosion to the extent of devaluation of biosimilars.

Policy Recommendation 3: Provide Exemptions for Biosimilars from Wider Cost-containment Policies

The need for cost-containment of pharmaceutical expenditure has grown in the face of budgetary pressures. Countries often apply mechanisms such as clawbacks, paybacks or rebates to ensure that healthcare budget requirements are met by requiring manufacturers to repay the government a share of their revenue when exceeding a budget threshold.[49] Cost-containment can also be achieved through periodic mandatory price discounts after launch, intervening to systematically increase the erosion of prices over time.

Existing alongside the already fierce price competition, these cost-containment mechanisms often disproportionately impact biosimilars by resulting in a 'double' price erosion. Biosimilar prices are initially reduced at launch and face heightened downward pricing pressure in the market through cost-containment policies and competition. These combined forces can result in withdrawals impacting the security of supply, as occurred in the UK in 2023 where rebate climbed to 26.5% making it unviable to continue biosimilar business. To create a sustainable biosimilar environment, healthcare systems must recognize the key role biosimilars already play in achieving efficiencies and put in place policies to protect biosimilars from excessive and unsustainable price erosion.

Specific mechanisms to reform price controls of biosimilars' lifecycle management include:

• Introduction of a minimum price boundary line, at which biosimilar price is protected from any further price erosion and continued procurement is guaranteed

• Broader recognition in policy agendas by payers and national authorities on the role of biosimilars in achieving cost efficiencies and ability to redistribute spending

• Adjustment of cost containment measures (e.g., clawbacks, paybacks, rebates) with appropriate exemptions or appropriate rules for biosimilars

Despite persistent use of cost-containment measures, several countries are implementing changes that potentially reduce the impact on biosimilars, for example:

• In 2024, the UK updated their industry agreement (Voluntary Scheme for Branded Medicines Pricing, Access and Growth; VPAG). Although this new scheme did not go as far as exempting biosimilars from clawbacks, there are significant improvements versus the previous scheme, VPAS. Under the new scheme, biosimilars are classed as 'older medicines' and must payback a basic clawback of 10%; although this can raise to 35% in some circumstances, this demonstrates the first steps in the recognition of the different challenges biosimilars face.[50,51]

• In France, each year the Social Security Financing Bill (PLFSS) sets out a safeguard clause, which outlines the money manufacturers are required to pay back to the healthcare system. In 2025, the proposed pharmaceutical payback is €1.6 billion, including off-patent branded medicines (e.g., generics and biosimilars). Although, there are reports that contribution from generics and biosimilars would increase from €100 million to €330 million,[52] the unchanged cap at €1.6 billion, and at 10% of total turnover per company is seen as a step in the right direction.

Policy Recommendation 4: Update Tendering Processes to Adequately Consider Biosimilars and Support Competition

The contracting process at all levels (including national, regional and local) should be inclusive, consider broader factors in decision making and support competition. Tenders that do not allow for multiple competitors to be on the market (such as winner takes all tenders, those with unclear guidance on allocated volumes and where tendering framework is not implemented in practice) significantly reduce the sustainability of the market and also may lead to supply restrictions. For example, Norway's tendering system aims to fosters biosimilar access through multi-winner tenders which considers many factors, such as environmental impact, sustainability of supply, and stakeholder viewpoints. Although these provide a good foundation for competition, the lack of contracted volume shares across winners leads to a situation where only one product is procured and

C_EU_202506_006_250708

monopolizes the market. Additionally, in markets with sub-national tendering, such as Italy, regional health authorities can further increase price pressure by setting a maximum bidding price (base price) for companies submitting to a tender.

Specific mechanisms to update the approach to tendering and contracting across Europe include:

- National, regional and local tenders should support diversification of supply and fair competition through multi-winner tenders with contract volume shares, transparent and periodic tender opening and a broad set of value criteria considerations
- Implementation of security of supply in tender criteria to incentivize manufacturers to make strategic investments in more robust supply chains

The ideal contracting and procurement approach can be taken from an amalgamation of the individual practices employed by countries in the EU. However, no countries are yet optimized across all aspects (Figure 7).

