Are we heading into a biosimilar void? The UK biosimilar landscape (2026–2032)

Created by Medicines UK, based on a report delivered by Aharav Consultants
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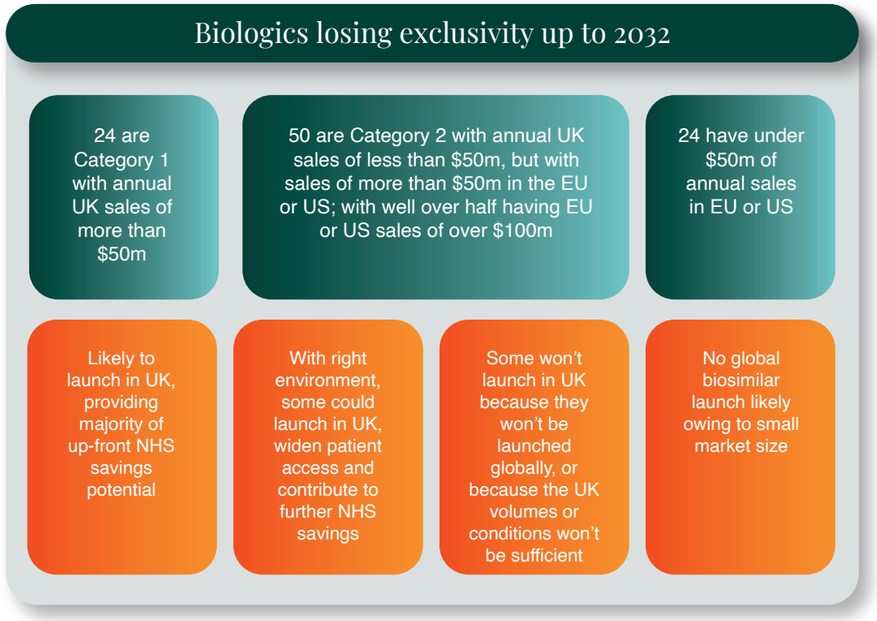
Executive summary

Overview

The UK market is entering a transformative period for biologics[1]. Between 2026 and 2032, 74 major biologic products are expected to lose exclusivity.

Biosimilars[2] are subsequently developed and commercialised based on the global market opportunity, in order that they may provide a return and cover their costs, currently averaging several hundred million US dollars[3] (over £200m)[4]. Confirmatory phase III trials amount to roughly half the costs. In 2021, the MHRA published updated guidance removing their automatic requirement as part of a biosimilar licence application, a change which EMA and FDA look set to adopt. By contrast, a generic medicine may typically require no more than £5m to develop and bring to market[5].

This report, commissioned by Medicines UK and authored by Aharav Consultants, categorises these biologic products into high value UK targets (Category 1) and products with limited opportunity to enter the UK's biosimilar market owing to currently low UK use of the patent-protected biologic compared to the EU and US – suggesting that the UK may not benefit from biosimilar competition (Category 2)[6]. We have not analysed products with low annual sales in the EU or US (under $50m or £37.5m), of which there are 24 products (14 US and 17 EU, with an overlap of 7).



The report will inform discussion of the potential size of the 'biosimilar void' – biologic medicines whose patents have ended but for which there are no competing biosimilars – and how it will affect the UK. To complement this analysis based on market size, Medicines UK interviewed six of its biosimilar company members, representing a significant proportion of the market. We did this to understand their perspectives on the biosimilar void, the UK market, and how the NHS can take full advantage of a range of biosimilars to ensure secure supply, provide cost savings and widen patient access.

Category 1: High value UK biologics: annual UK sales of more than $50m (£37.5m)

The analysis identified 24 core products poised for loss of exclusivity, as well as the following findings.

- Harmonised launch: 23 of these products share identical UK and EU patent expiry dates.
- In contrast, launch timings often vary between the UK and US. Current information suggests that for 7 products, the UK will likely see a launch before the US due to earlier patent expiries, while for 10 products, the US will likely launch a biosimilar before the UK due to different intellectual property (IP) strategies. In practice, however, potential litigation and settlements in the US may delay the timing for nearly half of the molecules for which the US theoretically has an earlier launch advantage.
- Key patent cliffs:
  o 2028: High value entries worth approximately $880m (£656m) expected in the UK.
  o 2031: A massive revenue shift of approximately $3bn (£2.23bn) expected in the UK.

Overall, the total annual brand value – or the combined NHS List Price cost paid by the Health Service each year – of these 24 patent-protected biologics is £5.1bn. This excludes any confidential discounts offered to the NHS by originators, including drugs supplied through patient access schemes.

Category 2: Products with annual UK sales of less than $50m (£37.5m) in the UK but more than $50m in the EU or US

50 products have annual UK sales of less than $50m (£37.5m).

In the EU, 29 of these products have annual sales exceeding $100m and all 50 have a total annual brand value of $10.4bn (£7.8bn). In the US, 39 of these products have annual sales exceeding $100m and all 50 products have a total annual brand value of $27bn (£20.3bn). By contrast, these patent-protected products have total annual NHS sales of $810m (£608m). Notwithstanding any confidential originator discounts offered, this cost is actually much higher since it will be borne each year from 2026 to 2032 by health system payers until patent expiry.

Of course, the UK is a far smaller market than the EU or US, so this difference in sales is to be expected. However, the UK's low sales for these biologics could be due to NHS value-for-money access restrictions rather than limited clinical need. While current volumes may appear unattractive, the UK may be able to benefit from likely launches in the EU, which will sometimes be years ahead of the US due to its complex 'patent dance'.

