NHS
Surrey Heartlands

CLIN 20

Biological & Biosimilar of Best Value Policy

Policy number	CLIN 20
Version	1.0
Approved by	Medicines Optimisation Board
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Version control sheet

Version	Date	Author/ Committee	Status	Comments / changes since last version
0.1	17/3/23	PSJ/SR	Draft	Adopted from Sussex Hospitals policy. Updated and tailored to Surrey region
0.2	11/3/24	PSJ/SR	Draft	Comment from Medicines Resource Unit and ASPH
0.3	13/3/24	PSJ	Draft	Out for consultation: APC members and Clinical Network members
0.4	29/5/24	PSJ	Draft	Updated for final review at APC and corporate and quality teams
0.5	11/06/24	PSJ	Draft	Updated with comments from APC for approval at MOG
1.0	19/06/24	Medicines Optimisatin Board	Final	Approved subject to amendment of patient information appendices
1.0	02/07/24	Governance Team	Final	Compliance check undertaken.

With thanks to University Hospitals Sussex for allowing the adaption of their policy for use in Surrey Heartlands.

Equality statement

Surrey Heartlands Integrated Care Board (ICB) is committed to promoting equality and diversity in all its activities and to promoting inclusive processes, practices and culture.

- We will strive to work to eliminate any unlawful or unfair discrimination including direct or indirect discrimination, discrimination by association, discrimination linked to a perceived characteristic, harassment and victimisation.
- We will remain proactive in taking steps to ensure inclusion and engagement for all the people who work for and with us.
- We will continue to strive towards a culture that is diverse and inclusive that recognises and develops the potential of all staff and service users.
- We recognise the business benefits and opportunities of having a diverse community of staff who value one another and realising the contribution they can make to achieving the ICB's vision.

This includes promoting equality and diversity for all irrespective of:

- age*
- disability*
- ethnic group*
- sex*
- gender reassignment*
- religion or belief*
- sexual orientation*
- marriage and civil partnership*
- pregnancy and maternity*

*Under the Equality Act (2010) these are known as "protected characteristics".

In addition, it includes promoting equality and diversity for carers, people with diverse communication needs and members of the Armed Forces Community.

The ICB aims to meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. We take into account the Human Rights Act 1998 and promote equal opportunities for all. We embrace the seven staff pledges in the NHS Constitution that represent a commitment by the NHS to provide high-quality working environments for staff. This policy is consistent with these pledges.

This document has been assessed to ensure that no employee or member of the public receives less favourable treatment based on their protected characteristics.

Members of staff, volunteers or members of the public are invited to request assistance with this policy if they have particular needs. If the member of staff has language difficulties and difficulty in understanding this policy, the use of an interpreter will be considered.

Quality and Equality Impact Assessment

Completed	17/5/24
Lead Author	Sarah Watkin, Associate Director of Pharmacy, Surrey Heartlands
Responsible Director	Linda Honey, Director of Pharmacy, Surrey Heartlands
Location of full QEIA	A full QEIA should be completed and attached as an appendix for all policies. You will find the template at the following link: https://intranet.surreyheartlandsccg.nhs.uk/resources/forms-templates-images/templates-cat/surrey-heartlands-icb
Outcome	**Outcome 2 - Adjust the service/function/policy** to remove barriers identified by the QEIA or better advance equality. Policy to be reviewed initially after 1 year.

Contents

1. Introduction and Policy Objective

1.1 In the ever-evolving landscape of healthcare, the utilisation of biological medicines has become integral to the treatment of various chronic and severe conditions, such as rheumatoid arthritis, diabetes, and certain forms of cancer.

1.2 As patents for these biological medicines expire, biosimilars – which are highly similar, but not identical, to the originator product – enter the market, offering a more cost-effective alternative while maintaining similar efficacy and safety profiles. There may be instances where the originator product offers better value to the NHS, for example if the price were to reduce in response to market competition.

1.3 This has been developed as an ICB policy that outlines the Surrey Heartlands Trusts' approach to utilising biologicals and biosimilars, in pursuit of achieving the best value without compromising the quality of patient care. The aim is to have system-wide agreed policy to achieve NHS England aspirations that at least 90% of new patients will be prescribed the best value biological medicine within 3 months of availability, and at least 80% of existing patients within 12 months. This policy has been developed in line with recommendations from the NHS England Commissioning Framework for Biological Medicines[1], the Cancer Vanguard Guidance[2], and the European Medicines Agency[3].

1.4 Review of this policy

1.4.1 This policy is to be reviewed after one year in the first instance and subsequently at least every 3 years by Area Prescribing Committee and approved by Surrey Heartlands Medicines Optimisation Board.

2. Legislative Framework / Core Standards

2.1 This is a new policy that outlines the system-wide commitment to achieving the best value in the procurement of biologicals and biosimilars. In instances where brand patents have expired and generic/biosimilar alternatives are available, Trusts will adopt a switching strategy to the most cost-effective option.

2.2 The aim is to capitalise on the potential cost savings offered by generics, while maintaining the high quality of patient care. Clinicians play a crucial role in this process and are responsible for identifying any patients who may not be suitable for the switch to a biosimilar alternative. In such cases, it is the responsibility of the clinician to communicate with Pharmacy, providing clear and documented reasons for the necessity of the originator product.

2.3 This policy is aligned with Surrey Heartlands ICB partner organisations commitment to fiscal responsibility, efficiency, and the delivery of exceptional patient care.

3. Scope

3.1 This policy is intended for use across all organisations within Surrey Heartlands Integrated Care System to ensure equity within the local health economy.

3.2 The purpose of this policy is to stipulate the governance requirements and stakeholder responsibilities to facilitate the Trust to achieve use of the best value biological and biosimilar medicines in an agile, systematic, and safe way.

4. Definitions

Term	Definition
Biological medicine	medicine derived from living cells or organisms, consisting of large highly complex molecular entities which may be difficult to characterise.
Best value biological medicine	the biological product that represents optimal economic efficiency to the healthcare economy*. This is likely to be a biosimilar of an originator product. *A region may be allocated a biosimilar or originator that is more expensive than comparator products for the provider, but whose instructed implementation will provide best value for the NHS nationally.
Biosimilar medicine	a medicine that is highly structurally similar, but not identical, to the licensed originator biological medicine and shows no clinically meaningful difference in terms of quality, safety, and efficacy.
Generic medicine	a medicine that is the same as the branded medicine because they contain the same active ingredients.
Interchangeability	the medical practice of changing one medicine for another that is expected to achieve the same clinical effect in a given clinical setting and in any patient on the initiative or with the agreement of the prescriber.
Stakeholders	all members of the clinical team including, but not exclusively; doctors, pharmacists and nurses; plus patients, ICS commissioning representatives, NHSE specialised commissioning, Commercial Medicines Unit (CMU) representatives and homecare service leads.

5. Roles and Responsibilities

5.1 Chief Pharmacist

5.1.1 Accountable for establishment and maintenance of governance frameworks to assure efficacious, safe, and cost-effective management of biological medications.

5.1.2 Accountable for ensuring accurate high-cost drug (HCD) data is available in a timely manner for review by ICS partners.

5.1.3 Responsible to support adherence to the principles of this policy to advance the triple aim of improving health outcomes, service quality and sustainable value.

5.2 Medical Director

5.2.1 Advocate adherence to the principles of this policy to advance the triple aim of improving health outcomes, service quality and sustainable value.

5.3 Trust (Provider) Divisional Operational and Clinical Directors

5.3.1 Support assessment and provision of the necessary operational and clinical resources to facilitate adherence to the principles of this policy.

