Biosimilar Adoption Process Timeline

Click on each task for further details and materials

Pharmacy-Led
- Horizon Scanning
- Quantify Opportunity
- Form MDT Steering Group
- Engage Patients and Patient Groups
- Commence Staff Education

Month
-6
-3
-0
3

Trust Level

Evaluate Service Impact
- Agree Adoption Process
- Review Biosimilar Data

Optimise Reference Biologic

- Calculate Actual Budget Impact
- Review Resource Impact
- Monitoring

Complete Preparation
- Introduce Biosimilar
- Review Monitoring Data

Click on each task for further details and materials
Horizon Scanning

Regularly scanning for biosimilar launches ensures that institutions are informed in sufficient time to have smooth biosimilar adoption.

Scanning will also show if other biosimilars in the same therapy area are expected around the same time. This will prevent duplication and enable planning in case of competition between molecules.

There are a variety of resources available. Check with your procurement pharmacist for ones used within your institution, or alternatively click on the links below.

Click here for link to UK Medicines Information (UKMi) website to register for market updates.

Click here for link to National Institute of Health and Care Excellence (NICE)/Department of Health (DoH) Pharmascan website for additional market updates on new drugs in development.

Click here to read latest insights into oncology product launches in the British Oncology Pharmacy Association (BOPA) newsletter.
Quantify Opportunity

Prior to commencing any biosimilar adoption process, it is critical to consider what is to be gained and what challenges are to be anticipated.

Checklist:

✓ Quantify current usage of biologic under consideration across all indications and treatment pathways in terms of number of patients, quantity of drug (in both mg and dose units) and current spend on different presentations

✓ Review current biological medicines guidance, including cost-effectiveness guidance from NICE, adoption toolkits, Key Therapeutic Topic (KTT) and case studies which may impact future usage of the biologic/biosimilar

✓ Consider formulations used in current practice and their likely biosimilar availability (timing of product launches, compounding, dose banding, presentation sizes, delivery devices and stability data)

✓ Assess the risk of introduction, for example consider:
  • Is the data package supported by clinicians?
  • Is the supply chain history good?

✓ Evaluate costs of implementation, capacity of clinical teams and how it will be funded (see service impact study for details). Account for patient support services currently available

✓ Take account of system incentives including Specialised Commissionings for Quality and Innovation (CQUINs), gain share possibilities and NHS England or Clinical Commissioning Group (CCG) direction. Evaluate how savings made can be reinvested to improve clinical service. Model return on investment and timeline for anticipated savings

✓ Establish if data collection, reporting or monitoring of patient outcomes will be required as part of biosimilar introduction

✓ Consider contracting opportunities for wider improvements to biological medicines such as: standard terms, service development and improvement plans (SDIP) and data quality improvement programmes (DQIP)

Timeframe: Around 6 months prior to availability
Task: Assess viability and impact of adopting a biosimilar
Lead: Pharmacy
Involved: Specialist Pharmacists, Clinical Leads
Resource: Checklist, Service Impact Study

Service Impact Study
Form MDT Steering Group

Biosimilar adoption works best when everyone who is affected by it is informed early and given the opportunity to get involved. This prevents any stakeholder anxiety and allows time for an institution to make decisions on usage before commissioning pressures are imposed. Defining everyone’s role and establishing regular communication will help the adoption process run smoothly.

Checklist:

- ✔ Involve at least one lead clinician and identify lead to drive adoption
- ✔ Seek members from across all departments where reference biologic under consideration is currently used
- ✔ Agree roles in steering group
- ✔ Ensure commissioning and clinician collaboration
- ✔ Appoint biological (oncology) pharmacist to project manage
- ✔ Consider additional clinical and pharmacy specialists and administrative support
- ✔ Identify key stakeholders to engage with (stakeholder plan for internal and external stakeholders including clinicians, pharmacists, nurses, patient and professional groups and wider NHS)
- ✔ Use regional pathways to facilitate clinician trust

Timeframe: Around 5 months prior to availability
Task: Identify and engage key stakeholders early
Lead: Trust level
Involved: multidisciplinary team (MDT) in affected therapy area
Resource: Checklist
Evaluate Service Impact

While the financial savings opportunity offered by a biosimilar is relatively easy to determine, it is critical to evaluate the wider impact of the biosimilar on the whole Trust.

