Cancer Vanguard

Biosimilars Trust Policy – Template

Aim of this document:

The document provides generic guidance and outline for the development of local trust policies in relation to the adoption of biosimilars in trusts. All trusts work in slightly different ways and have different processes with the goal of achieving similar outcomes. The document aims to highlight key points in the use and adoption of biosimilars, which can then be developed and adapted to individual trust needs and processes as appropriate. The focus of the template is on haematological and solid tumour biosimilars, however it can be adapted to biosimilars used in all therapy areas. The policy is seen as an overarching policy which will link into specific SOPs for individual biosimilar medicines.

Summary:

What are biologics?

Medicines that are made or derived from a biological source and as such are complex with inherent variability in there 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.

What are 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.

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1. Background & scope

The policy has been developed in line with recommendations [*insert detail here, this may include different organisation e.g. Cancer Vanguard Guidance, BOPA position statement on biosimilars, NICE & others*].

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, 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 early adoption process in order that the benefits can be realised early. The use of biosimilars will not alter the care provided to patients, with the patient seeing no change in the treatment experience.

Detailed guidance will be provided on the following topics:

- Adoption process for biosimilars including:
  - Considerations prior to adoption
  - Approach to homecare if required
  - Existing versus New Patients
  - Governance requirements and local approval
  - Informing and involving patients in introduction
  - Prescribing requirements
  - IT readiness
  - Pharmacovigilance and monitoring
  - Clinical outcomes monitoring
  - Tracking of any savings

The policy is overarching and should be used in conjunction with individual SOPs developed for the introduction and use of specific biosimilars at the trust.

2. Definitions:

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

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.

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. Duties & Responsibilities

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

Lead Consultant (and clinical team)

- Support the proposed biosimilar introduction, in the agreed patient groups and endorse the DTC submission on behalf of the clinical unit
- Carry out initial patient consultation with patients in lead up to biosimilar medicine adoption (see also specialist nurses and pharmacists)

Pharmacy Department

- Coordinate and manage an effective implementation programme
- Specialist and unit pharmacists to be able to provide information on biosimilars to HCPs and patients
- Provide required detail for management of trust prescribing systems and aseptics unit work sheets (if required)
- Reporting on uptake of the biosimilar medicine following any biosimilar introduction and reporting financial savings realised from adoption
- Procurement of the selected biosimilar

- If the biosimilar is to be delivered via a Homecare delivery service, coordination and requirements of a biosimilar introduction will need to be considered

Specialist nurses and specialist pharmacists (who have direct involvement with relevant patients)

- Carry out initial consultation with patients in lead up to biosimilar medicine adoption
- Be available to answer patient questions and provide information regarding biosimilar medicines to patients and other HCPs should it be required

4. Core elements:

Introduction of a new biosimilar

This section provides potential requirements to be taken into consideration when reviewing initial adoption of a biosimilar.

4.1 Considerations to be taken prior to adoption

General:

Points to be included in policy should include:

- Does the biosimilar have the required licensed indications?
- Anticipated launch date and supply chain details
- Patient groups to be included:
- Adult and paediatric setting? Will the biosimilar be intended for all indications or only specific indications?
- Process to be adopted:
  - to be introduced by the Trust for existing patients
  - to be introduced by the Trust for new patients
  - both of the above
- Are the biosimilar presentations i.e. strengths, concentration & preparation the same as for the originator?
- Are the biosimilar 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 the trusts DTC?
- Are a number of 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 (see also section 4.10 pharmacy purchasing).

- Possible resource implications of the adoption process. These may include:
  - patient counselling requirements
  - MDT education and training requirements
  - possible administration route change e.g. SC to IV
  - possible administration duration change
  - is the biological medicine given in the Homecare setting and will this have to be reviewed (e.g. for initial dosing or patient self-administration training)

4.2 Internal governance requirements

- DTC submission as per local requirements. The submission should include points highlighted in 4.1.

4.3 Commissioner position

Prior to undertaking the change from originator biological medicine to a new biosimilar medicine, the position of the commissioner e.g. NHSE should be sought, with adoption meeting the requirements of any NHSE initiative such as CQUINs within the required timeline.