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[1] *Biologic or biological medicines are derived from living organisms. In the UK and EU, peptides and oligonucleotides are classed as biologic medicines, whereas in the US, both are regarded as small-molecule drug categories.*
[2] *'A biosimilar medicine is a biological medicine which has been shown not to have any clinically meaningful differences from the originator medicine in terms of quality, safety and efficacy.' https://www.england.nhs.uk/medicines-2/biosimilar-medicines/*
[3] *US dollars were converted to pounds sterling at $1 = £0.75 using online currency converters on 28 May 2026.*
[4] *https://www.mckinsey.com/industries/life-sciences/our-insights/an-inflection-point-for-biosimilars*
[5] *Not including value-added medicines, where a generic company has invested in changes to the reference product to enhance the patient and NHS system benefit or improve environmental performance (new form, strength or combination product).*
[6] *All annual sales are based on expected 2026/27 revenues, based on the NHS List Prices and using the three previous years of sales as a reference.*

By prioritising these molecules, developers can (depending on the effectiveness of the treatment) potentially unlock massive latent demand; discounted biosimilars can trigger a review of clinical patient treatment pathways. This may lead to a shift in their use from last-resort to early-line therapy, transforming niche products into high volume commercial successes while significantly reducing NHS treatment costs.

A question, then, is whether the UK should do more to attract some of these products for which annual UK sales are below $50m (£37.5m), since they make up two-thirds of all major biosimilars losing their exclusivity before 2032. We are, after all, likely to see an EU launch for a significant proportion of these products, and biosimilar suppliers may well consider making them available to the UK market if there is encouragement to do so. The savings – potentially amounting to more than £40m each year on average – could supplement the admittedly larger NHS savings opportunities from the Category 1 high value UK biologics losing exclusivity in the UK. A second question is whether lower acquisition prices resulting from biosimilar competition could make treatments where use of the patent-protected biologic is currently limited due to its high cost a more cost-effective treatment option for a larger number of patients. This will, of course, vary from one biosimilar launch to another, but there will very likely be a group of patent expiries where biosimilar competition could require a review of previous guidance restricting patient access in some way.

Company perspectives on the void and on launching biosimilars in the UK

These questions and others are explored at the end of this report in a summary of our members' views on launching biosimilars, the extent of the biosimilar void and what the UK can do to reduce the void.

In most cases, members felt that the UK will only be supplied if the product is being launched internationally. However, the UK can encourage the development and commercialisation of biosimilars with smaller markets. This would allow the UK to build on the MHRA's initiative of not requiring confirmatory studies. The impact of the MHRA adopting a streamlined approach in 2021 has not been enough on its own to affect companies' global development plans and timelines, but with regulators like FDA, EMA and others following, the streamlined approach is now likely to be factored in by biosimilar suppliers. The effect of this change will become clearer over the next few years. The UK needs to ensure that its internal market remains attractive as biosimilar demand and uptake grow elsewhere, and that domestic supply constraints and withdrawals are kept to a minimum, by securing the capacity the NHS and patients need.

Practical measures to support these objectives mentioned by members include:

- Employing an aligned approach by the MHRA, Office for Life Sciences and NHS to explain that the ending of confirmatory phase III trials as routine for biosimilars is based on regulatory experience and on what is required to successfully demonstrate similarity with the reference product. A failure to do so could allow this change, begun by the MHRA and followed by other leading regulators, to wrongly infer biosimilars as being of lower quality.
- Copying Health Canada's approach of presuming that confirmatory studies will not be required for a biosimilar to be licensed in the UK.
- Considering the impact of VPAG in applying a significant clawback to NHS biosimilar sales, particularly for lower value biosimilar markets. Some respondents felt that biosimilars in small patient cohort areas should even be viewed as 'orphan drugs' for which a broader range of incentives are in place to attract patent-protected medicines to serve these disease populations.
- Building on commitments to enhance horizon-scanning and lengthen tender lead times, NHS England should publish a list of upcoming lower value biologic patent expiries, which include biosimilars for which the patient cohort could grow through the supply of more affordable versions and which could benefit from NHS switching incentives.
- Utilising the centrally developed gainshare agreement, for lower value but strategically important biologic loss-of-exclusivity medicines should be considered by the NHS. This would send clear a message to the market and encourage switching when cost-effective competition occurs. For these molecules, the incentive to switch for NHS trusts and ICBs may not be so immediately apparent, but the cumulative savings potential will enable widened patient access at the same time.
- Tendering for certain important but lower value biosimilars as a single cross-UK NHS entity to maximise volumes and attractiveness, while taking care not to impact speed of biosimilar entry.
- Deploying a small portion of the UK's research architecture to support biosimilar research, including explicitly encouraging applicants to research biosimilars where none exist (including biosimilar cell and gene therapies) in areas of clinical need.
- In addition, the National Institute for Health and Care Research (NIHR) Industry Hub should develop a biosimilar pathway (including support for phase 1 trials) and promote it to the biosimilar industry.
- Last, reflecting some members' comments of a finite global biosimilar production capacity that restricts the number of biosimilar entrants, considering whether the UK's existing stakes in domestic manufacturing could be efficiently redirected to support biosimilar development.

These are individual member ideas generated from the interviews and do not always represent policy proposals that have been agreed upon by the Medicines UK membership.

