European Commission

Capacity building to support the uptake of biosimilars in a multistakeholder approach

AUGMENT Biosimilars
Country fiche UNITED KINGDOM

Excerpt from:

European Commission: European Health and Digital Executive Agency, Vogler, S., Habimana, K., Helter, T., Knoll, V. et al., Capacity building to support the uptake of biosimilars in a multistakeholder approach – Final study report. Annex 7, AUGMENT, Country fiches, Publications Office of the European Union, 2025

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augment biosimilars

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Manuscript completed in November 2025

First edition

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Luxembourg: Publications Office of the European Union, 2025

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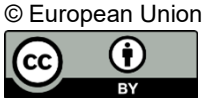

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PDF ISBN 978-92-95239-98-2 doi: 10.2925/9409811 HW-01-25-049-EN-N

Annex 7.32

AUGMENT Biosimilars country fiche: United Kingdom 2025

Capacity building to support the uptake of biosimilars in a multistakeholder approach

The AUGMENT Consortium produced this country fiche as part of the project "Capacity building to support the uptake of biosimilars in a multistakeholder approach (HADEA/2023/OP/0040)" commissioned by the European Health and Digital Executive Agency (HaDEA). The AUGMENT Consortium consists of the Austrian National Public Health Institute (Gesundheit Österreich Forschungs- und Planungs GmbH / GÖ FP), as consortium lead; the Polish Agency for Health Technology Assessment and Tariff System (Agencja Oceny Technologii Medycznych i Taryfikacji / AOTMiT), the Medical University Sofia (MUS), and the NOVA National School of Public Health in Lisbon.

In this project (abbreviated AUGMENT Biosimilars project), the AUGMENT Consortium performed a **comprehensive study** which aimed to offer a **mapping and** an **analysis of existing policies and practices** to encourage biosimilar uptake and competition in 32 European countries (all European Union (EU) and European Free Trade Association (EFTA) Member States, and the United Kingdom). In the analysis, the impact of biosimilar policies on improving patient access to medicines as well as barriers and facilitators in the policy implementation will be studied. For further information see biosimilars.goeg.at.

Key terms related to biosimilar policies can be found in the project's Glossary.

Contributors

This country fiche was produced by GÖ FP based on information the PPRI network was used, and findings from systematic and narrative literature reviews.

We gratefully acknowledge the validation of this country fiche by:

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How to quote: Knoll V, Helter T: AUGMENT Biosimilars country fiche: The United Kingdom 2025. Annex to the study on "Capacity building to support the uptake of biosimilars in a multistakeholder approach", AUGMENT, 2025. Commissioned by the European Health and Digital Executive Agency (HaDEA)

1 Summary of biosimilar policies and practice in the United Kingdom 2025

Key stakeholders

Key stakeholders involved in designing and implementing biosimilar policies include the Department of Health and Social Care (DHSC), which is responsible for legislation, pricing, and reimbursement policies. The Medicines and Healthcare products Regulatory Agency (MHRA) oversees regulatory provisions, quality assurance, and pharmacovigilance. The National Institute for Health and Care Excellence (NICE) provides health technology appraisals and position statements on biosimilars. The NHS England Medicines, Procurement and Supply Chain (MPSC) manages procurement and tenders. The British Biosimilars Association (BBA) represents the biosimilar industry. Position papers and guidelines have been published by these stakeholders to support biosimilar prescribing and use. For example, NHS England has published the updated commissioning framework for best value biological medicines , which provides detailed guidance on the use of biosimilars. The MHRA has issued guidelines on the licensing of biosimilar products, outlining the regulatory requirements for biosimilars in the UK.

Major biosimilar policies and practices

England does not use a biosimilar price link but employs tendering processes, particularly in the inpatient sector, to procure biosimilars. Contracts are awarded based on the Most Advantageous Tender (MAT) criteria, which consider a range of factors beyond just price, including cost-effectiveness, quality, supply reliability, and the ability to meet specific clinical needs. Biosimilars are included in outpatient reimbursement and hospital formularies. England has no reference price system in place, but for adalimumab products the same reimbursement price is applied country-wide. Doctors are recommended to prescribe biosimilars to naïve patients and decide on a case-by-case basis to switch those already on biologics to a biosimilar. Prescribing by the International Non-Proprietary Name is voluntary but strongly encouraged, however, it is discouraged for biologics. Community pharmacists are not allowed to substitute medicines (neither generics nor biologics). Information and educational activities (for instance, regular seminars and workshops conducted by NHS England or brochures, online resources from NICE and the Patient Information Forum) are targeted at healthcare professionals and patients to build trust in biosimilars.