5.3.2 Provide necessary leadership to support relevant prescribing members of the Divisional Multi-Disciplinary Team (MDT) adhere to the principles of this policy.

5.3.3 Ensure resilience strategies are in place to support continued implementation of the adoption of best value biologicals practice as the market evolves and support any necessary updates to prescribing pathways accordingly.

5.3.4 Support implementation and running of switch-back request processes as per local agreement with commissioners.

5.3.5 Promptly communicate any relevant identified issues to the high-cost drugs team in pharmacy and collaborate and support in finding resolutions.

5.4 Pharmacy Department

5.4.1 Procurement duties:

- Provide the required technical and logistical support for the management of Trust prescribing systems and, if required, aseptic unit work sheets.
- Procurement, storage, and supply of the selected best value biological.
- Effective stock management to minimise wastage related to product switches.

5.4.2 Business duties:

- Coordinate effective implementation programmes for best value biologicals.
- Produce relevant analysis reports including estimated savings, resource requirements, percentage uptake of the best value biological medicine and related efficiencies.
- Fill in the Best Value Biological & Biosimilar Adoption form (see Appendix 1).
- Support the relevant clinical MDT in the selection process of the most appropriate products to update prescribing pathways.
- Co-ordinate and disseminate relevant procurement and contractual information to the relevant specialties.

5.4.3 Homecare duties:

- Coordinate and manage relevant Service Level Agreements (SLAs) to facilitate an effective switch.
- Update master copies and distribute prescription and registration templates as required to the relevant clinical teams in a timely manner.
- Coordinate homecare delivery service.
- Support switch-back requests processes via the MDT.
- Coordinate patient communication to notify them of pending switches and any relevant operational changes such as transition to a new homecare supplier. Escalate any clinical related concerns or complaints to the clinical team or the HCD team.
- Escalate any communicated concerns or complaints to the HCD team.
- Update relevant price lists and maintain financial governance practices to assure accurate and timely invoicing and payments.
- Support MDT with Service Impact Assessment (SIA) and, if required, escalate any issues highlighted as per flow chart (see Appendix 2 and 3).

5.5 Prescribing / Clinical teams

5.5.1 Empower patients to make informed shared decisions regarding selection of treatments that are clinically appropriate for them[4].

5.5.2 Prescribe biologicals of best value (as advised by Trust validated treatment pathways or the HCD team) as default in the absence of clinical factors which may determine otherwise.

5.5.3 Prescribe the brand of best value as default. Biologicals should be prescribed by brand, but patients should be counselled and consented using the generic drug name as reference.

5.5.4 Actively engage with system and regional clinical networks and keep up to date with newly approved products and new evidence. Ensure that up to date biological prescribing pathways are established and adhered to.

5.5.5 Counsel patients at treatment initiation to notify them to expect that brand switches will be implemented in line with market updates throughout the course of treatment.

5.5.6 Engage with the HCD team in a timely manner to discuss pending biological/biosimilar of best value switches.

5.5.7 Identify, quantify, and rationalise any switch resource requirements and work with the HCD team to complete a Service Impact Assessment (see Appendix 2).

5.5.8 Provide assurances regarding the safety and efficacy of biosimilars to patients who flag concerns.

5.5.9 Provide reports as requested (and as per local Trust procedure) on assurance of appropriate exemption for patients who are deemed clinically excludable from a switch programme or who are deemed eligible to switch back from a biosimilar.

5.6 Patient information

5.6.1 Information referred to in this policy which is to be shared with patients must be provided in line with the Accessible Information Standard and language requirements to ensure optimal medicines use.

6. Procedure

6.1.1 The Trust is fully committed to utilising the most cost-effective biological & biosimilar agents and generic medicines when clinically suitable, as part of its duty to maximise NHS resource efficiency. Clinicians should primarily prescribe the biological that offers the best value, unless clinical circumstances dictate otherwise. The specialty clinical team hold the responsibility to inform and support patients in agreeing to the most appropriate clinical treatment. In cases where multiple clinical treatments are viable, and in the absence of clinical or comorbidity factors, the biological providing the best value should be the preferred recommendation.

6.1.2 When multiple brands of a recommended clinical treatment exist, clinicians must prescribe the biological that ensures best value. Biosimilar products are deemed interchangeable with their reference product[5], or between biosimilars of the same reference product[6], while expecting the same therapeutic results. Although patients should be given the opportunity to make an informed choice regarding their treatment, they should not be given the option to choose from different brands of a selected medication.

6.1.3 The governance of best value biological agents within the provider Trusts will be overseen by the Trust Pharmacy HCD teams and Drug and Therapeutics Committee, in collaboration with the relevant commissioner(s) and supported by Surrey Heartlands Area Prescribing Committee and Medicines Optimisation Board. These teams are tasked with supporting regional clinical networks in developing and sustaining treatment decision pathways. This includes keeping key personnel informed about which biologicals or biosimilars are of best value in specific settings and notifying prescriber of any changes, such as the introduction of a new biosimilar or adjustments in contract price. Prescribers are expected to comply with the Trust's stance on the utilisation of best value biologicals and biosimilars.

6.2 Considerations prior to switching to a biological/biosimilar of best value.

6.2.1 The transition to a best value biological or biosimilar medicine should be meticulously planned, ensuring that all stakeholders are sufficiently prepared, and any potential additional activities required for the switch are duly considered and accounted for.

6.2.2 The Best Value Biological & Biosimilar Adoption form and the Service Impact Assessment form (refer to Appendices – Appendix 1 and 2) are essential tools in facilitating this planning process for the introduction of each best value biological and biosimilar medicine. These forms should be collaboratively filled out by the High-Cost Drugs (HCD) team and the clinical specialties.

6.2.3 In instances where the Service Impact Assessment highlights the necessity of supplementary resources to support the switch, the onus falls on the clinical teams to pinpoint, quantify and justify these resources. Pharmacy will review this request for resources and forward response from the commissioner(s) to the Division, as per flow chart in Appendix 3.

6.2.4 If there is a possibility of multiple best value biological or biosimilar medicines becoming available within a span of 6 months from a prospective switch, a strategic decision needs to be made regarding which medicine will be adopted and when. This decision should be grounded in a careful evaluation of financial and resource implications, with the goal of minimising additional changes in the short-term (12 months) to mitigate governance risks and preserve patient confidence.

6.2.5 For stability and to foster patient confidence in the use of biosimilar medicines, it is recommended that, barring any changes in clinical circumstances, a biological or biosimilar of best value should be continued for a minimum period of one year before contemplating further switches for economic reasons. This approach also helps to manage the workload for healthcare professionals and organisations engaged in switching schemes. It is important to note that there is no stipulated maximum number of switches between biologicals and biosimilars.

6.3 ICB position

6.3.1 The partnership between ICB colleagues and providers should foster a collaborative environment that address national commissioning priorities and initiatives, with biosimilars playing a crucial role in this process. Regular liaison between the clinicians, ICB colleagues and providers is vital to align positions and share switch metrics as necessary. Providers are expected to offer transparent feedback regarding any obstacles or delays encountered in switch programs.

6.3.2 ICB colleagues should offer the necessary support and incentives to facilitate efficient switch programs, where possible to ensure agile and safe transitions between biological brands.

6.3.3 ICB colleagues and Trust Pharmacy teams should engage in annual horizon scanning exercises to inform commissioning policy and address any resource concerns related to quality, equity, or value. Moreover, ICB colleagues should assist providers in transitioning to biologicals or biosimilars of best value by aiding in the development and maintenance of clinical networks.

6.3.4 To encourage adoption of biologicals/biosimilars of best value, budgets will be adjusted during horizon scanning to account for estimated savings. Estimated savings will usually be based on NHSE expectations of at least 90% of new patients being prescribed the best value biological medicine within 3 months of availability, and at least 80% of existing patients within 12 months – with adjustments to account for timing.