As we enter a 'golden decade' for biosimilars, with many biologics losing exclusivity, this report looks ahead over the period from 2026 to 2032. Although not all of these products will be marketed, the UK can and should continue to play an important role in maximising the domestic and global healthcare opportunities from those biosimilars that are launched.

Background

Commissioned by Medicines UK, this report looks at biosimilar opportunities in the UK from 2026 to 2032, focusing on potential biosimilar launches in the UK compared to those in the EU and US. The following analysis is based on the HORIZONS® dataset created by Aharav Consultants.

The benchmarking for the UK market is based on UK vs EU/US approvals and launches, as well as practical feasibility, regulatory hurdles and pricing strategies.

The findings presented are intended solely as a directional analysis and represent the 'most likely' trajectory for biosimilar entry based on current IP landscapes. Due to the inherent fluidity of patent litigation, secondary patent filings and regulatory shifts, the dates provided should be regarded as estimates rather than definitive launch timelines.

This evaluation does not account for external commercial variables, including technical and manufacturing complexity, regulatory and pricing hurdles, and market dynamics.

The sales data used in this report have been sourced from publicly available, open-access repositories. These figures may thus be subject to revision, and they may not reflect actual market value at the date of publication or any confidential discounts provided. The report should therefore be used as a strategic guide rather than a definitive commercial forecast.

Differences between UK and EU/ US regulatory and IP frameworks

UK vs EU frameworks

Regulatory

Biosimilars, like generics, face a twin track of originator market protection before they can be launched. Biosimilars and generics are launched when both the regulatory track and the patent track are understood to no longer be in force.

Looking at the regulatory side, in the UK and EU, biosimilars are approved through the MHRA and EMA scientific comparability routes, respectively, which emphasise product-specific analytical similarity, immunogenicity, and clinical and pharmacokinetic comparability. Note that clinical endpoint studies are becoming less internationally important for regulatory decision-making as in vitro techniques become more powerful[7]. Confirmatory efficacy studies are also now accepted as being a less sensitve tool and are not required to demonstrate biosimilarity – analytical and clinical pharmacokinetic studies are sufficient. Once the first biologic is approved, periods of data exclusivity (8 years) and marketing exclusivity (bringing the total to 10 years, which can become 11 years if the originator obtains authorisation for at least one new therapeutic indication providing a 'significant clinical benefit') automatically become applicable[8]. The EU process is generally less litigation-structured than the US process at the regulatory level, because patent disputes are handled separately.

Patents and IP

In the UK and EU, the patent for biologics (as with small molecules) can be extended for up to 5 years via supplementary protection certificates[9] (SPCs), with an additional 6-month paediatric extension upon agreeing a paediatric investigation plan (PIP).

Because SPCs are granted on a country-by-country basis, rather than through a centralised EU authority, developers must file separate applications in the UK and in each EU member state. This decentralised process can result in inconsistent approval timelines or even rejections in specific territories. While SPC expiry data are generally fairly harmonised, discrepancies can arise, creating fragmented loss of exclusivity dates. This offers strategic windows for early biosimilar launches in certain markets while the reference product remains protected in others.

Actual dates of potential loss of exclusivity/biosimilar entry are based not just on the SPC but also on later-expiring use patents, method-of-administration patents or blocking patents, which are likely to extend the originator brand's monopoly further.

Finally, patent enforcement is fragmented across countries. The UK and EU have historically enabled earlier biosimilar commercialisation than the US because approval is not coupled to a mandatory patent exchange mechanism.

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[7] *https://www.gov.uk/government/publications/guidance-on-the-licensing-of-biosimilar-products/guidance-on-the-licensing-of-biosimilar-products; https://www.ema.europa.eu/en/reflection-paper-tailored-clinical-approach-biosimilar-development; https://www.fda.gov/regulatory-information/search-fda-guidance-documents/scientific-considerations-demonstrating-biosimilarity-reference-product-updated-recommendations*

[8] *Agreed in December 2025, the EU 'Pharma Package' will change this landscape in the EU once it becomes effective. Similarly, the proposed EU Biotech Act could also do so.*

[9] *An SPC is an intellectual property right that extends the protection of patented pharmaceutical products for up to 5 years after patent expiry to compensate for regulatory delays.*

UK vs US frameworks

Regulatory

The regulatory and patent tracks are linked in the US. A biosimilar approval [351(k) biosimilar application] can be filed with the FDA from 4 years after the reference product's initial licensure. Even if the FDA finishes its review in year 6 or 7, it is statutorily prohibited from granting final approval until the full 12-year exclusivity period has lapsed. The FDA may grant originators an additional 6 months' paediatric exclusivity.

IP

Under the 351(k) pathway and the BPCIA[10], US biosimilars undergo a structured 8-month 'patent dance' to exchange manufacturing data and patent lists before litigation. While the reference product enjoys 12 years of exclusivity, litigation is typically divided into an initial exchange phase and a second phase triggered by a 180-day commercial notice. Although recent case law allows applicants to omit the dance to reach court faster, it does not eliminate the underlying patent risks. Filing at year 4 allows the patent dance and litigation to begin nearly 8 years before the product can actually launch.

Practical takeaway

The US pathways are linked via the complex BPCIA patent dance, while the UK/EU system is delinked, allowing regulatory and patent tracks to move independently. This streamlined European approach often leads to earlier market entry, as litigation can begin at any time – even before filing – via revocation actions.