- France tenders included non-price criteria in their contracting and procurement, including technical quality, value-added services, design, inactive ingredients, traceability, and supply sustainability. Of the 49 biosimilar tenders with visible award criteria, 82% included non-price criteria, and 35% included 'technical quality'.[53,54]
- Denmark introduced adalimumab biosimilars through offering multi-winner tenders alongside updated treatment guidelines. This was successful in increasing biosimilar uptake, with over 90% of patients switching to biosimilar adalimumab within three weeks of introduction. However, without a minimum volume guarantee included in the multi-winner tender, the impact on sustainability is capped. This highlights the importance of introducing reforms across all aspects of tendering approach.[55]

- Active communication of stakeholders to increase demand predictability- procurement authority to provide demand volume estimates and manufacturers to provide supply commitment
- Tender designs should reflect types of products depending on characteristics (e.g., Using Most Economically Advantageous Tender (MEAT) criteria, enabling switch between products with different administration, length of contract depending on treatment duration)

Box 3: Specific Policy Solutions to Support Different Types of Biosimilars in Maintaining Their Market Sustainability in Procurements

- **For orphan biosimilars,** the small eligible patient populations require greater transparency in procurement and establishment of minimum volume guarantees to support supply sustainability.
- **For biosimilars administered by healthcare professionals (HCP),** tender criteria to reflect HCP needs such as device convenience, packaging, etc to incentivize manufacturers to invest in product development.
- **For chronic biosimilars** (e.g., autoimmune disease), given the substantially larger patient populations and the generally lower prices of reference biologics in this segment, a competitive landscape is essential. Tender frameworks for these products should favour multi-winner models to diversify supply sources and mitigate risks, ensuring continuity and resilience in long-term treatment scenarios.

Promote Greater Uptake and Appropriate Use of Biosimilars for Patients

For a biosimilar to reach one and each patient in need and alleviate the burden of healthcare costs, fostering prescriber confidence and patient acceptance is crucial. Supporting uptake through well-structured incentive schemes and education is critical to achieving this goal.

Policy Recommendation 5: Encourage Prescription of High-quality Biosimilars While Preserving Stakeholder Autonomy

To increase biosimilar uptake, there must be sufficient demand and prescription of biosimilars. Physicians play a pivotal role in this process, and policies that encourage prescription, such as incentive schemes are vital. Rather than being seen solely as a cost-reduction mechanism, biosimilars should be valued as effective treatment options for patients and as catalysts for continuous innovation in their development. These policies are a key factor underlying biosimilar penetration, and countries with inadequate incentives or quotas, such as Bulgaria, have lower levels of biosimilar uptake, compared to countries with a robust incentive system, such as France, demonstrate higher biosimilar uptake.[56,57]

Specific mechanisms to incentivize appropriate uptake of best value products across Europe include:

- Formal prescription incentives such as gain/benefit sharing should be sustainable and introduced to stimulate biosimilar uptake while preserving competition and autonomy

France includes benefit sharing programs in hospitals for prescription of biosimilars, allowing savings to be immediately reinvested into improving patient care, expanding access to treatments and fostering innovation.[58] A pilot program, which ran from 2018-2023 for etanercept, adalimumab and insulin glargine, allowed specific clinical departments to keep 30% of the savings achieved from prescribing biosimilars, rather than spreading savings hospital-wide. This scheme resulted in 8.3 point higher uptake for biosimilars compared to a compulsory scheme (CAQES) which offered 20% of cost-savings hospital-wide.[59,60,61]

- Prescribing and dispensing decision should be guided by shared decision making, rather than biosimilar pharmacy substitution, to support communication and input from physician, pharmacist and patient to achieve best outcomes (particularly important for outpatient setting / chronic disease management)