6.4 Homecare

6.4.1 When a best value biological becomes an option for a medicine administered via homecare, meticulous planning is necessary to guarantee prescriptions are updated promptly. Organising homecare logistics is essential to minimise any potential disruptions for patients. Homecare providers must establish appropriate Service Level Agreements (SLAs) and ensure all necessary documentation is revised and shared with the pertinent Multidisciplinary Team (MDT) members. Furthermore, homecare services are obligated to supply clinical teams with a newly updated prescription form that adheres to the timelines set forth by the agreed-upon switch program.

6.5 Informing patients

6.5.1 New patients:

The specialty clinical team has a duty to properly inform and counsel patients, ensuring they can make an informed decision about the most appropriate clinical treatment. In situations where multiple clinical treatments are deemed suitable, and no specific clinical or comorbidity factors dictate the choice, the best value biological or biosimilar should be the recommended option. Clinical teams must adhere to what is agreed through our Trust Formulary and in accordance with Surrey PAD, which will dictate prescribing pathways. When multiple brands of a suitable clinical treatment are available, clinicians must opt for the best value biological or biosimilar. New patients should not be offered a choice of brands when initiating treatment with a selected medication.

Furthermore, patients initiating treatment with a biological medicine must be made aware that as patents expire, or contracts are renewed, they will automatically be switched to the most cost-effective version of that biological. This information should be provided during their initial consultation and as part of the consent process. If written information about the efficacy and safety equivalence of biosimilars is provided to the patient, it must be sourced from an approved NHS associated entity. An example of such a document can be found in Appendix 5.

6.5.2 Existing patients:

Apart from patient cohorts identified in the SIA, the expectation is for all other existing patients be transitioned to the best value biological or biosimilar. This includes all patient subgroups, such as those who have recently begun therapy and those who have transferred from other areas.

- Clinic setting:
    - In a clinic setting, patient receiving medication should be systematically consented before each administration with the generic name of the drug utilised instead of the brand name.
- Homecare setting:
    - Patients self-administering medication in a homecare setting must receive written notification about the switch. They should also be offered training if the device design differs from what they are used to, or if they request support. The written notification should include a product-specific Patient Information Leaflet (PIL), a generic biosimilar Question and Answer (Q&A) document (Appendix 4) and contact information for the appropriate healthcare practitioner for further discussion about the switch.
    - Clinical teams should designate suitable staff and include their contact information on the Q&A document to handle any queries from patients. Any concerns regarding resources should be addressed using the Service

Impact Assessment tool. The guidance provided in Appendix 4 and Appendix 5 should be referred to and followed by relevant teams when counselling patients. It is required the employees and representatives of the Trust provide accurate and consistent information to patients, in line with Trust policy and clinical evidence.

6.6 Requests to prescribe an originator or more expensive biosimilar.

6.6.1 Requests to prescribe an originator or more expensive biosimilar than the best value biological for a group of patients should come from the clinical team to the HCD team. Any concerns regarding resources needed to manage switches should be quantified and address through the Service Impact Assessment form, with support from the HCD teams prior to a switch program, as outlined in Appendix 3.

6.6.2 Unfounded worries about efficacy and safety without evidence will not be considered a valid reason. If a satisfactory resolution cannot be reached, the case may be escalated to the Drug and Therapeutics Committee or equivalent.

6.6.3 New patients:

New patients should not have a choice of brands for a selected medication when starting treatment. Requests for prescribing a more expensive brand will not be considered unless there is a clinical precedent, such as the patient or cohort experiencing adverse effects with the best value brand that affects treatment adherence and quality of life, or if the device design poses a challenge for those with limited dexterity. Unsubstantiated concerns regarding efficacy and safety without evidence will not be considered a valid reason. Requests must be made in advance via the Trust Pharmacy team, according to local Trust procedure.

6.6.4 Existing patients:

- Clinic setting:
  - Patients have the right request a consultation to address any concerns or questions about the switch. These patients may then be referred to the relevant lead pharmacist or clinical lead for further discussion. Treatment should not be delayed or interrupted during this time.
- Homecare setting:
  - While it is not required for patient to give consent to switch brands, they should be notified and offered training if necessary. Patients also have the right to contact the clinical team and request a consultation to address any concerns or questions about the switch. These patients should then be referred to the relevant lead pharmacist or clinical lead for further discussion. Treatment should not be delayed or interrupted during this time.

6.7 Prescriber decision not to switch.

6.7.1 Prescribers should follow the Trust's policy on adopting best value biologicals and biosimilars. If a clinician decides not to switch an individual patient (outside of pre-determined cohorts in the approved implementation plan), it is recommended that the HCD team is informed of the decision, according to local Trust procedure.

6.7.2 Although clinicians can proceed without waiting for a response, prescribing patterns may be monitored and potentially challenged. If a clinician feels it is inappropriate to switch a cohort of patients, this concern must be formally raised as part of the implementation plan, or directly with the HCD team.

6.8 Prescribing requirements

6.8.1 Biological and biosimilar medicines must be prescribed by their brand name, following the format "International Non-proprietary Name (INN) (Brand Name®)", for

example, filgrastim (Zarzio®) and adalimumab (Imraldi®). This practice prevents the unintended substitution of one best value biological or biosimilar brand for another without the review and consideration of the prescribing clinician or team.

6.8.2 Cohorts should be switched within a reasonable time frame. Homecare patients should be switched at the time of their next delivery as standard, unless otherwise specified. Clinics are expected to switch when their existing stock has been used up. Requests to switch homecare cohorts at the point of prescription renewal (maximum six months) must be submitted to and reviewed by the HCD team in advance.

6.9 I.T. (Information Technology) readiness

6.9.1 Relevant IT systems, such as Pharmacy dispensing systems and electronic prescribing systems, must clearly differentiate between biological brands.

6.10 Reverting to use of the originator product

6.10.1 When a patient experiences a disease relapse after a switch, current evidence suggests the relapse would also have occurred with the original brand. Switching back to the original brand is not recommended; instead, the clinical team should consider escalating treatment as per relevant clinical pathways and guidelines. If a patient experiences new adverse effects impacting treatment adherence after a switch, the clinical team may choose to revert to the original brand, in the absence of a second alternative biological or biosimilar of better value as recommended by the relevant commissioners, or the Pharmacy. Similarly, if device-related difficulties affect treatment adherence, reverting to the original brand may be considered.

Consulting the MDT prior to switching back is advised. If a patient experiences adverse effects affecting adherence, prompt action will be taken by reporting to Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card scheme. Depending on local Trust procedures, Pharmacy may be informed.

6.11 Pharmaco-vigilance and monitoring

6.11.1 The Trust will maintain a patient-centred pharmacovigilance framework, including national registries and the yellow card scheme, to monitor and report outcomes and any adverse effects impacting treatment adherence associated with biological therapy. Suspected adverse drug reactions should be reported using the MHRA yellow card scheme, including the brand and batch number. Yellow card reporting should comply with Trust policy. Clinical teams should consider and quantify necessary resources to meet governance expectations, detailing these requirements via the Service Impact Assessment.

7. Monitoring arrangements

7.1 Clinical Outcomes Monitoring

7.1.1 The clinical team overseeing the switch must ensure the patient has been offered post-switch advice, including routes of communication for the patient if they consider they are having an Adverse Drug Reaction (ADR) or reduced efficacy.