A key hurdle in both regions is identifying the relevant patents. While the US Purple Book has become more transparent due to 2021 and 2024 updates requiring the listing of patents exchanged during the dance, it still lacks the comprehensive, upfront 'automatic' listing found in the small-molecule Orange Book. Consequently, Europe – including the UK – generally remains faster and more predictable than the US. Without a mandatory dance, biosimilars in Europe can launch upon expiry of the later of the patent/SPC and the 10-year data/marketing exclusivity. By comparison, US litigation often delays entry for several years beyond the 12-year exclusivity window (or the patent if that is still in force).

Scope of analysis

The main data points for evaluation, based on the most relevant patent landscape information, were screened using the HORIZONS® dataset created by Aharav Consultants. This generated a total of 74 significant biologics (including peptides and oligonucleotides[11]) in the UK that are likely to lose their exclusivity between 2026 and 2032.

UK patent expiries (2026–2032)	Biologics	Peptides	Oligonucleotides
74	56	16	2

This screening, which takes into account later-expiring use patents, patent term extensions and other blocking patents, provides an estimation of the most likely date that a biosimilar would be launched. As mentioned above, the actual launches of biosimilars by companies would depend on company timelines, infringement analysis, market size and other factors.

[10] *https://www.fda.gov/drugs/biosimilars/biological-product-innovation-and-competition*
[11] *In the UK and EU, peptides and oligonucleotides are classed as biologic medicines, whereas in the US, both are regarded as small-molecule drug categories. We have included both synthetic and biological peptides and oligonucleotides.*

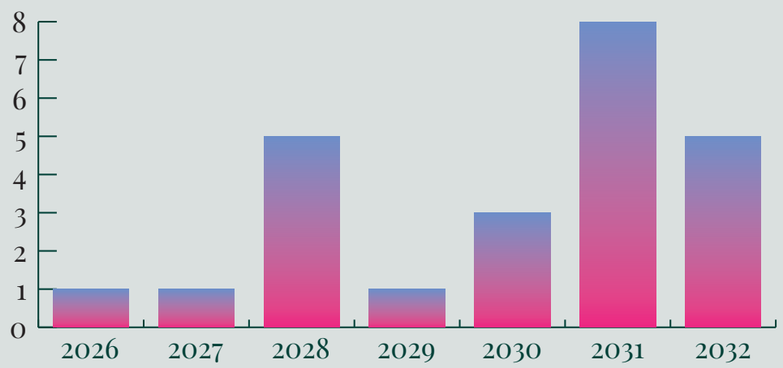
Category 1: High value UK biologics: annual UK sales of more than $50m (£37.5m)

Expected biosimilar launches (UK)

24 biologic products with annual UK sales exceeding $50m (37.5m) will lose their exclusivity between 2026 and 2032.

UK patent expiries (2026–2032)	Biologics	Peptides	Oligonucleotides
24	19	4	1

Expected numbers of biologics losing patent protection each year (2026–2032)[12]



[12] *HORIZONS® dataset created by Aharav Consultants.*
[13] *HORIZONS® dataset created by Aharav Consultants.*
[14] *The values of individual dosage forms are not considered for this report.*

Top 10 expected biosimilars by value between 2026 and 2032[13]

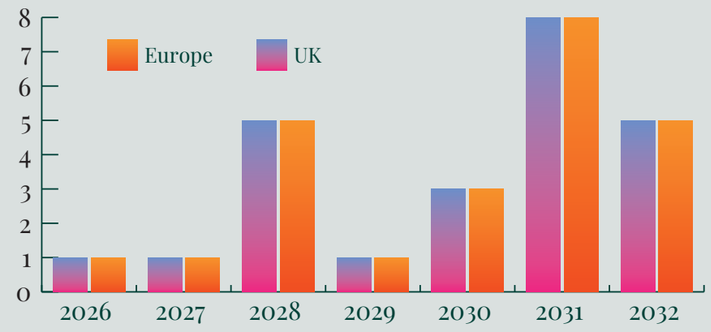
Active substance[14]	Revenue ($m)	Revenue (£m)	Earliest biosimilar launch
Pembrolizumab	1100–1200	825–900	21/01/2031
Daratumumab	650–700	488–525	22/03/2031
Vedolizumab	380–390	285–293	02/05/2032
Nivolumab	330–340	248–255	24/12/2030
Semaglutide (Ozempic and Wegovy)	310–320	233–240	19/03/2031
Ocrelizumab	280–290	210–218	15/12/2028
Secukinumab	250–260	188–195	03/08/2030
Ofatumumab	220–230	165–173	17/10/2028
Atezolizumab	180–190	135–143	24/09/2032
Ipilimumab	140–150	105–113	15/01/2027

UK and EU in harmony

There is an overwhelming commonality between these 24 products in the UK and EU. The concentration of high value products losing exclusivity in 2028 and 2031 represents the most significant biosimilar opportunity within the current forecast window.

- Synchronised launches: As depicted in the chart below[15], 23 of these products share identical UK and EU launch dates, facilitating simultaneous regional entries. The one that does not fully align, atezolizumab, is still due to launch in the same year in both the UK and EU.

Number of products launched in the UK vs Europe by year



- High value targets: 18 of the 24 products are ‘blockbusters’, with estimated annual EU sales of more than $1bn (£750m).
- Critical patent cliffs:
  - 2028: 4 of the 5 products are blockbusters.
  - 2031: A pivotal year: all 8 products losing exclusivity are blockbusters.