C.EU.202506.006.250708

Policy Recommendation 6: Increase Education of Key Stakeholders to Support and Understanding of Biosimilar Value

Alongside incentives, willingness to prescribe is strongly tied to the level of understanding of biosimilars. While the EMA announced that biosimilars could be used interchangeably with reference medicines in 2022, misconception persist among physicians and patients. For example, low biosimilar uptake in Spain has been attributed to a lack of confidence from physicians to switch from reference biologic once a biosimilar becomes available.[62] Similarly, a lack of patient understanding in France led to reduced biosimilar uptake due to concerns over a nocebo effect , where their pre-existing negative expectations for treatment would limit the effectiveness of the treatment.[63] To combat these concerns, wide-reaching education for all stakeholders is key to creating a sustainable biosimilar environment.

Specific mechanisms to support education and understanding of biosimilars' value across Europe include:

- Implement targeted education and awareness programs for key stakeholders including physicians, pharmacists, patients and other decision makers delivered by a credible authority (e.g., official body). The focus should be on improving education in areas where biosimilars are being introduced for the first time, such as orphan drugs, and emphasizing the holistic value of biosimilars and the advantages of their prescription beyond clinical benefits

In the Netherlands, the Dutch association of hospital pharmacists (NVZA) have created a practical guidance document to educate physicians and hospital pharmacists on the successful implementation of biosimilars.[64]

Similarly, to facilitate introduction of biosimilars in Denmark, a Taskforce was appointed to enhance education of biosimilar medicines among HCPs. This partially contributed to the rapid adoption of infliximab and etanercept, reaching 95% within the first 3-4 months of market entry.[65]

- Introduce infrastructure and programs for monitoring biosimilar uptake across specific biosimilars, patients and regions. Data from monitoring tools can be used to support devising targeted educational programs and adapt future policies
- Update guidelines in conjunction with European and National Societies, alongside Patient Advocacy Groups (PAGs)

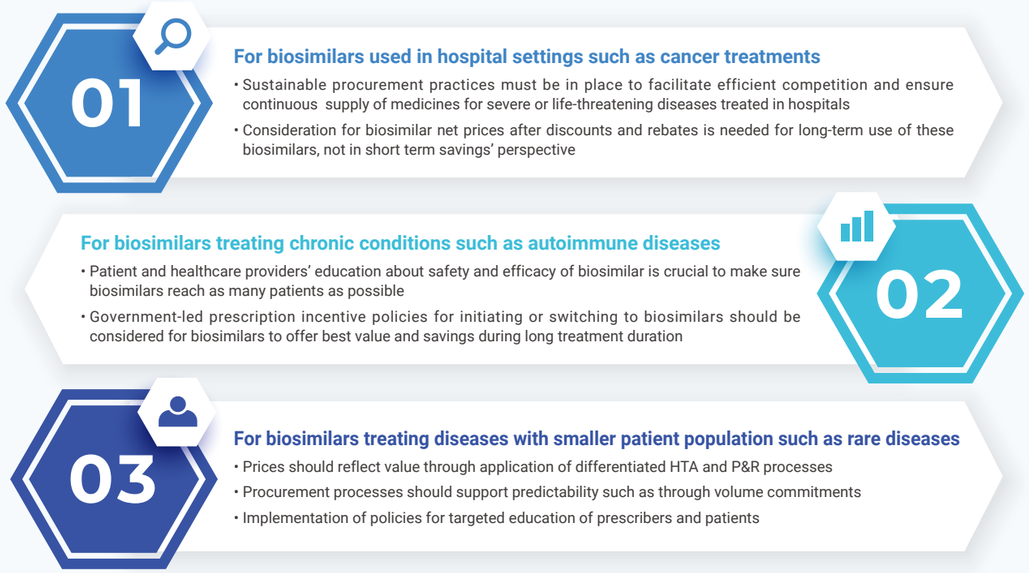
Box 4: Specific Policy Solutions to Support Different Types of Biosimilars Increase Their Uptake

- **For orphan biosimilars,** the small patient populations and the lower likelihood of access to the reference biologic in some markets necessitates targeted education and guidelines updates for when biosimilars becomes available.
- **For chronic biosimilars** (e.g., autoimmune diseases), the longer treatment duration and frequent treatment switches increases the need for specific policies that promote use of the biosimilar, including policies on incentives, education and guidelines for switching existing patients.