**Checklist:**

- Ensure implementation is feasible from a work resource perspective, i.e. can it be done within existing resources?
- Evaluate predicted savings
- Predict the resource required so that it can offset potential savings on drug acquisition to reveal the true cost of the drug
- Identify areas in need of additional preparation (i.e. coding for reimbursement, clinical trials, cold storage capacity, IT requirements etc.)
- Collect data on current service and develop process to implement service impact study

The Vanguard has developed a study template for determining and evaluating this impact. Please click on the Service Impact Study link below to view.

**Timeframe:** Around 4 months prior to availability

**Task:** Assess viability and impact of adopting a biosimilar

**Lead:** Pharmacy

**Involved:** Finance and Information departments

**Resource:** Checklist, Service Impact Study
Agree Adoption Process

Once the opportunity and impact to service have been evaluated, based on this information the next step is to agree the process for adopting the biosimilar into use in the Trust as a whole. Thorough understanding of how the reference medicine is used within the Trust is critical to identify and engage with every event, from vial to patient. Some specialities or individuals may be reluctant to use a biosimilar and the Trust must decide how to address and manage this.

For further pharmacy-focused activities, please refer to the BOPA guidance on biosimilar adoption.

**Checklist:**

- Agree which patients will be eligible for the new biosimilar: in-treatment patients, patients between reference biologic and biosimilar, and patients between biosimilars? For all indications or specific indications?
- Agree what monitoring, in line with reference biologic monitoring, will be conducted
- Conduct risk assessment and evaluate medicines governance implications
- Prescribing policy – consider electronic prescribing/supply implications and chemo regimens
- Biosimilars are prescribed by brand name; ensure that systems can accommodate brand name prescribing
- Pharmacovigilance considerations/traceability as per reference biologic
- Registry participation – in house or external
- Role of clinician choice in consultation with the patient
- Agree timeline to adoption
- Chair capacity

**Timeframe:** Around 4 months prior to availability

**Task:** Set up adoption process for this biosimilar

**Lead:** Pharmacy

**Involved:** Drugs and Therapeutics Committee (DTC), MDT

**Resource:** Checklist, BOPA, European Society for Medical Oncology (ESMO) and NICE Guidance

**Resources:**
- BOPA Position Statement
- NICE Advice on Biosimilars
- ESMO Biosimilar Position Paper
Engage Patients And Patient Groups

As biosimilars are a relatively new technology, patients and patient groups may not be familiar with them. The patient voice must be included when making the decision to use a biosimilar. A patient panel or patient advocate should be engaged. There are examples of where this has been highly beneficial to biosimilar implementation and resulted in almost complete biosimilar usage. Click here for link to the University Hospital of Southampton experience as an example.

Checklist:

☑ Set up a meeting to engage with patients or patient forum. If a patient forum doesn't exist within the Trust, discuss obtaining equivalent input with the Patient Advice and Liaison Service (PALS) within the Trust

• The meeting should be led by a Senior Clinician/CNS/Senior Pharmacist in consultation with the PALS
• Present details of biosimilar concepts, ensure reasonable level of biosimilar understanding
• Present details of planned introduction including the opinions of leading clinicians within the Trust and expected impact to patients, the Trust and the NHS
• Listen for areas of concern or knowledge gaps. Where possible, use these as themes for the patient information leaflet or frequently asked questions. Address queries in the meeting, checking suitability of answer and impact of response to patient confidence

Timeframe: Around 3 months prior to availability
Task: Understand patient perspective
Lead: Trust level
Involved: Service lead
Resource: Statements for professional bodies and patient groups, i.e. British Society for Rheumatology and National Rheumatoid Arthritis Society

Resources:
British Society for Rheumatology position statement
British Society of Gastroenterology position statement
National Rheumatoid Arthritis Society position statement
Commence Staff Education

Robust staff education on biosimilar principles improves the confidence of both staff and patients. Careful consideration should be given to the needs of each professional group to ensure training is as relevant and accessible to them as possible. The Vanguard has produced, piloted and validated an educational presentation. See below for link to this Biosimilar Principles educational presentation.