4.4 Informing and involving patients in introduction

- Local decision on requirement to inform new patients once the biosimilar has been approved and adopted at the trust. For new patients this is not a change but a recommended treatment by a clinician.
- Required at point of initial adoption to inform and educate currently-treated patients. How this is carried out will be dependent on the biological medicine in question e.g. how often it is prescribed, in what setting it is given (IP, OP, or Homecare), and how the clinics are set up.
- Possible methods for informing and involving patients may include:
  - focus groups prior to adoption
  - one to one patient consultation by trained clinician, nurse or pharmacist in lead up to the adoption (feasibility will be dependent on how the clinic is coordinated at the trust)
  - the utilisation of a patient information leaflet with Q&A section and contact details of relevant HCP if patients wish to discuss further
  - patient letter to be sent out to patients explaining:
    1. the planned change

2. how the decision has been undertaken
3. that clinical efficacy and safety have not been affected
4. that significant financial benefits will be achieved for the NHS and/or the Trust.

4.5 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. "Filgrastim (Zarzio®)"
(see section 4.6. for electronic prescribing systems).

Prescribing by brand reduces the risk of one biosimilar brand being substituted for another without a review and due consideration by the prescribing clinician/team. This does not mean that a biosimilar medicine cannot be changed from one brand to another, however this needs to be done as part of a clinically led management process.

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 local DTC.

Batch number must also be recorded as with all biologic medicines in case of requirement to report an ADR (*a local process dependent on prescribing systems should be adopted to ensure this*).

4.6 IT readiness

Points to be included in policy should include:

- If the originator biological medicine and biosimilar are both to continue to be used at the trust (e.g. in change over period or for different indications) the pharmacy systems clearly need to differentiate between the two (i.e. is brand name in the profile name). Systems will include dispensing and in some cases aseptic unit systems.

4.7 Patient Registration and consultation/ shared decision making

Following the adoption of a biosimilar at the trust it will be a local decision on how patients need to be consulted if a biosimilar change is to take place mid treatment. All new patients will follow the standard consent process as with the reference originator medicine.

4.8 Pharmacovigilance and monitoring

All biological medicines require additional monitoring for safety and any suspected adverse drug should be reported using the MHRA yellow card scheme, with the provision of the brand and the batch number.

4.9 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.

4.10 Monitoring patient satisfaction.

A patient experience survey in the form of a short questionnaire may be carried out pre and post implementation of biosimilar to ensure that the patient experience has not been negatively impacted following the introduction of the biosimilar medicine. The finding may also assist in supporting future biosimilar adoptions if shared with patients and MDTs.

4.11 Pharmacy Purchasing requirements

Close liaison with regional procurement leads should take place, in order to keep up to date with new biosimilar medicines:

- anticipated launch dates
- planned tenders and timelines
- product specifications
- pricing information

4.12 Tracking of savings and biosimilar adoption rate

Following implementation of a biosimilar medicine tracking of:

- the drug acquisition cost savings should be monitored and recorded on a monthly basis to calculate savings achieved from the change (see appendix 3. for example).
- breakdown of:
  - number of new patients on the biosimilar
  - number of patients changed to the biosimilar medicine part-way through current treatment, for the approved indication
  - reasons identified for those patients that have not been changed
  - metrics and indicators in line with any NHSE requirements e.g. Medicines Optimisation and CQUINs

4.13 Evaluation of Service impact on the Trust of adopting a biosimilar

Data should be collected through-out the change process in order to ascertain the resource impact of adopting the biosimilar in both new and mid-treatment change patients *(refer to Service impact tool on Biosimilar adoption process time line for further information)*.

5. Bibliography

(*papers utilised to complete this guidance & may further assist in development of local guidance*):

1. A clinicians guide to biosimilars in oncology. Hope S et al. Cancer treatment reviews 46. (2016) pp73-79. Available form <http://www.sciencedirect.com/science/article/pii/S0305737216300172>

2. Basingstoke, Southampton and Winchester District Prescribing Committee (2016). Biosimilar medicines position statement and guidance. Available from < http://www.westhampshireccg.nhs.uk/downloads/categories/medicines/guidance/1532-biosimilar-medicines-position-statement-and-guidance-june-2016/file>

3. BOPA. Draft Position Statement on Implementation of Biosimilar Monoclonal Antibodies (2017). Available from <awaited>

4. European Medicines Agency. Guideline on similar biological medicinal products containing biotechnology – derived proteins as active substance: non-clinical and clinical. December 2014. Available from <http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/10/WC500176768.pdf>