7.2 Financial Outcomes Monitoring

7.2.1 Post-implementation of a best value biological or biosimilar medicine, the Pharmacy must track drug acquisition cost savings, which should be monitored and recorded monthly to calculate the savings from the change. This includes tracking the number of new and existing patients switched to the best value biological/biosimilar medicine and reasons for any patients not switched, in addition to metrics and indicators in line with any NHSE requirements such as Medicines Optimisation and CQUINs. Without this, any agreed financial incentives may be at risk.

8. Bibliography

1. NHS England. NHS England Commissioning framework for biological medicines (2017).
2. Cancer Vanguard. Biosimilars – Getting it right first time (2017).
3. European Medicines Agency. Joint EMA-HMA statement on interchangeability (2023)
4. National Institute for Health and Care Excellence (NICE). Shared Decision Making 2023
5. NHS England. What is a biosimilar medicine? Publication (2023).
6. Medicines & Healthcare products Regulatory Agency (MHRA). Guidance on the licensing of biosimilar products. Updated 7 November 2022.

9. Appendix 1 – Best Value Biological Adoption Form

Brand(s) currently in use	
Biosimilar product(s) available	
Licensed Indication(s) - indicate any differences to original product.	
What is the anticipated biosimilar launch date?	
Please provide information on which manufacturer's biosimilar will be adopted, when and why this particular one has been chosen.	
Provide an overview of the implementation plan, noting the process for the introduction of the biosimilar and communication to patients.	

What patient groups are to be included:

From Day 1			Future Date – State when
	Yes	No	
New patients	☐	☐	
Existing Patients	☐	☐	
Paediatrics	☐	☐	

	Yes	No
Does the biosimilar cover the required licensed indications?		
Will the biosimilar be intended for all currently licensed indications?		*State which indications will be excluded*
Are the biosimilar presentations i.e. strengths, concentration & preparation the same as for the originator?		*State what the difference is and what the clinical significance of this is.*
Are the biosimilar administration requirements the same as for the originator i.e. route and duration of administration?		*State what the difference is and what the clinical significance of this is.*

Is the biosimilar stability, once prepared, and its storage conditions the same as the originator?		*State what the difference is and what the practical significance of this is.*
Are the required clinical outcomes data available for review by the Trust's Drugs and Therapeutics Committee (Please append)		
Is the biological medicine administered in patients' homes and will this have to be reviewed (e.g. for initial dosing or patient self-administration training)		
What are the potential resource implications of the adoption process *(See Service impact assessment form in Appendix 2)*	Patient counselling	
	Clinical team education and training	
What patient monitoring will be required?		
What is the required involvement in professional registries (i.e. British Society for Rheumatology–Biologics Register (BSRBR)?		
Patient Risk Assessment: *Include information on the steps to be taken to mitigate any patient risk and loss of patient confidence and governance implications.*		

10. Appendix 2 – Service Impact Assessment

Product Information

Branded product(s) in use:	
Biosimilar(s) to adopt:	
Date(s) of availability:	
Predicted date of switch:	

Condition(s)	Commissioner(s)	Division(s)	Stakeholders *Consultant(s) / Nurse(s) / Pharmacist(s)*

Number of eligible patients

Total number of patients prescribed drug under review		Total number of patients eligible for biosimilar switch (all patients without indication protected by patent or research protocol)	
Clinical trial patients			
Patients on commercial stock			
Patients on sponsor funded trial stock			

Drug acquisition costs

Current Drug contract price per dose unit *(commercially sensitive - please do not share outside of Trust)*	
Current Service delivery model (homecare)	
Do you expect this model to change as a result of using a biosimilar?	

Service costs

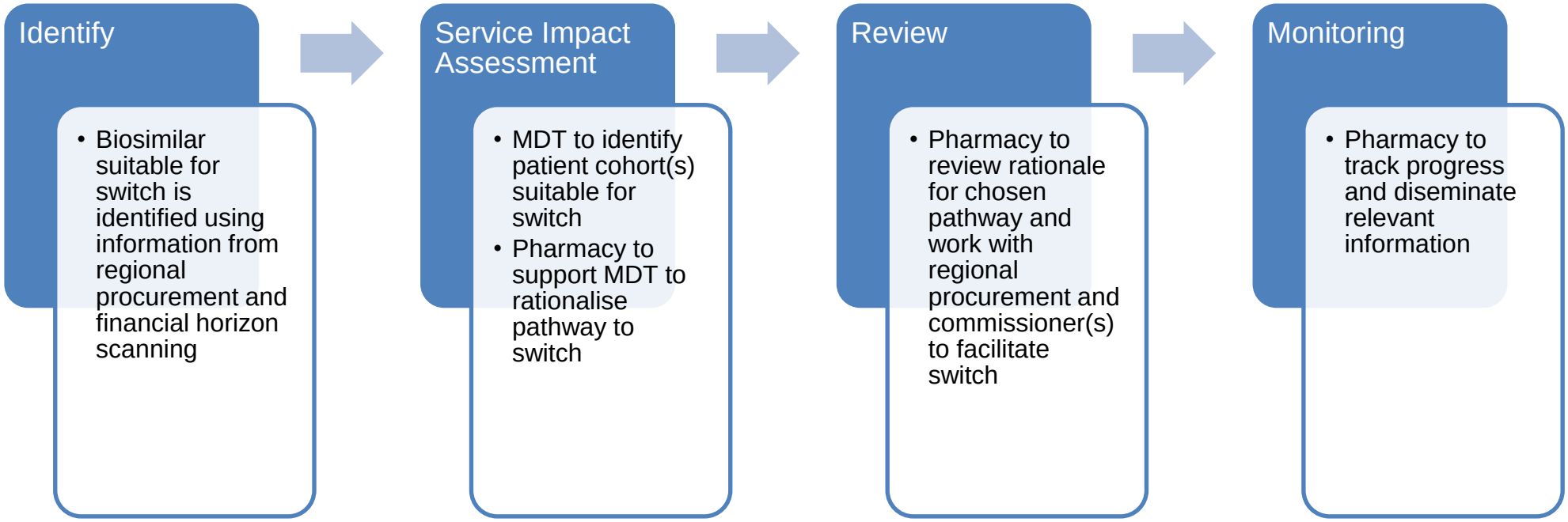
Service delivery model alternatives	

Costs associated with additional stock storage and risk minimisation activities	
Wastage (vial wastage, expired or unused infusions etc.)	
Do you use dose banding?	

Costs associated with biosimilar implementation

Counsel patients	
Development and delivery of patient focused and staff educational material	
Time associated with clerking patients	
Administration costs	
Chair time	
Monitoring	
Resources to maintain national databases / information governance	
Costs associated with prescribing	
Preparation and validation of aseptic worksheet	
Preparation for formulary application	

11. Appendix 3 – Service Impact Assessment flow chart



Points of contact for localisation

Pharmacy	ICB

12. Appendix 4 – Biologicals & Biosimilars Q&A document for patients (add to bottom of patient letter)

BIOLOGICALS & BIOSIMILARS

What is the difference between a biological and a biosimilar medicine?

Biological (sometimes known as biologic) medicines have been used to treat people for many years. Biosimilars are newer versions of the original biologicals. They are very similar in terms of quality, safety and how well they work to the original biological. They work in the same way.

Why are the changes happening?

All medicines made by drug companies have a patent that lasts several years. The patent means that only the company who made the medicine is allowed to sell it. The patent on many biologicals has ended. Other drug companies now make biosimilars and these are now available to the NHS.

What does this mean for the NHS?

Biosimilars are less expensive for the NHS to buy. As many drug companies are now making biosimilars, there is competition between them. This helps to lower the cost of the new medicine. It makes sense to offer patients these medicines as they work just as well and can also save the NHS millions of pounds.

Are biosimilars as safe as the original biological medicines?