[15] *HORIZONS® dataset created by Aharav Consultants.*

The UK annual brand values for the 24 products combined is currently £5.1bn. This means that the NHS stands to save billions of pounds from biosimilar competition in these molecules.

Key strategic findings

General trend: The synchronisation of biosimilar launch dates across Europe is primarily driven by the harmonised issuance of SPCs. Because these extensions are typically granted simultaneously across the UK and the 'big 5' EU nations (France, Germany, Italy, Spain and the Netherlands), the primary patent protection usually expires on the same day across the region.

Uniformity vs outliers: Discrepancies in how individual national patent offices process and grant SPCs can create high value strategic openings. While most EU member states eventually align, isolated rejections in specific markets can result in patent-free windows, allowing biosimilars to enter these territories months or even years ahead of the rest of Europe.

UK/EU divergence: A prominent example of regulatory decoupling can be seen with atezolizumab, where an active SPC currently maintains a blocking position in the UK, while equivalent protections have been granted in a handful of EU territories. This fragmented IP landscape has opened a clear path for biosimilar developers to launch in major European markets before the UK's legal barriers fall.

Comparison with the US launch calendar

We next compare the timing of expected UK biosimilar launches with those in the US. These are the earliest possible UK or US biosimilar launches. Note that a biosimilar will not always be on the market from day one of loss of exclusivity.

UK patent expiries 2026–2032	UK patent expiries before US	UK patent expiries same time as US	UK patent expiries after US
24	7	7	10

Active substance	UK launch	US launch[16]	UK vs US	Comments
Abatacept	2026	2028	Before US	Key patent expiry before the US for 125 mg/ml.
Ipilimumab	2027	2027	Same as US	Key patents expire in the same year.
Mepolizumab	2028	2027	After US	Key patent abandoned in the US but valid in the UK.
Benralizumab	2028	2029	Before US	Key patent expiry before the US.
Ofatumumab	2028	2030	Before US	Withdrawn in the UK – international recognition procedure may be considered for the UK.
Trastuzumab emtansine	2028	2028	Same as US	Non-infringing formulation needed. Patent dance may delay launch in the US.
Ocrelizumab	2028	2029	Before US	Key patent expiry before the US.
Dulaglutide	2029	2027	After US	Non-infringing formulation needed. Patent dance may delay launch in the US.
Secukinumab	2030	2031	Before US	Key patent expiry before the US.
Asfotase alfa	2030	2029	After US	Later SPC expiry in the UK.
Nivolumab	2030	2028	After US	Later key patent expiry in the UK.
Pembrolizumab	2031	2029	After US	Non-infringing formulation needed. Patent dance may delay launch in the US.
Semaglutide (injectable)	2031	2031	Same as US	US and UK patent expiry in same year.
Semaglutide (LAR)[17]	2031	2031	Same as US	US and UK patent expiry in same year.
Semaglutide (tablet)	2031	2033	Before US	UK launch expected before US.
Daratumumab	2031	2029	After US	Key patent expiry after the US.
Ixekizumab	2031	2030	After US	Non-infringing formulation advantage in the US subject to patent dance; UK launch after SPC.
Nusinersen Na	2031	2030	After US	Later key patent expiry in the UK.
Guselkumab	2031	2031	Same as US	Key patents expire in the same year.
Axicabtagene ciloleucel	2032	2029	After US	Later SPC expiry in the UK.
Vedolizumab	2032	2032	Same as US	Later launch due to dosage regimen patent-blocking.
Tezepelumab	2032	2032	Same as US	Key patents expire in the same year.
Atezolizumab	2032	2030	After US	SPC not granted in most EU countries; later SPC expiry in the UK.
Isatuximab	2032	2033	Before US	Key patent expiry before the US.

[16] *The launch dates are estimates and may differ depending on the patent dance.*
[17] *Long-acting release.*

Key strategic findings

As noted, UK and US market protection expiries are likely to vary in about 70% of cases. The following reasons could account for this gap between the UK/EU and the US:

Formulation hurdles: Success for key molecules like trastuzumab emtansine and dulaglutide depends on developing non-infringing formulations to bypass secondary patents. It may not be technically easy or cost-efficient to develop these products in the limited time window.

SPC/patent coverage: SPC expiries (in the UK) and abandoned patents could also affect precise launch timings.

Regulatory friction: Even where US patents expire earlier, the BPCIA patent dance and 180-day notice requirement often delay actual US entry, potentially giving the UK a functional lead. As can be seen in the earlier table comparing UK/US loss of exclusivity dates, this is the case for 4 molecules for which the patent is currently expected to expire earlier in the US.

Despite the variation, like the UK/EU, 2031 represents a massive opportunity for the US.

Overall conclusion for Category 1

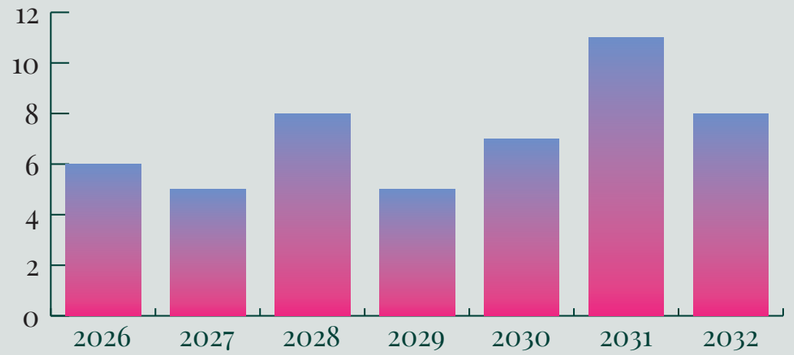
One can expect biosimilar launches in the UK to coincide with those in the EU for nearly all products. The UK's biosimilar market could offer a distinct 'first-mover' advantage due to its delinked regulatory framework, allowing launches to occur years ahead of the US in some cases.