Impact assessment

In England, the adoption of biosimilars has faced challenges due to concerns about adverse events, strong patient opinions, and device usability. Studies have shown that both healthcare professionals and patients are cautious about switching to biosimilars, despite regulatory assurances. The usability of devices associated with biosimilars has also been a significant barrier. However, supportive regulatory policies from the Medicines and Healthcare products Regulatory Agency (MHRA), such as updated guidance on the licensing of biosimilars, have been crucial in increasing

uptake. Educational initiatives by NHS England and other stakeholders, including seminars, workshops, and the dissemination of educational materials, have effectively raised awareness and understanding among healthcare professionals. The introduction of biosimilars like infliximab and etanercept has resulted in significant savings for the NHS, with cumulative savings of £38.8 million over two years. A nationwide campaign aimed at driving biosimilar uptake exceeded its target, achieving efficiency savings of £800 million a year. The NHS has set ambitious goals for biosimilar adoption, aiming for 80% of existing patients to use the best value biologic product within 10 months of a biosimilar becoming available and a 100% of new patients being started on a best value biologic where clinically appropriate.

Barriers, facilitators and good practice examples

Barriers to biosimilar adoption in England include complex regulatory frameworks, fragmented health systems, limited financial incentives and resources and stakeholder mistrust. Facilitators include clear national guidance, educational and financial initiatives, collaborative procurement strategies, and regulatory support from MHRA. Factors such as adverse events, strong clinician and patient opinions, and device usability have hindered biosimilar adoption.

Good practices involve multi-winner tenders, patient involvement initiatives, and informative publications and websites. Information and educational activities targeted at healthcare professionals and patients to build trust in biosimilars have been conducted, but evidence shows that there is still more to be done in this aspect. Supportive regulatory policies and educational initiatives have been effective in increasing biosimilar uptake and achieving policy objectives like improved patient access and affordability.

Recent developments

Over the past five years, the UK has seen significant developments in the biosimilar market. The NHS Long-Term Plan emphasizes biosimilar adoption, and the establishment of the Medicines Access and Value Directorate within NHS England focuses on maximizing value from medicines. Looking ahead, the NHS plans to further expand the use of biosimilars across different therapeutic areas and increase patient involvement in treatment decisions. Regulatory innovations are being explored to streamline biosimilar approvals.

Highlights and learnings

Key learnings from England's experience with biosimilars highlight the importance of clear policies, educational initiatives, and collaborative procurement strategies and implementation plans. A concrete example is the national framework tender for adalimumab, which was designed to ensure the best value biologic product for the NHS. This tender involved inviting manufacturers of biosimilar medicines and the originator to offer their best prices, resulting in significant savings. NHS England set nationally standardised reference prices for adalimumab, ensuring transparency and incentivising the use of the best value biologics and is planning on utilising this approach for future prioritised products.

The procurement strategy aimed to support a managed market with plurality of supply, ensuring long-term competition and value for money. Extensive engagement activities with key stakeholders, including patient groups, were undertaken to prepare the system for the use of the best value adalimumab product. This approach not only achieved substantial cost savings but also ensured patient involvement and acceptance, demonstrating the effectiveness of collaborative procurement strategies and regulatory support in building trust in biosimilars.

2 Key data regarding biosimilars in the United Kingdom

First biosimilar medicine launched (i.e. brought to the market):
somatropin (Omnitrope®) in 2006
Source: IQVIA 15 years of biosimilar experience in Europe

Number of the **biosimilars marketed**:
Over 20 molecules with biosimilars available, as of September 2024
Over 40 biosimilars (per trade name), as of September 2024
Source: IQVIA: Impact of biosimilar competition in Europe 2023

Biosimilar market shares in 2023 (or latest available data):

Over 80% **in volume** in 2022
Volume is defined as units dispensed

Value is defined as share of total pharmaceutical expenditure

The biosimilar market shares data relate to the total market (outpatient and hospital, public and private sectors)