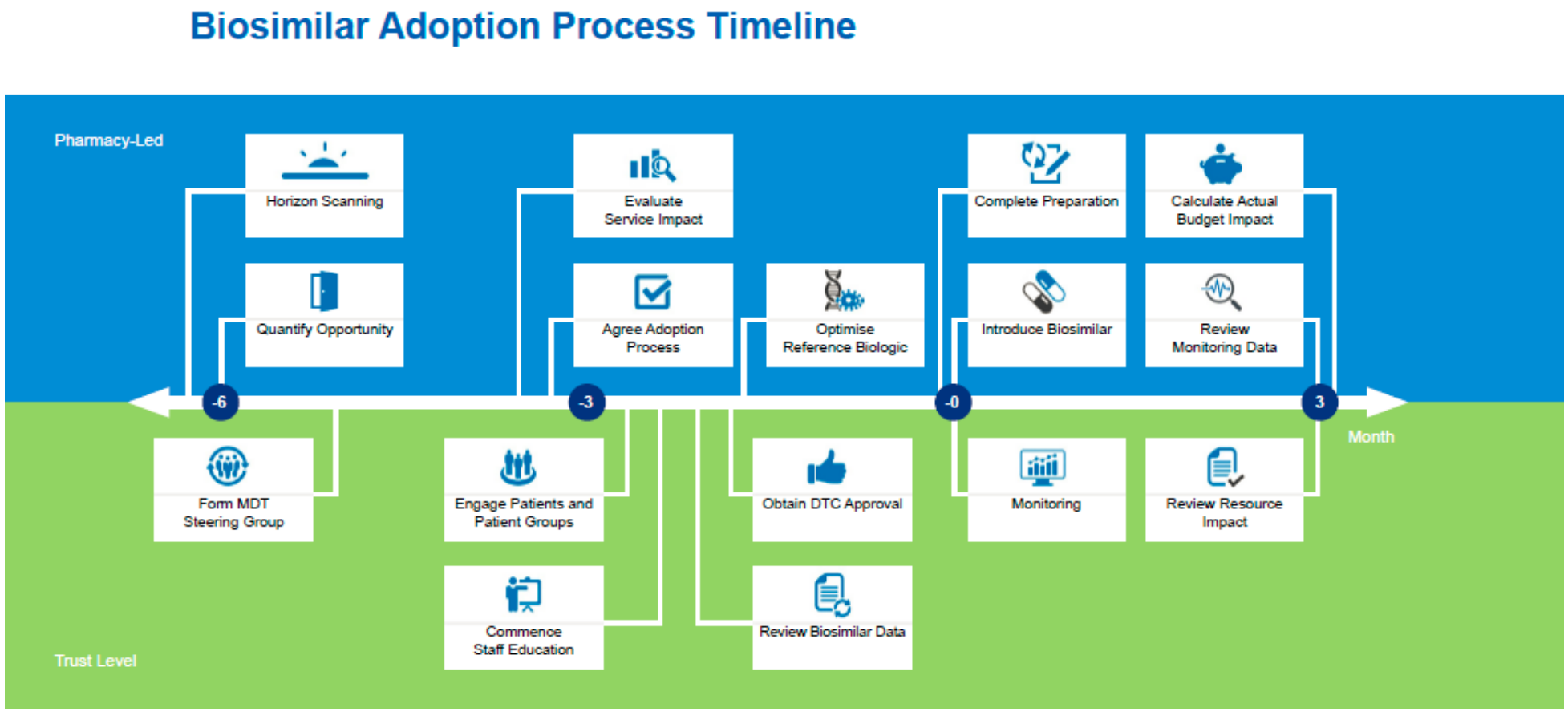
5. NHSE (2015). What is a biosimilar? Available from < https://www.england.nhs.uk/wp-content/uploads/2015/09/biosimilar-guide.pdf>

6. Linked documents

This will be different for individual trust and may include:

- Standard Operating Procedures for individual biosimilars
- Medicines Management Policy

Appendix 1. Biosimilar Adoption Process Timeline



Appendix 2. Biosimilars uptake tracker requirements

(to note NHSE may provide a tracker in relation to any CQUIN requirements).

The tracker will be used to provide details of biosimilar uptake and any associated savings made. Data from the tracker can be used to assist in reporting that CQUIN requirements on a local or national level have been met. It should initially be completed on a monthly basis. Once the adoption process has stabilised following initial uptake this may go to a quarterly review, although this should be agreed locally.

From initial adoption the tracker can be used to gauge success of the adoption programme, and predict when uptake by all patients anticipated to receive the biosimilar will be achieved. Detail of reasons why patients may not be receiving the biosimilar can be also be ascertained.

Information that should be tracked includes:

- 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