University Hospitals Bristol
NHS Foundation Trust

# Biosimilar Medicines Policy

| Document Data | | | |
|---|---|---|---|
| **Subject:** | Biosimilar Medicines Policy | | |
| **Document Type:** | Policy | | |
| **Document Reference** | 21598 | | |
| **Document Status:** | Approved | | |
| **Document Owner:** | High Cost Drug Pharmacist – [redacted] | | |
| **Executive Lead:** | Medical Director | | |
| **Approval Authority:** | Clinical Quality Group | | |
| **Review Cycle:** | 24 | | |
| **Date Version Effective From:** | **10 April 2018** | **Date Version Effective To:** | **10 April 2020** |

| What is in this policy? |
|---|
| This policy aims to ensure that University Hospitals Bristol NHS Foundation Trust (UH Bristol) is using the most appropriate and cost-effective high cost medicines. This includes the quick adoption of biosimilar and high cost generics. It includes governance processes to ensure equity in use of biosimilars and high cost generic medicines at UHB. |

| Document Change Control | | | | |
|---|---|---|---|---|
| **Date of Version** | **Version Number** | **Lead for Revisions (Job title only)** | **Type of Revision** | **Description of Revision** |
| 15/12/2017 | 1.00 | High Cost Drug Pharmacist | Major / Minor | First draft |
| | | | | |
| | | | | |
| | | | | |

## Table of Contents

## Do I need to read this Policy?

Are you involved in prescribing or administering of high cost drugs, or a member of pharmacy staff?

Must read the whole policy

# 1. Introduction

The policy has been developed in line with NHS England Commissioning framework for biological medicines[1]; Cancer Vanguard Guidance[2], and BOPA position statement[3] on biosimilars.

The use of biosimilars is set to increase in the next few years as patents of originator biologics expire. The adoption of biosimilars will help provide much needed savings to the NHS, which may be utilised to further benefit patient care. The purpose of the policy is to aid this early adoption process in order that the benefits can be realised early.

The policy is overarching and should be used in conjunction with individual implementation plans that will be developed for the introduction and use of each biosimilar at the Trust.

# 2. Purpose

The purpose of this policy is to ensure that biosimilar and high cost drug generics are being used cost-effectively and with appropriate governance arrangements within the Trust.

# 3. Scope

This policy relates to the use of all biosimilar and high cost generics at University Hospitals Bristol NHS Foundation Trust (UH Bristol).

# 4. Definitions

## *4.1 Biological medicine*

Medicine derived from living cells or organisms, consisting of large highly complex molecular entities which may be difficult to characterise.

## *4.2 Biosimilar medicine*

A biological product that is highly similar but not identical, to the licensed originator biological medicine and shows no clinically meaningful difference in terms of quality safety and efficacy.

## *4.3 Generic medicine*

Is identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

## *4.4 Extrapolation*

The decision by the Regulator whether to extend the efficacy and safety data from an indication for which a biosimilar has been clinically tested to other conditions for which the reference product is approved.

### *4.5 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.

## 5. Duties, Roles and Responsibilities

### *5.1 Director of Pharmacy*

(a) Responsible for the cost-effective use of biosimilars and high-cost generics; and the governance framework for these medications.

(b) Responsible for ensuring accurate high cost drug data is supplied to finance for invoicing

(c) Ensure that Pharmacy staff comply with this policy.

### *5.2 Medical Director*

(a) Supports the cost-effective use of biosimilars and high-cost generics

(b) Ensure that prescribers comply with this policy.

### *5.3 Trust Divisional Directors and Clinical Chairs*

(a) Support the introduction and use of biosimilars and high cost generics within their division.

### *5.4 Lead Consultant (and clinical team)*

(a) Support the planning for introduction of biosimilar drugs and high cost generics

(b) Support and implement the introduction of biosimilar drugs and high cost generics

(c) Support the continued use of cost-effective biosimilars and high cost generics

### *5.5 High Cost Drug Pharmacists*

(a) Coordinate and manage an effective implementation programme for each new biosimilar of high cost generic

(b) Report on uptake of the biosimilar medicine following any biosimilar introduction and report financial savings from adoption.

