Biosimilar policy UK

1. Introduction and Purpose

The purpose of this policy is to inform medical, nursing, pharmacy and relevant staff of the existence of biosimilars and its implementation into clinical practice. Biosimilar medicinal products which offers a less-costly alternative to existing biological medicinal products that have lost their exclusivity rights. The availability of biosimilar medicinal products enhances competition and offers potential economic benefit to GenesisCare UK (GCUK) while addressing the issue of new treatment options brought about by advances in medical science. GCUK is committed to providing safe and cost-effective treatment to private patients.

The policy has been developed in line with recommendations from the Cancer Vanguard – Biosimilar adoption programme

2. Terms and Definitions

- **Biologics** - Medicines that are made or derived from a biological source and as such are complex with inherent variability in their structure. As biological medicines are derived from living cells or organisms there is always a small degree of variability in the manufacturing process, thus biologics may show a degree of variation from batch to batch of the product. This is also the case for biosimilars.

- **Biosimilars** - are highly similar to the biological originator medicine (already licensed), shown by non-clinical studies (in vivo and in vitro analysis) and clinical studies to show no clinically meaningful differences from the originator biological medicine in relation to quality, safety and efficacy.

  To note: Biosimilar medicines are not considered as generic to the originator biological medicines the two are "similar" and not identical. However, in relation to licensing they have met stringent regulatory requirements based on a comprehensive scientific comparability exercise such that they do not have any clinically meaningful differences from the reference medicines in terms of quality, safety and efficacy

- **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.

- **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.

- **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.

3. Scope

The use of biosimilars in cancer is set to increase exponentially in the next few years as patents of originator biologics expire. The adoption of biosimilars will help provide much needed savings to the NHS and PMI, which may be utilised to further benefit patient care (however introduction should not be driven purely by financial considerations). The purpose of the policy is to aid this adoption process in order that the benefits can be realised early and needs to be in line with our Insurance expectation. The use of biosimilars will not alter the care provided to patients, with the patient seeing no change in the treatment experience.

4. Responsibilities

This policy applies to medical, nursing, pharmacy staff and other key staff involved in any aspects of providing biosimilar medicines to patients.

4.1. Chief Medical Officer is responsible for:

- Promoting and informing practising oncologists the introduction of Biosimilar within GCUK
- Signing off any policy or SOP relating to Biosimilars within GCUK
- Agreeing brand of biosimilars to be introduced within GCUK, which has been identified by Principal Pharmacist
- Guiding GCUK clinical staff with queries

4.2. Consultant Oncologists are responsible for:

- Supporting GCUK in the introduction of biosimilar in the agreed patient groups e.g. Rituximab (Truxima) in Haematology patients
- Carrying out initial patient consultation with patients regarding biosimilar adoption and consent
- Supporting patients refusing biosimilars and how to raise with insurance
- Providing relevant information if patients in unable to be treated with biosimilars

4.3. Principal Pharmacist is responsible for:

- Identifying appropriate biosimilars for GCUK
- Procurement of biosimilars are in accordance to GCUK policy
- Approaching relevant Pharma company for clinical information
- Supporting centre staff on training and implementation of biosimilars
- Developing relevant policies and SOPs relating to biosimilars
- Ensuring any chosen biosimilars are discussed at Medicine Management Committee meeting
- Providing audit tools and discussing any incident relating to biosimilars
- Ensuring biosimilars are prescribed by name within the electronic prescribing system as recommended by Vanguard, NICE and BOPA

4.4. Centre Pharmacists are responsible for:

- Providing information regarding biosimilars to Health Care Professionals (HCP)
- Arranging training from relevant biosimilar manufacturers
- Co-ordinating and managing an effective implementation programme
- Reporting on the uptake of biosimilars and monitoring that ePrescribing of biosimilars are in accordance with policy
- Conducting audits and reporting all adverse side effect via Datix reporting system and Yellow card.