Category 2: Products with annual UK sales of less than $50m (£37.5m) in the UK but more than $50m in the EU or US

50 biologic products with relatively low UK sales but higher sales in the EU or US will lose their exclusivity between 2026 and 2032.

UK patent expiries 2026–2032	Biologics	Peptides	Oligonucleotides
50	37	12	1

Expected numbers of biologics losing patent protection each year (2026–2032)



Untapped opportunity or impenetrable bottlenecks?

Comparison of annual sales between EU, UK and US markets

Revenue ($m)	No. of products (EU)	No. of products (UK)	No. of products (US)
0–25	3	37	2
26–50	6	13	1
51–100	12	-	8
101–500	24	-	27
501–1000	3	-	4
>1000	2	-	8
Estimated annual sales (total)	$10.4bn (£7.8bn)	$810m (£608m)	$27bn (£20.3bn)

Key strategic findings

Although all 50 products have comparatively low annual sales of less than $50m in the UK, 29 products in the EU and 39 products in the US have annual sales of more than $100m.

All 50 products in the EU have total annual sales of $10.4bn (£7.8bn), compared to total annual UK NHS sales of only $810m (£608m). The contrast with the US is even greater, with total sales of $27bn (£20.3bn) for the 50 products.

Even though the UK is a single nation, this is nonetheless a striking difference in estimated sales. It suggests that there is value in these products globally, but not in the UK. It also suggests that the UK could be a beneficiary by piggybacking on global launches. For example, in the case of denosumab, over 10 marketing authorisation holders wanted to supply a comparatively small UK market.

'Big gap' analysis: UK v EU

The sample of Category 2 products in the following table have significant EU sales, and so biosimilar competition is expected to develop. In that case, the cost leap of making biosimilars available in the UK would be comparatively small. However, the lower take-up in the UK may prevent biosimilar competition from developing.

Active substance	Earliest biosimilar launch year	EU est. sales ($m)	UK est. sales ($m)
Alirocumab	2029	1100–1200	30–35
Brentuximab vedotin	2030	500–550	30–35
Canakinumab	2026	800–850	25–30
Evolocumab	2031	1200–1300	40–45
Carfilzomib	2030	500–550	25–30
Albutrepenonacog alfa	2031	300–310	10–15
Blinatumomab	2029	330–340	30–35

'Updated gap' analysis: UK v US

Again, we note a sample of Category 2 products that are high value biologics in the US but have limited uptake in the UK.

Active substance	Earliest biosimilar launch year	US est. sales ($m)	UK est. sales ($m)
Linaclotide	2027	3700–3800	0–10
Lisocabtagene maraleucel	2032	750–800	15–20
Romosozumab	2031	1700–1800	25–30
Elasomeran	2031	1800–1900	0–10

Potential reasons for the gap

Pricing restrictions: The NHS, following on from NICE appraisals, deploys restrictions based on value-for-money assessments. If a biosimilar can be offered with a sufficient discount, NICE could widen the clinical guidelines, giving the drug greater potential to generate revenue.

Market dynamics: The marketing route for originator products via the NHS may also be a bottleneck due to the way brands are (or are not) promoted and prescribed, leading to low sales. This may make these products unattractive for biosimilar competition.