Summary of Policy Solutions for Different Biosimilar Types

The multi-pronged approach across the policy areas that affect the post-launch environment for biosimilars is critical to ensure a sustainable market. Based on the characteristics of different biosimilars, tailoring and prioritizing key solutions that address the unique challenges of these types of products will be vital. These is particularly important to create the right market conditions for existing products but also to signal the willingness to create a sustainable and adapted market which in turn shapes the incentives to continue investment in expanding the range of biosimilars available in the future. A summary of priority solutions by biosimilar types is provided below.

Figure 10: Policy Solutions Categorized by Biosimilar Type



Source: CRA analysis

06.

Conclusion

Biosimilars offer healthcare systems improved patient access through enhanced healthcare cost efficiency, reinvestment in innovation, broader treatment access, and bolstering system resilience – including supply security. However, realizing these benefits hinges on the development and distribution of high-quality, safe and effective biosimilars being sustainable.

Challenges in Development and Supply

The development and supply of biosimilars is a complex and costly process for biosimilar manufacturers. To sustain this investment, biosimilars must be procured in Europe at a reasonable price and with a guaranteed level of uptake.

Limitations of the Current Policy Environment

European biosimilar policies currently fail to acknowledge the full value of biosimilars, and therefore, is not well-adapted to incentivize the continued development of biosimilars. Upon market entry, biosimilars often face restrictive pricing and access conditions aimed at driving down the price of reference medicines. This is further exacerbated due to distorted competition in tender systems that prevent biosimilars from obtaining a significant and required market share. This environment is unsustainable for all stakeholders. Despite efforts from companies such as Samsung Bioepis, a looming biosimilar void underscores real risks to the future viability of European healthcare systems, supply security, and patient access especially in rare-disease space.

Policy Recommendations and Future Directions

However, by acting to create a sustainable biosimilar environment, the full value of biosimilars can be unlocked, now and in the long-term. Establishing a sustainable framework for biosimilars requires a nuanced understanding of their heterogeneous applications across clinical settings. Biosimilars are not uniformly deployed; rather, their use and impact can differ significantly based on the locale of dispensation, the route of administration, and the specific disease characteristics involved. Consequently, policy measures should be carefully designed to account for these contextual differences. Such adaptive policies will ensure that biosimilars are not only effectively integrated into diverse healthcare environments but also that their full therapeutic potential is realized for all patient groups.

This white paper has set out a collection of policy recommendations with the most important step being for policymakers to shift from perceiving biosimilars solely as a cost-saving tools to recognizing their vital role in strengthening market efficiency, patient access and system resilience. By adopting these strategic policy reforms, we will not only realize immediate cost efficiencies but also foster long-term innovation, fortify supply security, and ensure a resilient, patient-centric healthcare system for future generations.

C_EU_202506_006_250708

References

1. IQVIA (2025) The Impact of Biosimilar Competition in Europe. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2024.pdf

2. EMA. 2023. Biosimilars in the EU: Information guide for healthcare professionals. Available at: https://www.ema.europa.eu/en/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf

3. Mestre-Ferrandiz, J., Czech, M., et al. 2024. Capturing the holistic value of biosimilars in Europe – part 1: a historical perspective. Expert Review of Pharmacoeconomics & Outcomes Research, 24(2), pp. 237-250

4. EMA. 2023. Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU. Available at: https://www.ema.europa.eu/en/documents/public-statement/statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf

5. AJMC The Center for Biosimilars 2024. Biosimilar approvals: European Union. Available at: https://www.centerforbiosimilars.com/biosimilar-approvals