Yes. There are strict rules and testing in place to make sure biosimilars are of a high quality, are safe and work as well as the original biologicals.

How will this affect me?

• If you are a new patient, you will be started on a biosimilar. The manufacturer (or brand) may change throughout your treatment.

• If you are an existing patient, you will be switched to a biosimilar and there's only a small chance that you'll experience a difference in the way your body responds to the new medicine.

• If you do notice a difference, please ask your doctor, nurse or specialist for further advice.

What other help and advice can I get?

"ENTER RELEVANT CONTACT DETAILS HERE"**

13. Appendix 5 – Support document: Counselling patients about biological switches

Information sheet for biosimilar counselling

What is this leaflet for?

It is a requirement to inform patients initiating on biological therapy that the brand in use will be switched routinely in line with patent or contract changes. This leaflet may be used to assist a clinician counsel their patients regarding biosimilar switches, either at the point of initiation of therapy or at the point of a specific switch.

Assure patients of the safety, efficacy, and quality of biosimilars.

Biosimilar medicines are biological medicines that have been developed to be highly similar and clinically equivalent to an existing biological medicine and are marketed after the expiry of the patent on the originator or reference biological. No two batches of biological medicine will be identical, even if they are made by the same manufacturer. There will be some difference between batches due to the biological materials used and the way the medicines are made. As for any medicine, specification limits which each batch must meet are tightly controlled. These specification limits help manufacturers make sure that the biological medicine is safe, effective and of good quality. Biosimilar medicines have equivalent appropriate specifications and thus are comparable to the reference (originator) product in terms of safety, efficacy and quality.

Is a biosimilar medicine as effective as the reference biological medicine?

Yes. A biosimilar medicine is tested to make sure it is as effective as the original (reference) biological medicine.

Is a biosimilar medicine as safe as the reference biological medicine?

Yes. A biosimilar medicine is tested to make sure it is as safe as the original (reference) biological medicine. A biosimilar medicine should not have more side effects than its reference medicine. All medicines can have side effects. If you have any questions about side effects, talk to your doctor, nurse specialist or pharmacist.

Is a biosimilar medicine the same quality as the reference biological medicine?

Yes. A biosimilar medicine must meet equivalent quality standards to the reference (originator) medicine.

Explain the rationale for switching

Are there benefits to being prescribed a biosimilar medicine?

Yes. Biological medicines have changed and improved the treatment of many serious diseases such as cancer. But biological medicines are usually very expensive.

Biosimilar medicines encourage competition and may reduce the cost of biological medicines. This means that the NHS can save money and be more efficient. Reducing the cost of biological medicines can help free up resources for other important areas of healthcare.

Explain the process

What will the patient notice during a biosimilar switch?

Patients who have their biological delivered to their homes will receive written notification from the homecare company to alert them of the changes. If the new biosimilar will be delivered by a new homecare company, they will receive a welcome pack with all the relevant information for that company.

There will be no disruption to the supply of the medication. The device of the new product may have a different appearance to the original but will work in the same way. If the patient is not confident with the new device, training can be provided.

Patients who have their biological medication administered in clinic as an outpatient will not notice any difference to the process.

What should the patient do if they experience any new side effects or notice that their condition is getting worse?

Patients are advised to contact their clinical team. Please provide the patient with the relevant contact details.

14. Appendix 6 – Statement on the scientific rationale supporting the interchangeability of biosimilar medicines in the EU, 2023

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

21 April 2023
EMA/627319/2022

Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU

The EU experts on biosimilar medicines (Biosimilar Medicines Working Party or BMWP) and the Heads of Medicines' Agencies (HMA) Biosimilar Working Group have drafted a joint statement explaining the rationale for considering biosimilars approved in the EU as interchangeable from a scientific perspective. This statement has been endorsed by the Committee for Medicinal Products for Human Use (CHMP) and the Biologics Working Party (BWP).

Joint EMA-HMA statement on interchangeability:

Biosimilars approved in the EU are interchangeable

Interchangeability refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect.

HMA and EMA consider that once a biosimilar is approved in the EU it is interchangeable, which means the biosimilar can be used instead of its reference product (or vice versa) or one biosimilar can be replaced with another biosimilar of the same reference product. Interchange should only take place after careful consideration of the approved conditions of use (i.e., consulting the most recent product information).

Decisions on how to implement interchangeability either through switching (under the control of the prescriber) and/or substitution (the practice of dispensing one medicine instead of another medicine without consulting the prescriber, such as automatic substitution at the pharmacy level), are not within the remit of EMA and are managed by individual member states.

Background

Interchangeability in the context of this statement means using one medicine instead of another with the same therapeutic intent. How this is implemented is the responsibility of the individual member states.

Biosimilars approved via EMA can be used interchangeably if national rules allow it. From a scientific viewpoint, interchangeability of approved biosimilars has always been considered acceptable and did not raise any concern (1). However, EMA has to date not issued any recommendation on interchangeability.

At present the EU medicines regulatory network has identified the need to explicitly state that from a scientific point of view, biosimilars approved in the EU can be considered interchangeable.

This is because the absence of a clear EU-wide position on interchangeability has been identified as

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Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

a factor causing uncertainty among stakeholders on the use of biosimilars in clinical practice (2). Thus, EMA and HMA consider that a harmonised and clear EU wide position on interchangeability is needed to reduce any uncertainty that prescribers may have when deciding to prescribe biological medicines.

Scientific rationale

The EU regulatory network has been assessing, authorising and monitoring biosimilars for over 15 years and has gained very profound understanding of biosimilars after reviewing more than one hundred biosimilar candidate submissions, and monitoring their safety once they are placed onto the market.

Switching between biological medicinal products manufactured and commercialised by different companies has become common in clinical practice, and interchangeability of EU-licensed biosimilars has been confirmed (1, 2, 3, 4).

Approved biosimilars have demonstrated comparable efficacy, safety and immunogenicity compared with their reference products (5). Thus, EU experts consider that when approval for a biosimilar is granted in the EU, additional systematic switch studies are not required to support the interchangeability.

Considering all the available scientific evidence and the successful experience with biosimilars in clinical practice over the years, the CHMP and all working parties with expertise in biological medicines and biosimilars support that medicines approved as biosimilars in the EU may be prescribed interchangeably. This will allow more patients to have access to biological medicines necessary for treating diseases such as cancer, diabetes and rheumatic diseases.

Member States will continue to decide which biological medicines are available for prescribing in each territory and whether automatic substitution is allowed at pharmacy level.

Information sources on biosimilars

Patients and healthcare professionals with specific questions on interchangeability practices are recommended to contact the medicines regulatory agency in their member state: National competent authorities (human) | European Medicines Agency (europa.eu).

For questions on how biosimilars are approved and monitored in the EU, patients and healthcare professionals can contact EMA: Send a question to the European Medicines Agency | European Medicines Agency (europa.eu).