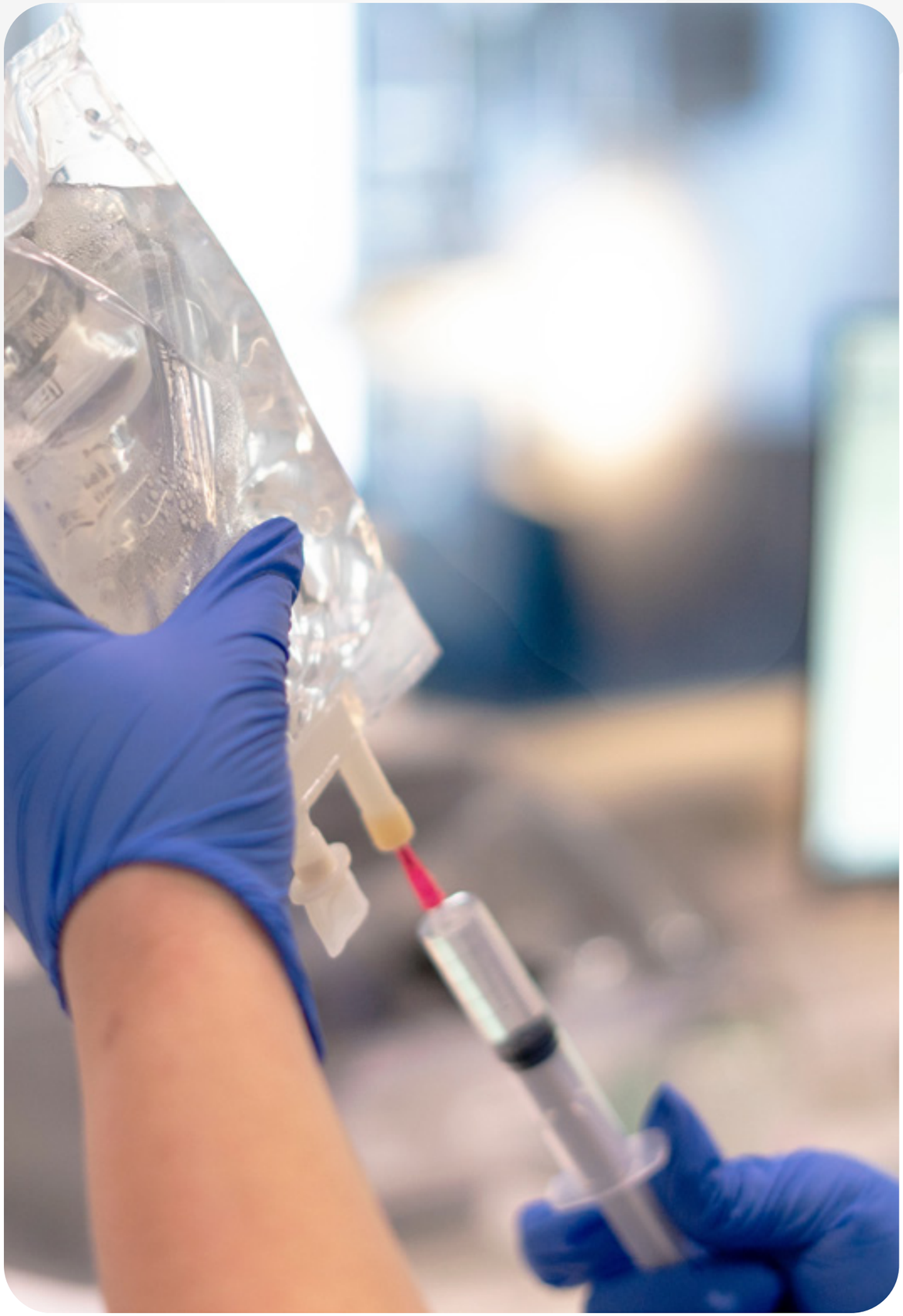
Lack of global awareness of UK sales potential: A lack of knowledge of the opportunity may also contribute to these products being deprioritised for biosimilar development. The NHS and government need to examine the potential of products, then pave the way for their biosimilars, rather than incorporate them within current policies.

Overall conclusion for Category 2

While the UK stands to benefit from most Category 1 medicines, the rationale for a company launching a biosimilar for a Category 2 medicine in the UK is less clear, owing to limited existing biologic sales. There are also no wider launch incentives, such as those available for orphan patented protected drugs. Meanwhile, the VPAG sales clawback still applies.

Yet, the UK could benefit from EU launches of these Category 2 products. Collectively, their adoption in the UK could potentially save the NHS on average more than £40m per year between 2026-2032 while widening access to hitherto limited treatments. As the years go on, the annual saving would far exceed this amount as the savings multiply over time.

If biosimilars enter the market and NICE subsequently decides to widen patient access, it could trigger a significant volume expansion, transforming previously 'unattractive' niche products into higher volume commercial UK successes. The question is how to encourage more lower value biosimilars launched in the EU to also launch and maintain a presence in the UK. The following member perspectives on launching biosimilars and the opportunities for the UK aim to answer this question and provide insight on other aspects of biosimilar supply.



Member perspectives: the evolution of launching biosimilars

Medicines UK interviewed six biosimilar companies that are members of Medicines UK. Those providing feedback were all companies' UK biosimilar or market access leads, often responsible for other European markets. Views were sought on why companies launch biosimilars, how the UK is viewed as a market, how the market could evolve, and what would make the UK a more attractive destination.

The companies questioned had a range of sizes, lengths of time in the biosimilar market, biosimilar portfolios and supply chain structures. Ideas offered by individual member companies do not necessarily constitute an agreed Medicines UK position. Some common themes emerged from the interviews:

Where does the UK rank?

- The UK is invariably seen as a top 5 European market in which to launch biosimilars. For most companies, to cover the cost of development and production, biosimilars launched globally are usually also launched in the UK.
- For some large European markets, biosimilars are primarily supplied in a community setting. In the UK, uptake has been typically driven by secondary care tenders. The relative ease of accessing the market via these tenders makes the UK particularly attractive for new entrants looking to launch into Europe. This can increase supply volatility, something NHS England is looking to address through value-based procurement.
- The UK is currently attractive for two reasons. First, it has clearly made biosimilars a priority, an approach that has penetrated to companies globally. Public targets and pro-biosimilar policies have been formulated, which politicians and NHS leaders have promoted. Second, the UK (particularly England) offers large volumes and increasingly fast uptake of biosimilars following loss of exclusivity of biologics, even though UK biosimilar prices are comparatively low and price erosion from patent expiry has become similar to that in generic markets.
- There are risks in continuing to rely on the UK's sizeable and fast uptake as its USP, as comparable European nations are actively seeking to increase biosimilar penetration; this year France and Germany have instituted more pro-biosimilar policies. Until now, Europe has led on biosimilars, while the US, the world's largest and most profitable pharmaceuticals market, has lagged. This may be about to change, in which case the finite biosimilar capacity will increasingly be prioritised to meet US demand.
- There is also a risk of the UK being viewed as a market in which to build up volume, followed by withdrawal as other more profitable markets emerge.