(c) Select the most appropriate product for the Trust within commissioner framework

### *5.6 Specialist and clinical pharmacists*

(a) Support planning and implementation of any biosimilar or high cost generic within the specialism

(b) Provide information on biosimilars to high cost drug pharmacists and patients.

(c) Provide required detail for management of Trust prescribing systems and aseptics unit worksheets (if required).

### *5.7 Responsibility for Monitoring Compliance*

(a) Medicines Advisory Group

(b) Director of Pharmacy

(c) High Cost Drugs Pharmacist

## 6. Policy Statement and Provisions

### *6.1 Biosimilar drugs*

The Trust fully endorses the use of and switching to biosimilar agents and generic medicines as part of its responsibility to ensure the most cost effective use of NHS resources.

The governance and introduction of biosimilars agents and high cost drug generics within the Trust will be overseen by the Medicines Advisory group (MAG) in discussion with the relevant commissioner. Prescribers will be expected to adhere to the Trust's position on the use of biosimilars.

### *6.2 Prescribing requirements*

Biologic/biosimilars must be prescribed by BRAND name. A biologic and its biosimilars are not interchangeable at dispensing and should only be substituted with the prescriber's knowledge and consent.

### *6.3 Considerations prior to adoption*

The introduction of a switch to a biosimilar medicine should be pre-planned so that stakeholders are well prepared and additional activity associated with introduction is minimised. A Trust implementation plan (see Appendix C) should be used to plan the introduction of each biosimilar medicine.

### *6.4 Homecare*

When a biosimilar becomes available for a drug that is delivered by homecare, pre-planning will be required to ensure that prescriptions are changed in a timely manner. Homecare arrangements must be organised to minimise any impact on patients.

### 6.5 Existing versus new patients

At the earliest opportunity new patients should be prescribed a biosimilar medication if it is approved for Trust use. The implementation plan will detail the agreed approach to switching existing patients to a new biosimilar within agreed time frames.

### 6.6 Governance requirements and local approval

Switching between a biologic and its biosimilars should be in accordance with a BNSSG formulary application and Trust implementation plan.

### 6.7 Informing and involving patients in introduction

Patients' whose treatment is affected by the introduction of a biosimilar medicine will be informed of the Trust's position on the use of biosimilars and encouraged to switch to a biosimilar in a timely manner. Patients should be fully informed when receiving treatment with a biosimilar, the method of informing patients should be agreed in the implementation plan. A standard letter for the Trust has been developed that can be adapted as needed, (see Appendix A).

Patients beginning treatment with a biologic drug that is likely to be available as a biosimilar imminently, should be informed of the situation and told that they will be switched to the biosimilar when it becomes available in-line with the Trusts implementation plan for the particular biosimilar.

### 6.8 Reverting to use of the originator product

If it is felt that a patient requires to be switched back to the originator product the form 'Request to switch back from Biosimilar to Originator Biologic' (Appendix B) should be completed and discussed at a suitable multi-disciplinary team meeting (eg Speciality Biologics meeting).

### 6.9 Pharmacovigilance and monitoring

The Trust will continue a patient-centred pharmacovigilance framework, including the use of national registries where they exist and yellow card scheme to monitor and report outcomes and any adverse effects associated with biologic/biosimilar therapy. Yellow card reporting should be completed as per Trust policy.

### 6.10 Clinical outcomes monitoring

As with all biologic medicines collection of clinical outcomes should take place, and after an agreed time period assessed to ensure quality of outcomes.

## 7. Standards and Key Performance Indicators

### 7.1 Applicable Standards

Medicine use within the trust will be in accordance with the policy requirements detailed in the chapters of the Trusts medicines code.

### *7.2 Measurement and Key Performance Indicators*

(a) Medication related clinical incidents will be monitored and investigated where the degree of actual harm is moderate or above. Trends will be identified and investigated.

(b) Prescribing will be in accordance with the prescribing chapters of the Trusts medicines code.