Source: IQVIA: Impact of biosimilar competition in Europe 2023

3 Stakeholders involved in and targeted by biosimilar policies in the United Kingdom

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-relevant publications by this stakeholder group
Legislator	Department of Health and Social Care (DHSC)	Prepares legislation	
National regulatory authority	Medicines and Healthcare products Regulatory Agency (MHRA)	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance	Guidance on the licensing of biosimilar products - GOV.UK
Pharmaceutical pricing authority	Department of Health and Social Care (DHSC)	Implements pricing legislation regarding biosimilars, decides on the prices	
Pharmaceutical reimbursement authority	Department of Health and Social Care (DHSC)	Decides on inclusion into reimbursement for biosimilars and their price. Produces prescribing guidelines for biosimilars, responsible for prescription quotas	
Procurement agency	NHS England	Involved in tenders and procurement	NHS England » Biosimilar medicines
HTA agency / body	National Institute for Health and Care Excellence (NICE) Healthcare Improvement Scotland (HIS) All Wales Therapeutics and Toxicology Centre (AWTTC)	NICE is responsible for applying existing guidelines for the originator biologic to the biosimilar once it becomes available. It is also responsible for including biosimilars in multiple technology appraisals (MTAs) alongside their reference products.	Biosimilar technologies: NICE position statement - information for the public | Technology appraisal guidance | NICE guidance | Our programmes | What we do | About | NICE
National competition authority	Competition and Markets Authority (CMA)	Enforcement of the competition law, anti-trust cases	https://www.gov.uk/government/news/cma-issues-provisional-decision-in-relation-to-drug-firms-pricing
National patent office	Intellectual Property Office / Intellectual Property Office (UK)	Granting and managing patents on biologic medicines	
Doctors	*Represented by:* British Medical Association (BMA) *Medical societies*: Royal College of Physicians (RCP)	Prescribe biosimilars. Through shared decision making with patients	
Nurses	*Represented by:* Royal College of Nursing	Nurse injectors, specialist nurse prescribers, role for supporting patients (i.e. with concerns, side effects, specifics of switching to another medicine), building trust with patient, advice capacity.	
Community pharmacists	*Represented by:* National Pharmacy Association (NPA) Pharmaceutical Society of Northern Ireland	Dispense medicines, support patients	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-relevant publications by this stakeholder group
Hospital pharmacists	*Represented by:* Guild of Healthcare Pharmacists (GHP)	Support procuring medicines, inform patients / health professionals / procurers Prescribing – non medical prescriber. Pharmacist led clinics Adverse event management Key relationship with doctors to help encourage switching of patients	
Patient organisations	*Represented by:* National Voices Association of Medical Research Charities (AMRC)		
Consumer organisations	Citizens Advice		
Biosimilar industry	British Biosimilars Association	Produces and supplies biosimilars	
Generic industry	*Represented by:* British Generic Manufacturers Association (BGMA)	BBA is a sector group of BGMA	
Pharmaceutical industry in general	*Represented by:* The Association of the British Pharmaceutical Industry (ABPI)		https://www.gov.uk/government/news/cma-issues-provisional-decision-in-relation-to-drug-firms-pricing
Pharmaceutical industry for new biological medicines	*Represented by:* BioIndustry Association (BIA)		
Further relevant stakeholder group	Patient Information Forum	Information materials	

Source: Stakeholder mapping done by GÖ FP (AUGMENT Consortium)

4 Biosimilar policies and practices in the United Kingdom

Below, information on different biosimilar policies and practices is provided (and in some cases, also on further medicines, e.g., on generics or other biosimilars – presented in the grey shaded lines in the tables). Note that the information relates to the year 2024, to the national level and to outpatient and inpatient sectors, unless specified differently. **The information on the policies relates to England only.**

4.1 Pricing and procurement policies 2025

Biosimilar price link

A **biosimilar price link** is in place.	No
It applies for the following situations:	Not applicable
Price reduction of the first biosimilar compared to the reference product	Not applicable

Price reduction of the second, third and further biosimilars	Not applicable
Price reduction for the reference product	Not applicable
Any further specificities	Not applicable
Generic price link	No

Source: PPRI 2025

External price referencing

External price referencing is applied for biosimilars.	No
If yes, it is applied for the following situations:	Not applicable
Any specificities	Not applicable
External price referencing is in place for other medicines than biosimilars.	No