What about the so-called biosimilar void?

- The void is real. Some companies take a more nuanced or portfolio-minded approach, for example, by balancing niche biosimilar candidates where they can make a real difference against competing for market share for blockbuster patent expiries.
- Nevertheless, companies herding or congregating around blockbusters has been a feature of the biosimilar market thus far. This is because high value biosimilars are considered lower risk. Indeed, the global market value of biologics pre-loss of exclusivity is a priority consideration for both biosimilar development and commercialisation.
- It remains to be seen whether the position that leading regulators have adopted – begun by the MHRA, to its credit – of not requiring confirmatory clinical studies as routine will, as a by-product, erode the void over the next few years. This regulatory-driven approach could lead to less herding and more selectivity in the biosimilar market.
- Nevertheless, some respondents felt that the void would still exist in some form because global biosimilar manufacturing capacity is finite. They also noted that biosimilar companies have limited bandwidth and have to launch selectively.

What do companies say about the mechanics of the UK market?

- Companies mostly agreed that being able to launch on day 1 of a tender is vital commercially. This approach provides market share and reflects the difficulty of switching patients' medicines following initial biosimilar entry. The number of companies that can launch on day 1 will be increased by clearer, more predictable lead times, particularly as biosimilar uptake from day 1 appears to be increasing. NHS England is transitioning towards such an approach.
- There is clear unease about the genericisation of the biosimilar market, particularly in the UK. There is concern that this trend will make the long-term market less attractive, which will result in less capacity allocated to the UK following launch. One participant, from a company that seeks out partners, was concerned that some of the original biosimilar players were no longer active or less active in the market.
- For rarer diseases, the cost of launching biosimilars is higher and the market is smaller. In these treatment areas, significant uptake may only occur from year 3 or 4, with clinicians and patients likely to be reluctant to switch. This takes more investment and requires more patience. Return-on-investment timelines are likely longer. Therefore, 'generic-like' reductions may not be possible.

So what can the UK meaningfully do about the biosimilar void?

- The companies acknowledged the role of MHRA in being the first major regulator not to require confirmatory studies. Some worried that the lack of routine phase III trials to demonstrate similarity with the reference product, a decision taken by MHRA and followed by other leading regulators, could lead to the misconception that biosimilars are of lesser quality than the originator version. The MHRA, Office for Life Sciences and NHS must adopt a concerted approach to prevent this.
- On phase III trials, some noted that the UK could now follow Health Canada's approach of presuming that confirmatory studies are not required unless a regulatory judgement has stated otherwise.
- The UK's VPAG[18] clawback of up to 35% of NHS sales up to the end of 2028 is a disincentive to launch, particularly for riskier, smaller-market biosimilars, and should be reconsidered for the next voluntary branded medicines pricing scheme. It also undermines international boardroom sentiment towards the UK, which can have broader investment impacts. Beyond VPAG, biosimilars serving smaller patient populations, such as for rare diseases, could be considered as orphan drugs, with incentives to encourage supply to unlock competition, wider access and savings potential.
- NHS England has a list of nationally prioritised biological medicines[19], for which biosimilar competition is most desired, which it published in April 2025. This list should be extended to cover lower value biologics that present strategic opportunities for the next 5 years in the updated iteration of its commissioning guidance. We understand that NHS England is currently looking into this to demonstrate the planning that goes on to support switching to the best value biologic for smaller market biologics losing exclusivity. Alongside this, companies listen to and sometimes act on major payors' requests for more niche products.
- This extended list could contain products whose market size is currently limited due to a restricted NICE appraisal but could be prescribed earlier or for additional indications following cost-effective competition.
- Indeed, several companies noted that NICE guidance or reappraisals that lead to expanded patient volumes can become relevant internationally, thereby supporting overall product viability. NICE is considering developing a bespoke off-patent reappraisal process, which could have clear value in these situations.
- These lower value, but strategically important products could be ideal candidates for a centrally coordinated gainshare payment to encourage NHS trusts to switch. Gainshare is arguably more important for lower value but strategically and cumulatively significant biosimilar opportunities than for blockbusters, which are likely to more easily attract local NHS interest.
- The home nations of the UK could purchase collectively for certain biosimilars where building volume may be helpful to strengthen market attractiveness, so long as early launch capability is not impacted.
- NIHR should proactively support research, including in partnership with industry, that drives biosimilar development. In particular, the NIHR's next Biomedical Research Centre competition should explicitly encourage applicants to research biosimilars where none exist (including biosimilar cell and gene therapies) in areas of clinical need.
- In addition, the NIHR Industry Hub should develop a biosimilar pathway (including support for phase 1 trials) and promote it to the biosimilar industry.
- Last, in view of global production limitations, the government should explore whether existing publicly funded domestic manufacturing could be efficiently redirected to support biosimilar development.

Disclaimer: This evaluation does not account for external commercial variables, including technical and manufacturing complexity, regulatory and pricing hurdles, and market dynamics. It is strongly recommended that a detailed and independent analysis is conducted for each potential product for the UK market. Future research could identify the biologic API categories more or less likely to attract biosimilar development.

[18] *https://www.gov.uk/government/publications/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth*

[19] *https://www.england.nhs.uk/long-read/commissioning-framework-for-best-value-biological-medicines/*

Are we heading into a biosimilar void? The UK biosimilar landscape (2026–2032)

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