6. Generics and Biosimilars Initiative. 2024. Biosimilars approved in Europe. Available at: https://www.gabionline.net/biosimilars/general/biosimilars-approved-in-europe

7. Vogler, S., Schneider, P., et al. 2021 Policies to Encourage the Use of Biosimilars in European Countries and Their Potential Impact on Pharmaceutical Expenditure. Frontiers in Pharmacology 12. Available at: https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2021.625296/full

8. IQVIA (2025) The Impact of Biosimilar Competition in Europe. Available at: the-impact-of-biosimilar-competition-in-europe-2024.pdf

9. OECD. 2023. Health at a Glance 2023. Available at: Access: Affordability, availability and use of services | OECD

10. The Lancet Haematology. 2015. The rising cost of orphan drugs. Available at: https://www.thelancet.com/journals/lanhae/article/PIIS2352-3026(15)00229-X/fulltext

11. The Korea Economic Daily (2024) Samsung Bioepis leads in Soliris biosimilar market in Europe. Available at: https://www.kedglobal.com/bio-pharma/newsView/ked202405270016#:~:text=Considering%20Soliris%20sales%20stood%20at,from%20direct%20sales%20of%20Epysqli.

12. IQVIA (2025) The Impact of Biosimilar Competition in Europe. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2024.pdf

13. EU4+UK countries consist of Germany, France, Italy, Spain and the United Kingdom

14. IQVIA MIDAS data

15. IMS institute for healthcare economics. 2016. Delivering on the Potential of Biosimilar Medicines: The Role of Functioning Competitive Markets. Available at: IMS-Institute-Biosimilar-Report-March-2016-FINAL.pdf

16. NHS England. 2022. NHS saves £1.2 billion on medicines over three years. Available at: NHS England » NHS saves £1.2 billion on medicines over three years

17. Dutta, B., Huys, I., et al. 2019. Identify Key Benefits in European Off-Patent Biologics and Biosimilar Markets: It is Not Only About Price! BioDrugs: Clinical immunotherapeutics, biopharmaceuticals and gene therapy. 34(2), pp. 159-170

18. EFPIA. 2024. The root causes of unavailability of innovative medicines and delay in access: Shortening the wait. Available at: root-causes-of-unavailability-and-delay-efpia-cra-2024.pdf

19. Simoens, S., Lacosta, T. B.,, & Inotai, A. 2024. Learnings from cross-border biosimilar pricing policies in Europe. Expert Review of Pharmacoeconomics & Outcomes Research, 24(5), pp. 585-588

20. Nemeth, B., Csanadi, M., et al. 2022. Access to high-priced medicines in lower-income countries in the WHO European Region. Oslo medicines initiative technical report. Available at: Access to High-Priced Medicines in Lower-Income Countries in the WHO European Region - NCBI Bookshelf

21. Car, E., Vulto, A. G., et al. 2023 Biosimilar competition in European markets of TNF-alpha inhibitors: a comparative analysis of pricing, market share and utilization trends. Frontiers in Pharmacology. 14

22. IMS institute for healthcare economics. 2016. Delivering on the Potential of Biosimilar Medicines: The Role of Functioning Competitive Markets. Available at: IMS-Institute-Biosimilar-Report-March-2016-FINAL.pdf

23. Mestre-Ferrandiz, J., Czech, M., et al. 2024. Capturing the holistic value of biosimilars in Europe – part 1: a historical perspective. Expert Review of Pharmacoeconomics & Outcomes Research, 24(2), pp. 237-250

24. NICE Guidance. 2019. Pertuzumab for adjuvant treatment of HER2 -positive early-stage breast cancer. Available at: https://www.nice.org.uk/guidance/TA569/chapter/1-Recommendations

25. Guntern, R. 2021. 15 years of biosimilar access in Europe. Available at: 15 years of biosimilar access in Europe - PharmaTimes