Source: PPRI 2025

Tendering

Some (or all) biosimilars are procured through tendering (or tendering-like) processes.	Yes
If yes, the scope with regard to the care sector:	Only inpatient sector
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	Several off-patent biological medicines, especially those to treat cancer, rheumatoid arthritis, and inflammatory bowel disease
Institutional framework	Centralized procurement for biosimilars is managed by NHS England
Information available on procurement procedures and practices	Contracts are awarded based on the Most Advantageous Tender (MAT) criteria, which consider a range of factors beyond just price, including cost-effectiveness, quality, supply reliability, and the ability to meet specific clinical needs.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	Example of national framework tender for adalimumab, inviting the manufacturers of biosimilar medicines and the manufacturer of the originator to offer their best prices to the NHS from 1 December 2018, with a minimum award period running from 1 December 2018 to 30 November 2019; this may be extended for an additional 24 months.
Institutional framework	
Information available on procurement procedures and practices	
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes Outpatient: No

Source: PPRI 2025; NHS England 2018, Vogler, Salcher-Konrad and Habimana 2022

4.2 Reimbursement policies 2025

Reference price system

Biosimilars are included into the reference price system (RPS) applied in the outpatient sector.	No
If yes, how many and under which specifications	Not applicable
If publicly accessible, indicate URL of RPS list	Not applicable
When were first biosimilars included in the reference price system?	Not applicable
Any further specificities	While England has no External Price Referencing in place, currently NHS England expects that Integrated Care Boards implement a regional reference price for key prioritized biosimilars. This allows some financial incentives to hospitals and encourages uptake at pace. This replaces any current block contact or pass through payments. It is encouraged that a best value pathway approach is considered.
In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered?	No

Source: PPRI 2025, NHS England 2019b

Inclusion into reimbursement and co-payments

Reimbursement in the outpatient sector	
Apart from their potential inclusion into the reference price system (see above), biosimilars are included in outpatient reimbursement (positive list).	Yes (in some cases)
If yes, how many and date of inclusion into reimbursement, if known)	
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	
Indicate URL of outpatient positive list	British National Formulary: https://bnf.nice.org.uk/
Co-payments for biosimilars for outpatient use	Not beyond the standard prescription charge
For medicines for outpatient use in general (other medicines than biosimilars) Positive list for medicines in general Percentage reimbursement rates are in place Co-payments for reimbursable outpatient medicines	While the UK does not use the terms "positive list" and "negative list" explicitly, the BNF serves similar functions by specifying which medicines are approved for use and which are excluded from reimbursement. There is a standard Prescription fee for each medicine.
Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level	Yes, additionally to the originator biological (and doctors are recommended to switch)
Any specificities regarding the process of inclusion into hospital	Biosimilars are often procured through framework agreements, which are typically valid for two years. These

pharmaceutical formularies compared to other medicines for inpatient use	agreements are created based on national tenders and are used by regional procurement hubs and individual hospitals. The timing of tenders for biosimilars is partly determined by market knowledge and horizon scanning, which includes monitoring patent expiry dates and the launch dates of biosimilar products.
Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	There is no national formulary other than the BNF - joint formularies are in place at a local level. An example of a local formulary: South East London Joint Medicines Formulary Formulary
Co-payments for biosimilars for inpatient use	No
For medicines for inpatient use in general (other medicines than biosimilars): Hospital pharmaceutical formularies Co-payments for medicines for inpatient use	No co-payments for medicines for inpatient use.

Source: PPRI 2025

4.3 Specific pricing, procurement and funding policies 2025

For defined medicines, public payers and payers have been piloting and implementing specific funding models (such conditional reimbursement, managed-entry agreements, and subscription models such as the Netflix models). Typically, these funding models apply for high-priced medicines with high uncertainties (e.g., originator biologicals) or for medicines with small populations whose uptake is aimed to be encouraged. The section provides information whether biosimilar medicines are also subject to specific funding models. Furthermore, it also looks into possible anti-trust cases.