References:

1. Interchangeability of Biosimilars: A European Perspective. Pekka Kurki, Leon van Aerts, Elena Wolff-Holz, Thijs Giezen, Venke Skibeli, Martina Weise. BioDrugs 2017 Apr;31(2):83-91
2. Regulatory Information and Guidance on Biosimilars and Their Use Across Europe: A Call for Strengthened One Voice messaging. Liese Barbier, Allary Mbuaki, Steven Simoens, Paul Declerck, Arnold G. Vulto, and Isabelle Huys. Frontiers in Medicine 2022, Vol 9, 820755
3. Safety, Immunogenicity and Interchangeability of Biosimilar Monoclonal Antibodies and Fusion Proteins: A Regulatory Perspective. Pekka Kurki, Sean Barry, Ingrid Bourges, Panagiota Tsantili, Elena Wolff-Holz. Drugs 2021 Nov;81(16):1881-1896
4. The safety of switching between therapeutic proteins. Ebbers H, Muenzberg M, Schellekens H. Expert Opinion Biol Ther. 2012;12:1473-85
5. Biosimilars in the EU - Information guide for healthcare professionals (europa.eu)

15. Appendix 7 – Patient letter: Biological originator with Homecare provider switch

[Insert_GENERIC Drug_Name]: Switching brands from [Insert_Originator_BrandName] to Insert_Biosimilar_BrandName]

We are giving you this letter because you are currently receiving treatment with a medicine called **[Insert_Drug_Name]** (brand name **[Insert_Originator_BrandName]**)

This medicine belongs to a group of drugs called “biological medicines”. Biological medicines are only made by one company at first. After an agreed upon number of years, other companies are allowed to make their own copies of the medicine. A copy of a biological medicine is called a “biosimilar”. There are now biosimilars of your medicine available to the NHS. Different companies sell the biosimilars, each with their own unique brand name.

Safety

The UK authorities thoroughly check biosimilars. The regulators have confirmed that biosimilars are just as safe and effective as the original brand.

Cost

The NHS can usually get biosimilar medicines much cheaper than the original brand.

This means that by switching our patients to a biosimilar, we will be saving money for the NHS. The saved money can be used to provide more care or treatment.

We do not expect any patients to have problems from switching to the current preferred biosimilar **[Insert_Biosimilar_BrandName]**. If you do have any problems, tell your nurse or doctor at the hospital. If you want any more information regarding biosimilars, please ask us at your next appointment.

Deliveries

A new company will deliver your new biosimilar. **([Insert_Homecare_CompanyName])** will make sure you get the new medicine. You won’t need to do anything. They will send you a welcome pack in the post with all the details. They will deliver your new biosimilar brand when your prescription is renewed by the hospital.

16. Appendix 8 – Patient letter: biological originator switch (same Homecare provider)

[Insert_GENERIC Drug_Name]: Switching brands from [Insert_Originator_BrandName] to Insert_Biosimilar_BrandName]

We are giving you this letter because you are currently receiving treatment with a medicine called **[Insert_Drug_Name]** (brand name **[Insert_Originator_BrandName]**)

This medicine belongs to a group of drugs called “biological medicines”. Biological medicines are only made by one company at first. After an agreed upon number of years, other companies are allowed to make their own copies of the medicine. A copy of a biological medicine is called a “biosimilar”. There are now biosimilars of your medicine available to the NHS. Different companies sell the biosimilars, each with their own unique brand name.

Safety

The UK authorities thoroughly check biosimilars. The regulators have confirmed that biosimilars are just as safe and effective as the original brand.

Cost

The NHS can usually get biosimilar medicines much cheaper than the original brand.

This means that by switching our patients to a biosimilar, we will be saving money for the NHS. The saved money can be used to provide more care or treatment.

We do not expect any patients to have problems from switching to the current preferred biosimilar **[Insert_Biosimilar_BrandName]**. If you do have any problems, tell your nurse or doctor at the hospital. If you want any more information regarding biosimilars, please ask us at your next appointment.

Deliveries

([Insert_Homecare_CompanyName]) will make sure you get the new medicine. You won’t need to do anything. They will send you a welcome pack in the post with all the details. They will deliver your new biosimilar brand when your prescription is renewed by the hospital.

17. Appendix 9 – Biosimilar & Homecare provider switch

[Insert_GENERIC Drug_Name]: Switching brands from [Insert_Current_Biosimilar_BrandName] to Insert_Biosimilar_BrandName]

We are giving you this letter because you are currently receiving treatment with a medicine called **[Insert_Drug_Name]** (brand name **[Insert_Current_Biosimilar_BrandName]**)

This medicine belongs to a group of drugs called “biological medicines”. Biological medicines are only made by one company at first. After an agreed upon number of years, other companies are allowed to make their own copies of the medicine. A copy of a biological medicine is called a “biosimilar”. Different companies sell the biosimilars, each with their own unique brand name.

Safety

The UK authorities thoroughly check biosimilars. The regulators have confirmed that biosimilars are just as safe and effective as the original brand.

Cost

The NHS can usually get biosimilar medicines much cheaper than the original brand.

This means that by switching our patients to a biosimilar, we will be saving money for the NHS. The saved money can be used to provide more care or treatment.

We do not expect any patients to have problems from switching to the current preferred biosimilar **[Insert_Biosimilar_BrandName]**. If you do have any problems, tell your nurse or doctor at the hospital. If you want any more information regarding biosimilars, please ask us at your next appointment.

Deliveries

A new company will deliver your new biosimilar. **([Insert_Homecare_CompanyName])** will make sure you get the new medicine. You won’t need to do anything. They will send you a welcome pack in the post with all the details. They will deliver your new biosimilar brand when your prescription is renewed by the hospital.

18. Appendix 10 – Patient letter: Biosimilar switch (same Homecare provider)

[Insert_GENERIC Drug_Name]: Switching brands from [Insert_Current_Biosimilar_BrandName] to Insert_Biosimilar_BrandName]

We are giving you this letter because you are currently receiving treatment with a medicine called **[Insert_Drug_Name]** (brand name **[Insert_Current_Biosimilar_BrandName]**)

This medicine belongs to a group of drugs called “biological medicines”. Biological medicines are only made by one company at first. After an agreed upon number of years, other companies are allowed to make their own copies of the medicine. A copy of a biological medicine is called a “biosimilar”. Different companies sell the biosimilars, each with their own unique brand name.

Safety

The UK authorities thoroughly check biosimilars. The regulators have confirmed that biosimilars are just as safe and effective as the original brand.

Cost

The NHS can usually get biosimilar medicines much cheaper than the original brand.

This means that by switching our patients to a biosimilar, we will be saving money for the NHS. The saved money can be used to provide more care or treatment.

We do not expect any patients to have problems from switching to the current preferred biosimilar **[Insert_Biosimilar_BrandName]**. If you do have any problems, tell your nurse or doctor at the hospital. If you want any more information regarding biosimilars, please ask us at your next appointment.

Deliveries

([Insert_Homecare_CompanyName]) will make sure you get the new medicine. You won’t need to do anything. They will send you a welcome pack in the post with all the details. They will deliver your new biosimilar brand when your prescription is renewed by the hospital.

19. Appendix 11 – Procedural Document Checklist for Approval

		Yes/No/ Unsure	Comments/ Details
1.	**Sponsoring Director**		
	Is there a sponsoring director?	Yes	LH
	Have they approved **this version** of the policy?	Yes	
2.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	Policy
3.	**Rationale**		
	Are reasons for development of the document stated?	Yes	In summary
4.	**Development Process**		
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	APC paper includes feedback from consultation
5.	**New or review**		
	Is this a new document?	New	
	Is the ratification date stated on the front cover?	Yes	
	Is the ratification Committee stated on the front cover?	Yes	
	Is the review date stated on the front cover?	TBC	After advice from corporate review
	Is the version control detailing the version history of the document?	Yes	
	If this is a review document, has the version number been amended throughout?	N/A	
6.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target group clear and unambiguous?	Yes	Roles and responsibilities noted
	Are the intended outcomes described?	Yes	Specific outcomes will be dependent on the which biological/biosimilar drug is being implemented
7.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	NHSE
	Are key references cited?	Yes	
8.	**Quality and Equality Impact Assessment**		
	Has a QEIA been completed?	Yes	
	Is the QEIA attached?	Yes	
9.	**Style and Format**		
	Is the style and format in line with the *Framework for the Production of Procedural Documents*?	Yes	SyH policy template followed