26. Mestre-Ferrandiz, J., Czech, M., et al. 2024. Capturing the holistic value of biosimilars in Europe – part 1: a historical perspective. Expert Review of Pharmacoeconomics & Outcomes Research, 24(2), pp. 237-250

27. Troein P, Newton M, Scott K, et al. The impact of biosimilar competition in Europe 2021. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2021.pdf (accessed 4th July 2024)

28. https://www.ema.europa.eu/en/documents/product-information/trazimera-epar-product-information_en.pdf

29. European Commission. 2024. EU Pharmaceutical Reform: Addressing shortages of medicines and ensure security of supply. Available at: https://health.ec.europa.eu/document/download/a7791296-df3b-4fc3-8f45-cafd2ccb6be3_en?filename=factsheet_shortage-management_en.pdf

30. European DATA Journalism Network. 2023. Drug scarcities: why medicines are still in short supply. Available at: https://www.europeandatajournalism.eu/cp_data_news/drug-scarcities-why-medicines-are-still-in-short-supply-a-cross-border-investigation/

31. European Commission (2024) Critical Medicines Alliance. Available at: https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview/critical-medicines-alliance_en#:~:text=The%20Critical%20Medicines%20Alliance%20(CMA,society%2C%20and%20the%20scientific%20community.

32. EAHP. 2023. EAHP 2023 Shortage Survey Report. Available at: https://www.eahp.eu/wp-content/uploads/2024/03/shortages_survey_report_final.pdf

33. Antoñanzas, F., Juárez-Castelló, C. & Rodríguez-Ibeas, R. Tenders for generics and biosimilars: a challenging purchasing policy. Eur J Health Econ 24, 485–487 (2023). https://doi.org/10.1007/s10198-023-01580-z

34. Li, E., Subramanian, J., et al. 2015. Development of biosimilars in an era of oncologic drug shortages. Drug Design, Development and Therapy. 24(9), pp. 3247-3255.

35. Lacosta, T. B., et al. 2024. Mapping Health Technology Assessment Agency Approaches for Biosimilar Value Assessment: An ISPOR Special Interest Group Report . Value Health. 2024; 27(5):543-551

36. Medicines for Europe. 2023. Market Review: European Biosimilar Medicine Markets. Available at: https://www.medicinesforeurope.com/wp-content/uploads/2023/09/Biosimilars-Market-Review-2023-final-06-09-2023.pdf

37. Vogler, S., Schneider, P., et al. 2021 Policies to Encourage the Use of Biosimilars in European Countries and Their Potential Impact on Pharmaceutical Expenditure. Frontiers in Pharmacology 12. Available at: https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2021.625296/full

38. Machado, s., Cruz, A., et al. 2024. Policy measures and instruments used in European countries to increase biosimilar uptake: a systematic review. Frontiers in Public Health. 12

39. Medicines for Europe. 2023. Market Review: European Biosimilar Medicine Markets. Available at: https://www.medicinesforeurope.com/wp-content/uploads/2023/09/Biosimilars-Market-Review-2023-final-06-09-2023.pdf

40. JC. Robinson. 2022. Social trust and regional variation in the adoption of biosimilars in Germany and Italy. GaBI 11(3):87-8

41. KJ. Schmidt et al. 2023. Navigating the road to successful biosimilar uptake in Europe – Still Some way to go? Xcenda. Available at: https://www.xcenda.com/insights/htaq-spring-2023-the-road-to-successful-biosimilar-uptake-in-europe.

42. IQVIA. 2023. The Impact of Biosimilar Competition in Europe. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2023.pdf

43. IQVIA. 2023. Assessing the Biosimilar Void: Achieving sustainable levels of biosimilar competition in Europe. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/assessing-the-biosimilar-void/iqvia-institute-assessing-the-biosimilar-void-10-23-forweb.pdf

44. IQVIA (2025) The Impact of Biosimilar Competition in Europe. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2024.pdf

45. This average is likely overreported, as countries such as Croatia, Estonia, Latvia, Lithuania and Greece do not report on biosimilar uptake, and are likely to report lower % uptake compared to western countries.