Application of special pricing, procurement and reimbursement models for biosimilars (e.g., delinkage / subscription-model, management-entry agreements (MEA))	Yes Both inpatient and outpatient sectors
Enforcement of anti-trust policies	Yes. The UK's Competition and Markets Authority (CMA) has actively investigated anti-competitive practices in the biologics sector. For example, it issued a provisional decision against pharmaceutical firms for excessive pricing of hydrocortisone, examined alleged anti-competitive discount schemes, and concluded an investigation into Remicade® for potential market abuse.
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Mix of financial- and performance-based MEAs

Source: PPRI 2025, CMA 2021a, CMA 2021b, CMA 2020

4.4 Supportive tools and practices for policy-makers 2025

Horizon scanning

Public authorities or public payers use a horizon scanning system to identify loss of exclusivity (patent expiry) of biologics	Yes, systematically

If yes, describe the process and the tools (e.g. regular consultation of a database, horizon scanning scoping meeting with stakeholders), including who use horizon scanning	NHS England and the Specialist Pharmacy Service regularly perform horizon scanning activities for both new innovation and patent expiry. PharmaScan Database systematically identifies emerging medicines and tracks patent expires, including those of biologics. Monitoring the market to determine the timing of tenders and the introduction of biosimilars. The timing of tenders for centrally procured medicines is partly determined by knowledge about the launch dates of biosimilar products. This helps in planning transition tenders within the usual two-year cycle to place new products on the market.

Source: PPRI 2025

Health technology assessment?

HTA is applied for biosimilar medicines	Yes, systematically
If yes, in which situations and settings (outpatient and inpatient)	Outpatient and inpatient For all biosimilar medicines aiming to be included into the reimbursement list
Differences in criteria and processes of HTA for biosimilars compared to other medicines	HTA reports for biosimilars often use rapid reviews or mini-HTAs, focusing on comparative studies and existing data from the reference product. But no formal difference in the criteria or assessment process.
Any specificities	

Source: PPRI 2025

4.5 Demand-side measures 2025

Doctors (and further prescribers)

Country context: Doctors and in a few cases other non medical (nurses and pharmacist) prescribers may prescribe. Qualified nurse prescribers can prescribe a range of medicines, including some biosimilars, within their scope of practice. This includes independent nurse prescribers and community practitioner nurse prescribers. Pharmacists who have completed the necessary training and qualifications can also prescribe medicines, including biosimilars, within their competence. In some cases, physician associates, who work under the supervision of a doctor, may be involved in the prescribing process, although their role is more limited compared to doctors and nurse prescribers.

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regard to prescription of biosimilars exist	Yes
If yes, what is recommended for naïve patients?	Recommendation to prescribe biosimilars for naïve patients
If yes, what is recommended for patients already on biologic treatment	Doctors are asked to decide on a case-by-case basis. Treatment decisions should always be based on the clinical judgement for individual patients, but if more than one medicine is suitable treatment, the best value biological medicine, including biosimilars, should be chosen
Prescription guidelines (including switching guidelines) were issued by	

URL of prescription & switching guidelines	NHS England. Biosimilar Medicines: Commissioning Framework. NHS England; 2017. Available from: NHS England » Commissioning framework for best value biological medicines
Prescribing quotas	
Prescribing quota for doctors with regard to prescription of biosimilars exist	Yes
If yes, which quota are defined for biosimilars	- 100% of new patients requiring biological medicines will be initiated on the best value biological, where clinically appropriate, within 3 months following its launch - at least 80% of existing patients will be on the best value biological medicine within 10 months of its launch
Any exemptions	Clinical discretion is allowed, meaning prescribers can exempt patients based on specific medical needs (i.e. adverse reactions).
Any sanctions in case of non-achievement	There are no direct sanctions for non-achievement, but adherence to targets is monitored, and non-compliance may affect performance evaluations.
Any (financial) incentives for achieving the quota	Financial incentives exist, such as incentives where savings from biosimilar use are reinvested into local healthcare services.
Prescribing quota were issued by	NHS England
Prescribing quota for other non-biosimilar medicines exists	Yes, for generics
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	Yes
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	Primarily in inpatient setting but can also be extended to outpatient settings. These models involve agreements between NHS Trusts and Integrated Care Systems (ICBs). Agreements often include financial rewards for meeting biosimilar adoption targets. Savings from biosimilar adoption are shared and reinvested into patient care, such as funding additional treatments or healthcare staff. These models have been in place since the NHS began promoting biosimilar use, particularly after the introduction of adalimumab biosimilars in 2018.
Publicly accessible information	
INN prescribing	
In general, prescribing by INN in place (information not focused on biologics)	Yes, indicative
If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	Exemptions for biologicals from INN prescribing: biologics and biosimilars may not be prescribed by INN
Further measures targeted at doctors	
Information materials for doctors	Yes (e.g., NHS England commissioning framework for best value biological medicines, SPS Guidelines on Prescribing by Generic or Brand Name, MHRA Biosimilar Guidelines)
Information events for doctors (e.g., seminars, trainings)	Position statements from associated royal college
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	Doctors provide clinical oversight, educate patients, collect data, and ensure the ethical conduct of the studies.