(c) High cost drug reporting will be in accordance with contract agreements with commissioners

(d) Medicines will be administered to patients in accordance with the administration of medicines policy and SOPs

## 8. References

NHS England Commissioning framework for biological medicines First published: 12 September 2017. Prepared by: Medicines, Diagnostics and Personalised Medicine Policy Team. National Medical Directorate, NHS England

Cancer Vanguard Guidance

BOPA position statement

# 9. Appendix A – Trust biosimilar switch letter template

**Department**
Address Line 1
Address Line 2
Bristol
Postcode

NAME OF PERSON
ADDRESS LINE 1
ADDRESS LINE 2
TOWN/CITY
COUNTY
POSTCODE

Tel 0117 342 xxxx
Fax 0117 xxx xxxx

Email: Appointment.Address@UHBristol.nhs.uk

**Date:** date-month-2010
**NHS Number:** 000 000 0000
**Hospital Number:** ABC 000000D

Dear

You have been given this letter because you are currently being treated with a drug called Click here to enter text..Click here to enter text. is one of a group of medicines called biologic medicines. We are planning to move to a different supplier of this medication and want to provide some background information on this prior to your next infusion unit visit where we can discuss this is detail and answer any additional questions to support your understanding as to why this change is being made.

Until recently, Click here to enter text. has been available from one manufacturer only under the brand name of Click here to enter text. The patent on Click here to enter text.has now expired meaning that other companies are now also allowed to make and sell biosimilarClick here to enter text..

In common with other hospitals in the UK, we are gradually changing to use of biosimilarClick here to enter text.. We expect the change will result in very substantial savings and we can use this money to support patient care in other ways. We do not expect any patients to experience problems as a result of switching to biosimilarClick here to enter text., and will continue to monitor every patient's response to the therapy as we have always done. As other biosimilar Click here to enter text. become available it may be necessary to change the product again.

There is a link to some frequently asked question which may be of interest at the end of this letter.

If you have any queries about your treatment with Click here to enter text. or any other medicine, please speak to the staff in the infusion unit.

Yours sincerely

The Click here to enter text.team

# 10. Appendix B- Request to switch back from Biosimilar to Originator Biologic form

University Hospitals Bristol NHS
NHS Foundation Trust

**Request to switch back from Biosimilar to Originator Biologic**

**Patient Information**

NHS number: _____

Condition being treated: _____

Consultant making request: _____

Biosimilar brand used: _____

Originator product requested:

| History of drug treatment of the relevant condition | | | |
|---|---|---|---|
| **Date** | **Medication** | **Dose** | **Patient response** |
| | | | |
| | | | |
| | | | |
| | | | |

| | | | |
|---|---|---|---|
| Dates of biosimilar used: From: | | To: | |
| Total number of doses of biosimilar received | | | |
| Clinical reasons for requesting a switch back to the originator product: | | | |
| | | | |

**11. Multi-disciplinary Team meeting decision**

Date of MDT:

Summary of MDT discussion

☐ Approved

☐ Rejected

Signature:

Comments:

# 12. Appendix C- Biosimilar/Generic product Implementation plan

| Product Information |
|---|

Branded product: _____

Biosimilar/Generic products available:

| Conditions product used in: | | | | | |
|---|---|---|---|---|---|
| Condition | Commissioner | Division | Pharmacist | Consultants | Specialist nurses |
| | | | | | |
| | | | | | |

| | |
|---|---|
| Predicted date of biosimilar/generic availability | |
| Date for introduction of biosimilar/generic at UHB | |

| Number of eligible patients | | |
|---|---|---|
| | Total number of patients prescribed drug under review | Patients eligible for biosimilar usage according to Trust policy (all patients without indication protected by patent or research protocol) |
| IV | | |
| SC | | |
| Oral | | |
| | | |
| Clinical trial patients | | |
| Patients on commercial stock | | |
| Patients on sponsor funded trial stock | | |
| **Drug acquisition costs** | | |
| Current Drug cost | | |
| Current Service delivery model | | |
| Do you expect this model to change as a result of using a biosimilar/ generic? | | |
| **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 +/- consent patients | | |
| • Preparation of patient materials and education | | |
| • Time associated with clerking patient | | |
| Administration costs<br>i. Chair time (Vs. total capacity)<br>ii. Monitoring | | |
| • Resources associated with ensuring reimbursement from commissioners | | |
| • Costs associated with prescribing or administration errors | | |

| | |
|---|---|
| • Preparation and validation of aseptic worksheet | |
| • Preparation for formulary application | |
| • Development/adaption of biosimilar policy and guidance | |
| • Development and delivery of patient focused and staff educational material | |
| • Costs of further education of staff (initial and ongoing) | |
| • Updating electronic prescribing and dispensing software | |
| • Costs due to lack of stability data/validated method | |
| • Costs associated with changes to prescribing activities and uncertainty | |
| **Patient satisfaction survey** | |
| Costs to perform patient satisfaction survey | |

| | |
|---|---|
| Staff consulted | |
| Patient information strategy | |
| Patient outcomes monitoring | |
| Enablers required | |
| Predicted PA cost savings | |
| Data collection and reporting | |