		Yes/No/ Unsure	Comments/ Details
	Does the footer include the title, date of ratification and version number?	Yes	
	Are definitions provided for the key terms used in the document?	Yes	
	If applicable, are abbreviations written according to the guidance in *Framework for the Production of Procedural Documents*?	Yes	
10.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
11.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how the document will be disseminated and implemented amongst the target group? Please provide details.	Yes	Internal provider governance routes, published on SyH internet and on Prescriibng Advisory Database
12.	**Process for Monitoring Compliance**		
	Have specific, measurable, achievable, realistic and time-specific standards been detailed to monitor compliance with the document? Complete Compliance & Audit Table.	Yes	
13.	**Review Date**		
	Is the review date identified?	Yes	
14.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for implementing and reviewing the documentation i.e. who is the document owner?	Yes	

20. Appendix 12 – Compliance and Audit Table

Criteria	Measurable	Frequency	Reporting to	Action Plan/ Monitoring
For each locally agreed biologic/biosimilar switch:				
Trust **starts new patients** to agreed biologic/biosimilar	90%	Within 3 months of locally agreed start date	Internal Trust Medicines Committee SyH Medicines Optimisation Board	Monitored via Secondary Care Financial Sustainability Group
Trust **transitions existing patients** to agreed biologic/biosimilar	80%	Within 12 months of locally agreed start date	Internal Trust Medicines Committee SyH Medicines Optimisation Board	Monitored via Secondary Care Financial Sustainability Group

21. Appendix 13: Quality and Equality Impact Assessment (QEIA)

Scheme/policy name: Biological & biosimilar of best value policy

Date commenced QEIA: 17/05/2024

1. Indicate below whether this scheme or policy will affect stakeholders at place (select which one(s)) or system level:

East Surrey ☐ Guildford & Waverley ☐ North West Surrey ☐ Surrey Downs ☐ Surrey Heartlands ☒ Surrey ☐

2. Brief summary of the proposal

This is a new policy that outlines the system-wide commitment to achieving the best value in the procurement of biologicals and biosimilars. In instances where brand patents have expired and generic/biosimilar alternatives are available, Trusts will adopt a switching strategy to the most cost-effective option.

The aim is to capitalise on the potential cost savings offered by generics, while maintaining the high quality of patient care. Clinicians play a crucial role in this process and are responsible for identifying any patients who may not be suitable for the switch to a biosimilar alternative. In such cases, it is the responsibility of the clinician to communicate with Pharmacy, providing clear and documented reasons for the necessity of the originator product.
This policy is aligned with Surrey Heartlands ICB partner organisations commitment to fiscal responsibility, efficiency, and the delivery of exceptional patient care.

3. Engagement and Involvement (Duty to Involve)

Who has been or needs to be involved with developing this QEIA? A key principle for completing impact assessments is that **they should not be done in isolation.** Consultation and engagement with affected groups and stakeholders is vital and needs to be built in from the start, to enrich the assessment and develop relevant mitigations/actions. Detail here who is supporting the completion of this QEIA.

List any groups / forums you have approached, such as service users, carers, protected characteristic groups etc.	Activity undertaken e.g., meeting; workshop; focus group
Surrey Heartlands Specialist Clinical Networks	Virtual circulation for comment. No patients/service users are on these groups. Clinicians provided feedback on patient experience from previous similar projects.

List any individuals you have consulted with, either from your own organisation or partner agencies:	
Job Title	**Organisation**
Provider organisations via Pharmacy Departments	Virtual circulation for comment
Area Prescribing Committee consultation distribution list	Virtual circulation for comment
Area Prescribing Committee members present at the meeting on 5th July 2024	Item as part of TEAMs meeting
Head of Corporate Governance and Risk	Surrey Heartlands ICB
Senior Quality and Safety Manager	Surrey Heartlands ICB
Associate Director of Patient Experience and Partnerships	Surrey Heartlands ICB

4. Equality and Health Inequalities Impact Assessment *(see Appendix 1 for notes on definitions)*

Note: Whilst the outcome may be similar, you need to tailor your response and rationale to each characteristic. Do not enter the same answer for every row.
Consult Surrey i for current information alongside other research data.
Protected characteristics under the Equality Act 2010 must all be considered, and information included for each characteristic.

Duties as to reducing health inequalities: Where relevant to your proposal, please also provide details on how the proposal impacts on the following:

(a) Reducing inequalities between persons with respect to their ability to access health services; and
(b) Reducing inequalities between persons with respect to the outcomes achieved for them by the provision of health services.

Protected equality characteristic	Summary explanation of the main potential positive or adverse impact of your proposal. Describe concerns regarding the proposal/policy for these groups.	Main recommendations from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Age older people; middle years; early years; children and young people	The policy covers all age groups – there is no impact on any one specific age group. Clinical choice of drug based on age is not within the scope of this policy.	N/A
Disability Physical, sensory, and learning impairment, long-term conditions, mental health condition)	The policy requires patients to understand that they are being switched to a biosimilar that is the same drug but will have a different brand name and possibly a different device. This could impact on those with learning impairment, mental health conditions or those with dexterity problems. People with visual and hearing impairment will require adjustments to be made under the AIS to enable them to participate in their care as stated in the policy.	Information referred to in this policy which is to be shared with patients (verbal and written) must be provided in line with the Accessible Information Standard and language requirements to ensure optimal medicines use. Organisations must ensure that their clinical system enables advance notice of adjustments required ahead of consultations when decision to switch will be discussed. Training is provided if devices are changed significantly Learning Disability Liaison teams should be involved in consultations for patients with LD and written communication in line with Easy Read
Gender reassignment and/or people who identify as Transgender	There is no to reference gender identity in the policy that would result in any positive or negative impact on trans people.	N/A
Marriage & civil partnership People married or in a civil partnership	This policy does not impact adversely on this group.	N/A

Protected equality characteristic	Summary explanation of the main potential positive or adverse impact of your proposal. Describe concerns regarding the proposal/policy for these groups.	Main recommendations from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Pregnancy & maternity Women before and up to one year after childbirth	Being pregnant and taking particular medication can present a risk to the unborn child - Clinical choice of drug based on pregnancy is not within the scope of this policy.	N/A
Race[1]	People belonging to different races may not speak or understand English as a first language	Information referred to in this policy which is to be shared with patients must be provided in line with language requirements to ensure participation in decisions regarding their own care and optimal medicines use.
Religion & beliefs People with different religions/faiths or beliefs or none.	This policy does not impact on religion and beliefs	N/A
Sex Men; women	There is no reference to sex in the policy that would result in any positive or negative impact on males or females.	N/A
Sexual orientation Lesbian; Gay; Bisexual; Heterosexual.	The policy covers all people within Surrey Heartlands who need biological medicines irrespective of their sexual orientation	N/A

Briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). Please state N/A if your proposal will not impact on patients who experience health inequalities. Complete for those that apply.

[1] Addressing racial inequalities is about identifying any ethnic group that experiences inequalities. Race and ethnicity include people from any ethnic group including Black and Minority Ethnic communities, non-English speakers, Gypsies, Roma and Travelers, migrants etc. who experience inequalities so includes addressing the needs of BME communities but is not limited to addressing their needs; it is equally important to recognise the needs of White groups that experience inequalities. The Equality Act 2010 also prohibits discrimination on the basis of nationality and ethnic or national origins, issues related to national origin and nationality.