Source: PPRI 2025, NHS England 2017

Pharmacists (and further dispensers)

Country context: Pharmacists and in a few cases also other health professionals may dispense. While pharmacists are the primary professionals responsible for dispensing medicines in the UK, pharmacy technicians (under the supervision of a pharmacist), doctors and nurses (in remote and rural areas) may also dispense medicines.

Substitution policies	
(Automatic) substitution for biosimilars	No, not allowed
If yes, for which biologic substances and under which prerequisites?	Not applicable
If yes, since when, and when was it extended? (process of implementation)	Not applicable
Any specificities	Not applicable
URL of underlying law	Not applicable
Generic substitution in place	No, not allowed
Gain-sharing models	
Gain-sharing models for pharmacists	Yes
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	Outpatient: Gain-sharing models are implemented in community pharmacies, which are involved in dispensing medications and providing patient education. Inpatient: Hospital pharmacies participate in gain-sharing models, focusing on the procurement and management of medicines within hospital settings. Contract Parties include the NHS Trusts and Integrated Care Boards (ICB).) and Pharmaceutical Companies. Content and incentives include cost savings, performance-based incentives, and educational support. Introduced following the 201 Carter Review.
Publicly accessible information	
Further measures targeted at pharmacists	
Information materials for pharmacists	https://www.sps.nhs.uk/articles/understanding-biological-and-biosimilar-medicines/
Information events for pharmacists (e.g., seminars, trainings)	National webinars by SPS but also in house local training.

Source: PPRI 2025

Patients

Information and educational measures	
Information materials for patients	Yes
If yes, provide URL of most common materials	NHS England » What is a biosimilar medicine?
If yes, key producers of education measures	NHA England
Information events for patients (e.g., seminars, trainings)	No
If yes, key providers of educational events	NHS England, Westminster Health Forum, British Biosimilar Association, Patient Information Forum
Gain-sharing models	
Gain-sharing models for patients	No
If yes, pls. describe	
Publicly accessible information	

Source: Specialist Pharmacy Service 2025

5 Impact of biosimilar policies and practices in the United Kingdom

The table below informs about outcome indicators on patient access (e.g., higher number of patients treated), affordability (e.g, savings for the public payers, savings for patients) and availability (inclusion on the reimbursement list, time between market authorisation and reimbursement / market entry) which were caused by specific biosimilar policies or practices.

Evidence from the literature on impacts of biosimilar policies and practices in the United Kingdom