46. IQVIA. 2023. The Impact of Biosimilar Competition in Europe. Available at: the-impact-of-biosimilar-competition-in-europe-2023.pdf

47. Simoens, S., Lacosta, T. B., & Inotai, A. 2024. Learnings from cross-border biosimilar pricing policies in Europe. Expert Review of Pharmacoeconomics & Outcomes Research, 24(5), pp. 585-588

48. IVM. 2023. Savings from the use of biosimilars amount to almost 800 million euros per year (press release). Available at: https://www.medicijngebruik.nl/projecten/persbericht/5508/besparingen-door-inzet-biosimilars-lopen-op-tot-bijna-800-miljoen-euro-per-jaar-(persbericht)

49. https://www.iqvia.com/-/media/iqvia/pdfs/china/viewpoints/iqvia-institute-general-use-of-medicines-2024-for-print.pdf

50. https://www.gov.uk/government/publications/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth-summary-of-the-heads-of-agreement/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth-summary-of-the-heads-of-agreement

51. Pharmaceutical Technology. 2024. Out with the old, in with the new: Decoding biosimilar access with VPAG. Available at: https://www.pharmaceutical-technology.com/features/out-with-the-old-in-with-the-new-decoding-biosimilar-access-with-vpag/?cf-view

52. APM (2024) Call for measures on generics and biosimilars to be added to French draft budget for 2025. Available at: https://www.apmhealtheurope.com/story/21106/90281/call-for-measures-on-generics-and-biosimilars-to-be-added-to-french-draft-budget-for-2025

53. https://www.ispor.org/docs/default-source/euro2022/valid-insightispor-2022trends-in-european-pharmaceutical-tender-requirements-and-pdf.pdf?sfvrsn=969b3fb_0

54. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/advancing-biosimilar-sustainability-in-europe.pdf

55. Simon-Kucher. 2016. Payers' price & market access policies supporting a sustainable biosimilar medicines market. Available at: https://www.medicinesforeurope.com/wp-content/uploads/2016/09/Simon-Kucher-2016-Policy-requirements-for-a-sustainable-biosimilar-market-FINAL-report_for-publication2.pdf

56. IQVIA. 2023. The Impact of Biosimilar Competition in Europe. Available at: the-impact-of-biosimilar-competition-in-europe-2023.pdf

57. Moorkens, E., Vulto, AG., et al. 2017. Policies for biosimilar uptake in Europe: An overview. PLoS ONE, 12(12)

58. https://www.gabionline.net/reports/incentives-promoting-use-of-biosimilar-medicines-in-France

59. https://www.insee.fr/en/statistiques/fichier/8186110/08_ES542_Attia_et-al_EN.pdf

60. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/shared-savings-programs-in-europe/iqvia-institute-biosimilar-shared-savings-programs-in-europe-12-22-forweb.pdf

61. https://link.springer.com/article/10.1007/s40259-022-00523-z

62. Xcenda. 2023. Navigating the road to successful biosimilar uptake in Europe – Still some way to go? Available at: https://www.xcenda.com/insights/htaq-spring-2023-the-road-to-successful-biosimilar-uptake-in-europe

63. Scherlinger, M., Germain, V,m et al. 2018. Switching from originator infliximab to biosimilar CT-P13 in real-life: The weight of patient acceptance. Joint Bone Spine, 85(5). pp. 561-567

64. NVZA. 2017. NVZA Toolbox Biosimilars. Available at: https://nvza.nl/wp-content/uploads/2017/04/NVZA-Toolbox-biosimilars_7-april-2017.pdf

65. https://statements.eahp.eu/sites/default/files/resources/GPI%202.1-2.2%20add.pdf

C_EU_202506_006_250708

SAMSUNG
BIOEPIS

C_EU_202506_006_250708