Comments:

☐New JAC files added

☐Stocks of branded product reduced, new re-order levels set

☐All relevant guidelines updated

☐Implementation discussed at MAG

☐Commissioner agreement for implementation plan

**Completed by:**

## 13. Appendix D- Monitoring Table for this Policy

| Objective | Evidence | Method | Frequency | Responsible | Committee |
|---|---|---|---|---|---|
| Biosimilar and high cost generics being used appropriately | CQUIN performance<br>NHSi Model Hospital Dashboard | Review at MAG | Bi-monthly | Director of Pharmacy | MAG |

## 14. Appendix E – Dissemination, Implementation and Training Plan

| Plan Elements | Plan Details |
|---|---|
| **The Dissemination Lead is:** | [redacted] |
| **This document replaces existing documentation:** | No |
| **Existing documentation will be replace by:** | [DITP - Existing documents to be replaced by] |
| **This document is to be disseminated to:** | All Pharmacy staff, all prescribers, nurse specialists in appropriate specialties |
| **Method of dissemination:** | Medicines Advisory Group and Medicines Governance Group<br>Email to all of Pharmacy staff for information and to further disseminate to relevant clinical colleagues.<br>Sent to Non-Medical Prescribers Group<br>Sent to all Consultants and Clinical Specialist nurses regularly prescribing biologic medicines |
| **Training is required:** | No |
| **The Training Lead is:** | [DITP - Training Lead Title] |

| Additional Comments |
|---|
| [DITP - Additional Comments] |

# 15. Appendix F – Document Checklist

| Checklist Subject | Checklist Requirement | Document Owner's Confirmation |
|---|---|---|
| **Title** | The title is clear and unambiguous: | Yes |
| | The document type is correct (i.e. Policy, Policy, Protocol, Procedure, etc.): | Yes |
| **Content** | The document uses the approved template: | Yes |
| | The document contains data protected by any legislation (e.g. 'Personal Data' as defined in the Data Protection Act 2000): | No |
| | All terms used are explained in the 'Definitions' section: | Yes |
| | Acronyms are kept to the minimum possible: | Yes |
| | The 'target group' is clear and unambiguous: | Yes |
| | The 'purpose and scope' of the document is clear: | Yes |
| **Document Owner** | The 'Document Owner' is identified: | Yes |
| **Consultation** | Consultation with stakeholders (including Staff-side) can be evidenced where appropriate: | Yes |
| | The following were consulted: | MAG Group |
| | Suitable 'expert advice' has been sought where necessary: | Not Applicable |
| **Evidence Base** | References are cited: | Yes |
| **Trust Objectives** | The document relates to the following Strategic or Corporate Objectives: | We are accountable for our use of public resources |
| **Equality** | The appropriate 'Equality Impact Assessment' or 'Equality Impact Screen' has been conducted for this document: | Not Applicable |
| **Monitoring** | Monitoring provisions are defined:<br>(a) Medication related clinical incidents will be monitored and investigated where the degree of actual harm is moderate or above. Trends will be identified and investigated. Via Medicines Governance Group.<br>(b) Prescribing will be in accordance with the prescribing chapters of the Trusts medicines code.<br>(c) High cost drug reporting will be in accordance with contract agreements with commissioners<br>(d) Medicines will be administered to patients in | Yes |

| Checklist Subject | Checklist Requirement | Document Owner's Confirmation |
|---|---|---|
| | accordance with the Trust Administration of medicines policy and related SOPs | |
| | There is an audit plan to assess compliance with the provisions set out in this procedural document: | Not Applicable |
| | The frequency of reviews, and the next review date are appropriate for this procedural document: | Yes |
| **Approval** | The correct 'Approval Authority' has been selected for this procedural document: | Yes |

| Additional Comments |
|---|
| [DCL - Additional Comments] |