4.5. Centre chemotherapy nurses are responsible for:

- Attending training and supporting GCUK adoption of biosimilars
- Carrying out initial consultation with patients in lead up to biosimilar medicine adoption
- Being available to answer patient questions and provide information regarding biosimilar medicines to patients and other HCPs should it be required
- Reporting all adverse effects via Datix.
- Completing Biosimilar audits

5. Biosimilar

GC has taken the decision to adopt biosimilars for all NEW patients. The following was considered prior to biosimilar adoption:

- Does the biosimilar have the required licensed indications?
- Anticipated launch date and supply chain details

- Patient groups to be included
- Will the biosimilar be intended for all indications or only specific indications?
- Are the biosimilar presentations i.e. strengths, concentration & preparation the same as for the originator?
- Are the biosimilars stability once prepared and storage conditions the same as the originator?
- Are the biosimilar administration requirements the same as for the originator i.e. route and duration of administration?
- Are the required clinical outcomes data available prior to review by Medicine Management Committee?
- Are several biosimilars medicines for the same originator biological medicine anticipated to be launched around the same time by different manufacturers? If so, a decision will need to be made on which will be adopted, and when, with an aim to avoid further changes in the short-term which may introduce risk and damage patient confidence
- Possible resource implications of the adoption process. These may include:
    - patient counselling requirements
    - MDT education and training requirements
    - possible administration duration change

Biosimilar products adopted by GC

Reference product (substance)	**Biosimilar products**
Herceptin® (Trastuzumab)	Herzuma
MabThera® (Rituximab)	Truxima

6. Prescribing requirements & interchangeability

It is recommended that biosimilar medicines be prescribed by brand name for example, "International Non-proprietary Name (INN) (Brand name®)" i.e. "Rituximab (Truxima®)" (see section on electronic prescribing systems). This will ensure that automatic substitution of a biosimilar product does not occur when the medicine is dispensed by the pharmacist.

Automatic substitution is not appropriate for biological medicines, including biosimilars. Biosimilars are interchangeable. Interchangeability is the practice of changing one medicine for another that is expected to achieve the same clinical

effect. The decision to interchange is one that again requires review and due consideration by the prescribing clinician/team and approval via the MMC.

Batch number must also be recorded as with all biologic medicines in case of requirement to report an ADR.

All new GC patients to be started on biosimilars, will follow the standard consent process as with the reference originator medicine (Consent Policy QR-POL-045).

7. Electronic Prescribing System

GenesisCare will continue to allow the prescribing of both the originator biological medicine and biosimilar depending on clinical reasons (e.g. in change over period, agreement with insurance or for different indications) pharmacy electronic systems will clearly differentiate between the two (i.e. brand name in the profile name and prescription). Systems such as ePrescribing and ordering system will include dispensing and ordering profile for both original and biosimilars.

8. Evaluation

This policy will be monitored by Principal Pharmacist annually or inclusion of new biosimilars. Uptake will be monitored. (Appendix 1)
Use of biosimilars will be audited using Rapid Rituximab and Trastuzumab monitoring form.

9. References

- SPC Herzuma
https://www.medicines.org.uk/emc/product/9101/smpc
- SPC Truxima
https://www.medicines.org.uk/emc/product/8878/smpc
- NHS Commissioning framework for biological medicines (including biosimilar medicines)
https://www.england.nhs.uk/wp-content/uploads/2017/09/biosimilar-medicines-commissioning-framework.pdf

- Cancer Vanguard Biosimilars Trust Policy http://cancervanguard.nhs.uk/wp-content/uploads/2017/06/UK_MKT_SDZ_17_0027f2-Policy-template-DR4.pdf
- RM Partners Trastuzumab Biosimilars https://cancervanguard.nhs.uk/wp-content/uploads/2018/05/RMP-patient-leaflet-trastuzumab-for-breast-cancer-May-2018-1.pdf
- MHRA Biosimilar products https://www.gov.uk/drug-safety-update/biosimilar-products
- Cancer Vanguard NHS 2017 http://cancervanguard.nhs.uk/wp-content/uploads/2017/03/UK_MKT_SDZ_17_0027d-Vanguard-Introduction-Training-Slide-Set-for-website-FINALii-1.pdf

10. Appendix

- Appendix 1: Biosimilars Uptake Monitoring

Revision History

Version	Date Created	Created By	Description of change
1.0	February 2020	Principal Pharmacist	New Policy

Appendix 1. Biosimilars uptake monitoring

Monitoring will be used to provide details of biosimilar uptake and any associated savings made.

Once the adoption process has stabilized the review requirement may be adjusted as mutually agreed. From initial adoption the tracker can be used to gauge success of the adoption programme.

Suggestions of information that could be tracked include:

- Indication for which biosimilar has been approved for use* (if more than one possible indication for use)
- Number of vials of biosimilar used per month

OR

- Number of mgs (or other mass unit) used per month (if manufactured by a 3rd party provider)
- Number of patients treated using biosimilar
- Number of vials of originator biologic used per month (for same indication*)

OR

- Number of mgs (or other mass unit) used per month (if manufactured by a 3rd party provider)
- Number of patients treated using originator biologic