Outcome indicator	Caused by	Findings	Publication
Savings for the public payer	Market entry of infliximab and etanercept biosimilars (no specific policy mentioned)	The market entry of infliximab and etanercept biosimilars resulted in cumulative savings of £38.8 million for the public payer over two years. The annual cost saving from the introduction of infliximab biosimilars in rheumatology specialties was £2.66 million in the first year, reducing total annual expenditure on infliximab by 7.76%. The market entry of the etanercept biosimilar in the first year saved £23.4 million, reducing overall expenditure on etanercept by 19.10%.	Aladul 2017
Biosimilar uptake	Impact analysis of policies and practice but qualitative perception of role of information and educational formularies	According to a survey with healthcare professionals, factors preventing them from prescribing biosimilars included the occurrence of unexpected adverse events and increased incidence of adverse events at local or national levels. Healthcare professionals believed that strong patient opinions against biosimilars would prevent switching. Device usability and availability of all dosage strengths were also significant barriers.	Aladul 2018
Biosimilar uptake		Based on a review of local formularies, factors related to physicians' lack of confidence in prescribing biosimilars, absence of encouraging national policies, and no substitution at the community pharmacy level resulted in slow adoption of biosimilars.	Alnahar 2016
Savings for the public payer	Faster and more complete switch to biosimilars than the average in England	The faster and more complete switch to biosimilars policy driving this adoption includes NHS England's mandate that hospitals prescribe the best-value biologic to new patients within three months of biosimilar availability and to at least 80% of existing patients within 12 months*. This policy acts as a guideline and obligation for prescribers to prioritise switching patients to biosimilars promptly. The hospital's approach exceeded these national targets, demonstrating a more efficient implementation of the policy. The approach to biosimilar adoption outperformed the English average and permits patients to revert to their original biosimilar post-switch if appropriate.	Barron 2023
Biosimilar approval and uptake	Regulatory policies and guidance	The study examined biosimilar approval pathways in the UK and found that supportive policies, such as product-specific guidance, extrapolation, shorter exclusivity periods, and switching, correlated with greater success in biosimilar approval and uptake. Differences in testing requirements, indication extrapolation, exclusivities, and switching policies contributed to varied successes of biosimilars.	Knox 2024
Biosimilar use and savings	Pricing and procurement practices	The study highlighted that pricing policies, including mandatory price reductions and tendering, were effective in achieving lower prices and increasing biosimilar uptake. Practices such as target setting, quotas, and financial incentives, as well as guidelines and recommendations for biosimilar prescription, were also effective in encouraging biosimilar use.	Kim 2024
Biosimilar uptake and switching	Design of prescribing policies	The analysis found that physicians were more comfortable prescribing biosimilars to treatment-naïve patients than switching stable patients to biosimilars. Policies that ensured physician autonomy in treatment decisions and mandatory brand-name	Reilly 2022

Outcome indicator	Caused by	Findings	Publication
		prescribing (i.e. exclusion of biologics from INN prescribing) were reported to be crucial in maintaining physician and patient trust in biosimilars.	
Savings for the NHS	National tender for adalimumab	NHS England implemented a national tender for adalimumab following the patent expiry of Humira. The policy aimed to secure the best-value biologic through competitive tendering, ensuring cost savings while maintaining patient care. The impact was significant, with NHS spending on adalimumab projected to drop by 75%, saving approximately £300 million annually. These savings were reinvested into patient care, such as funding additional treatments and healthcare staff. The findings highlighted the success of the tendering strategy, which included engaging with patients and clinicians to facilitate the transition to biosimilars and ensure widespread adoption.	NHS England 2018

*Note: * recent update to at least 80% of existing patients within 12 months*

Source: see last column and further details on the full citation in the bibliography at the end of this country fiche

6 Barriers for biosimilar uptake and policy implementation in the United Kingdom

Organisational barriers (health-systems or health institutions-related)

The UK's fragmented health system presents significant organisational barriers to biosimilar uptake. Different competences and funding responsibilities between outpatient and inpatient sectors create inconsistencies in biosimilar adoption. For example, while some NHS trusts (semi-independent organisations overseen by the government) may actively promote biosimilar use, others may lack the necessary implementation plans and accountability structures (Alnahar et. al 2016). The lack of a unified approach across public and private healthcare settings further exacerbates these challenges. Additionally, local and national efforts are not always aligned, creating organisational barriers (Barron et. al 2023).

Financial barriers

Financial barriers in the UK include limited staff capacity to implement and enforce biosimilar policies. The lack of financial incentives for NHS organizations or for health professionals to prescribe, dispense, or use biosimilars is a significant issue (Alnahar et. al 2017). Gain-sharing schemes, where savings from biosimilar use are available and shared with NHS provider organisations, exist but may not be widely adopted. (Alnahar et. al 2017). Moreover, biosimilar prices are often considered too low or static by suppliers, which can discourage market entry does hinder long-term sustainability (IQVIA 2023).

Evidence and communication-related barriers

Policy-related barriers include insufficient or absent demand-side measures and the application of certain policies that do not favor biosimilar adoption. The lack of evaluation studies on biosimilar policies and limited dissemination of switching studies are critical evidence and communication-related barriers. This gap in evidence makes it difficult for healthcare providers to confidently prescribe biosimilars (Aladul et. al 2018). This also includes the lack of a clear inclusion of biosimilars or generics into the National Institute for Care Excellence (NICE) evaluations or guideline reviews.