Groups who face health inequalities[2]	Summary explanation of the main potential positive or adverse impact of your proposal. Describe concerns regarding the proposal/policy for these groups.	Main recommendations from your proposal to reduce any key identified adverse impact or to increase the identified positive impact.
Armed forces	Nothing specific in our policy. NHSE makes separate provision for specialised services but our policy would not impact either positively or negatively on this group.	N/A
Carers of patients Unpaid, family members.	There should be no adverse impact on carers who can support decisions regarding switching, especially if they are responsible for administration of medication	N/A
Digital exclusion[3]	ICT access by patients is not required to implement this policy. All communication will be	All communication will be either face to face in clinic setting or by letter for those under homecare arrnagements
Domestic abuse	N/A	N/A
Homeless people People on the street; staying temporarily with friends/family; in hostels or B&Bs	This group may be difficult to contact to inform of the switch but there is no negative impact to the patient if they do not switch	N/A
Looked after children & young people	N/A	N/A
People living in remote and rural locations	N/A	N/A
People or families on a low income	N/A	N/A
People living in deprived areas	N/A	N/A
People with addictions and/or	N/A	N/A

[2] Please note many groups who share protected characteristics have also been identified as facing health inequalities.

[3] Digital exclusion is where a section of the population has continuing unequal access and capacity to use Information and Communications Technologies (ICT) that are essential to fully participate in society (Schejter, 2015; Warren, 2007).

Groups who face health inequalities[2]	Summary explanation of the main potential positive or adverse impact of your proposal. Describe concerns regarding the proposal/policy for these groups.	Main recommendations from your proposal to reduce any key identified adverse impact or to increase the identified positive impact.
or substance misuse issues		
People involved in the criminal justice system. Offenders in prison/on probation; ex-offenders	N/A	N/A
People with poor literacy or health literacy e.g. poor understanding of health services, poor language skills	The policy requires patients to understand that they are being treated with the same drugs but a different brand name and possibly a different device. This could impact on those with poor literacy or health literacy	Patient information will be provided that is easy to comprehend - plain English; use of Easy Read for all patient groups to ensure that this vulnerable group are catered for
Refugees, asylum seekers or those experiencing modern slavery	This group may be difficult to contact to inform of the switch but there is no negative impact to the patient if they do not switch	N/A
Other groups experiencing health inequalities (please describe)	N/A	N/A

5. Quality Impact Assessment *(see Appendix 2 for notes on definitions and Appendix 3 for how to calculate Risk Score)*

Note: Whilst the outcome may be similar, you need to tailor your response and rationale to each section. Do not enter the same answer for every row.

In the table below describe the positive and negative impacts associated with the scheme for each area.

If any area is identified as having a potential negative effect, you must calculate the overall risk score for this by multiplying the score for level of impact and the score for likelihood of occurrence together, using the risk matrix in Appendix 3. Insert the total in the appropriate box.

If a negative effect is identified, please also provide any suggested mitigations.

Area	**Positive Impacts:** Describe any positive impacts your scheme could have on each area.	**Negative Impacts:** Describe any negative impacts your scheme could have on each area. (Pre any mitigations already in the scheme/policy)	**Risk Score Pre-Mitigations** Appendix 3	**Suggested mitigations:** (These can be mitigations already identified within the scheme/policy, or new in response to the QEIA)	**Risk Score Post-Mitigations** Appendix 3
Patient Safety:	Standardises processes for all patients to ensure the safe management of switches.	Some risk of adverse effect due to different excipients. Small risk of patient deterioration if device changed. Possible risk of disease flare but this could be due to natural disease progression.	2x3=6 Moderate	Training on any changed device is given – in policy. Patients will be given access to a specific contact within the Trust if they have any post-switch issues.	2x2=4 Low
Staff Safety:	Provides staff with an agreed process to follow	Some patients may be resistant to switching that could create a difficult situation for staff affecting their safety	1x3=3 Low	Staff are used to managing difficult conversations regarding treatments. Ensure staff are up to date with stat and mand training	1x1=1 Low
Clinical Effectiveness:	Based on evidence from MHRA and NHSE guidance to get the best value from these medicines.	Small risk of patient deterioration if device changed. Possible risk of disease flare but this could be due to natural disease progression.	2x3=6 Moderate	Training on any changed device is given – in policy. Patients will be given access to a specific contact within the Trust if they have any post-switch issues. Pharmaco-	2x2=4 Low

Area	Positive Impacts: Describe any positive impacts your scheme could have on each area.	Negative Impacts: Describe any negative impacts your scheme could have on each area. (Pre any mitigations already in the scheme/policy)	Risk Score Pre-Mitigations Appendix 3	Suggested mitigations: (These can be mitigations already identified within the scheme/policy, or new in response to the QEIA)	Risk Score Post-Mitigations Appendix 3
		Some risk of adverse effect due to different excipients.		vigilance and monitoring section already included in the policy	
Patient Experience:	Standardises experience for patients to give similar outcomes.	Small risk of patient deterioration if device changed. Possible risk of disease flare but this could be due to natural disease progression. Some risk of adverse effect due to different excipients.	2x3=6 Moderate	Training on any changed device is given – in policy. Patients will be given access to a specific contact within the Trust if they have any post-switch issues. Patient information reviewed by lay member and comms team	2x2=4 Low
Staff Experience:	The policy ensures consistency and a reference for all staff	Some patients may be resistant to switching that could create a difficult situation for staff affecting their safety. Possibly more work for some staff	2x3=6 Moderate	P Staff are used to managing difficult conversations regarding treatments. Patient information reviewed by lay member and comms team. Trusts will socialise and communicate to teams	2x2=4 Low
Organisation Experience:	Financial benefits attached to this policy will benefit the overall ICS and partner organisations, releasing resources for other use	Possible risk of complaints from patients regarding the switching policy and potential media exposure.	2x3=6 Moderate	Mitigations - comprehensive complaints service; ensure all relevant staff are aware of the change in policy.	2x1=2 Low

6. Recommendation

Based on your assessment, please indicate which course of action you are recommending to decision makers.

Outcome No.	Description	Tick

Outcome One	**No major change to the service/function/policy required.** This QEIA has not identified **any** potential for discrimination or negative impact, and all opportunities to promote equality have been undertaken. Proceed and review QEIA periodically.	☐
Outcome Two	**Adjust the service/function/policy** to remove barriers identified by the QEIA or better advance equality. Are you satisfied that the proposed adjustments would remove the barriers you identified? Proceed with adjustments, amend and review QEIA periodically.	☒
Outcome Three	**Continue with the service/function/policy** despite potential for negative impact or missed opportunities to advance equality identified. You will need to make sure the QEIA clearly sets out the justifications for continuing with it. You need to consider whether there are: • Sufficient plans to stop or minimise the negative impact, • Mitigating actions for any remaining negative impacts and plans to monitor the actual impact. Proceed, monitor, and evaluate. Discuss with SRO.	☐
Outcome Four	**Stop and rethink** the service change/proposal/policy when the QEIA shows actual or potential unlawful discrimination. Review with the SRO for this area of work within 28 days of completion of QEIA.	☐
Please explain in the blank box below the rationale for your recommendation and how your proposal gives due regard to the Public Sector Equality Duty by aiming to: • Eliminate discrimination. • Advance equality of opportunity. • Foster good relations between different people		
This policy is being introduced to provide a standard framework for organisations within Surrey Heartlands to follow when undertaking switches of biological medicines. Any impact on protected characteristics or those facing health inequalities have been mitigated within the policy as far as possible to allow equality of opportunity to switch. However, there is no negative impact for those who are not suitable for switching, originator products are as clinically effective as the new biosimilars. Initial review planned for 12 months due to this being a new policy.		
Signature (Director / Senior Responsible Officer)		
Job title	**Director of Pharmacy**	
Organisation	**NHS Surrey Heartlands**	
Date	Click or tap to enter a date.	