Policy-related barriers

England's policies for biosimilars, such as the lack of mandated INN prescribing and automatic substitution, aim to encourage their adoption but face challenges. The static pricing system, which does not adapt to market competition, may limit cost savings and disincentivize manufacturers (Aladul et. al 2017). Additionally, criticism has been raised regarding the uncertainty of volumes for tender winners and the lack

of mechanisms to adjust treatment guidelines as lower prices could allow broader patient access (IQVIA 2023).

Stakeholder-related barriers

Stakeholder-related barriers in England were reported to significantly impact the adoption of biosimilars. Limited knowledge and mistrust among health professionals and patients were reported to be prevalent. Collaboration between doctors and pharmacists is often inadequate, and the higher workload associated with the improved use of biosimilar medicines was found to also contribute to resistance among healthcare providers. These factors collectively were said to create an environment of skepticism and reluctance towards biosimilars (Alnahar et. al 2016).

Factors preventing healthcare professionals from prescribing biosimilars include the occurrence of unexpected adverse events and increased incidence of adverse events at local or national levels. Healthcare professionals believe that strong patient opinions against biosimilars would prevent switching. Device usability and the availability of all dosage strengths are also significant barriers (Aladul et. al 2018).

Physicians' lack of confidence in prescribing biosimilars, the patchy implementation of encouraging national policies, and banned substitution at the pharmacy level have resulted in the slow adoption of biosimilars. Physicians are more comfortable prescribing biosimilars to treatment-naïve patients than switching stable patients to biosimilars (Reilly et. al 2022).

7 Facilitators and good practice examples in the United Kingdom

England has implemented several facilitating factors and good practices to encourage the uptake and competition of biosimilars. NHS England has articulated a very clear policy with specific targets to promote competition and the use of best value biologic medicines (NHS England 2025). Additionally, a long-term medicine strategy is in place to support the development of a multi-player off-patent biosimilar manufacturer ecosystem (IQVIA 2023). Educational initiatives have been launched to increase awareness and understanding among healthcare professionals, while collaborative procurement strategies have been adopted to negotiate better prices (IQVIA 2023). Regulatory support from the Medicines and Healthcare products Regulatory Agency (MHRA) ensures high standards of safety and efficacy (MHRA 2022). Furthermore, patient involvement initiatives help ensure treatment decisions are patient-centred (MHRA 2021). Supportive publications and websites reinforce key policy messages on biosimilars, and multi-winner tenders in England contribute to a sustainable market by maintaining competition and sharing total volume among several companies (IQVIA 2023). Last but not least, supportive policies, such as product-specific guidance, extrapolation and shorter exclusivity periods were found to contribute to higher rates of biosimilar approval and uptake (Knox et. al 2024).

Good practice example: The NHS England adalimumab initiative involved a tendering process that prioritised patient engagement to ensure the adoption of cost-effective biosimilars after the patent expiry of Humira®. This policy aimed to reduce healthcare costs while maintaining high-quality care and achieved significant impact, including substantial savings for the NHS, improved equitable access to treatment, and setting a precedent for involving patients in decision-making processes related to medicine procurement (NHS England 2018). Uniform reference pricing further supported transparency and fairness in the system (NHS England 2019).

8 Developments in the United Kingdom

Recent changes

Over the past five years, England has seen significant developments in the biosimilar market. The NHS Long-Term Plan, introduced in 2019, emphasizes the adoption of biosimilars to improve patient access to effective treatments while reducing costs, setting ambitious targets for biosimilar uptake (NHS 2019). The establishment of the Commercial Medicines Directorate within NHS England has focused on securing maximum value for the NHS and taxpayers from its growing spend on medicines (DHSC 2024). Additionally, various educational programs have been launched to increase awareness and understanding of biosimilars among healthcare professionals, helping to build trust and confidence in prescribing these alternatives (NHS England 2024a).

Plans or under discussion

Looking ahead, the NHS plans to further expand the use of biosimilars across different therapeutic areas to maximize savings and improve patient outcomes (Deloitte 2021). There are ongoing discussions about increasing patient involvement in treatment decisions, particularly regarding the use of biosimilars, which could improve acceptance and adherence to these treatments (NHS England 2024b). The UK is also exploring regulatory innovations to streamline the approval process for biosimilars, making it faster and more efficient (MHRA 2021).

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