Checklist:
- Seek support for training from Trust management
- Identify key groups most likely to be involved in usage of this biosimilar
- Assess current level of biosimilar knowledge and preferred means of receiving training
- Where possible, conduct small group training on biosimilar principles. Consider feedback forms that allow staff to identify remaining knowledge gaps. Molecule-specific information should follow discussions on biosimilar principles
- Consider constant information updates through newsletters or questions of the week on intranet, etc.
- Ensure the way staff can get further information is clearly identified on all material
- Consider running workshops within the institution, inviting others from nearby centres with experience to contribute to programme

Timeframe: Around 3 months prior to availability
Task: Foster confidence in biosimilar concepts
Lead: Trust level
Involved: Biosimilar champions, education and training leads
Resource: Checklist, Biosimilars Educational Slide Deck, Education Impact Assessment Questionnaire
Review Biosimilar Data

Due to the stringent EMA regulation of biosimilar development, data associated with biosimilars is different from that of the reference molecule. In particular, not every indication of the reference molecule needs to be studied. Prior to considering a biosimilar, a DTC should review all available data and timing of future publications for the biosimilar under review (see next page).

**Checklist:**

- ✓ Review available published clinical data
- ✓ Understand and analyse the biosimilar data package, relevance of the endpoints etc.
- ✓ Consider the patient number, duration of follow-up and applicability of endpoints assess likely involvement in professional registries (i.e. British Society for Rheumatology–Biologics Register (BSRBR))
- ✓ Scan for future, pending data releases and ongoing studies. The manufacturer’s medical information service can provide this information

**Timeframe:** Around 2 months prior to availability

**Task:** Check biosimilar data is understood

**Lead:** Trust level

**Involved:** Lead only

**Resource:** Checklist, Service Impact Study, Biosimilars Trust Policy – Template
Obtain DTC Approval

DTC approval processes will vary from Trust to Trust. If not present on the DTC, ensure lead clinician affected by the biosimilar introduction is significantly involved in preparing application and that they endorse its use.

**Checklist:**

- ✓ Follow biosimilar policy guidance on DTC approval process
- ✓ Complete implementation checklist as part of DTC application
- ✓ Agree groups of patients eligible for biosimilar use across indications and the whole Trust
- ✓ Agree process for the coordinated and timely introduction of the biosimilar
- ✓ Agree review date for biosimilar usage
- ✓ Agree required monitoring parameters

**Timeframe:** Around 2 months prior to availability

**Task:** Obtain formulary approval

**Lead:** Trust level

**Involved:** DTC, Clinical Unit Leads, Specialist Pharmacist

**Resource:** Checklist, Biosimilars Trust Policy – Template
Optimise Reference Biologic

Prior to introducing a biosimilar, it is good practice to ensure the reference molecule is being used as optimally as possible. This provides the best possible platform for the biosimilar to be introduced and evaluated.

**Checklist:**

- Where possible, collect and analyse relevant pharmacokinetics (PK) and pharmacodynamics (PD) markers (e.g. ATA, serum concentrations, markers of disease activity)
- Where appropriate, alter dose or frequency of reference molecule to ensure optimal treatment in line with established guidelines

**Resources:**

- The Pharmaceutical Journal article from Southampton: Biosimilars and inflammatory bowel disease: a switch programme using CT-P13

**Timeframe:** Around 3 months prior to availability

**Task:** Assess viability and impact of adopting a biosimilar

**Lead:** Pharmacy

**Involved:** Clinician Lead

**Resources:**
The Pharmaceutical Journal article from Southampton
Complete Preparation

Biosimilar adoption will be more successful in environments that have planned well, and completed their preparations sufficiently in advance of usage to minimise stakeholder anxiety. Early preparation also allows for time to address any late-rising educational needs.

**Checklist:**

- Set up product in dispensing software
- Prepare changes to product in prescribing software in test environment where possible
- Order stock of biosimilar in all preparations expected to be used. Confirm delivery date and quarantine on receipt. Ensure capacity in pharmacy and wards/units for biosimilar storage
- Follow local standard operating procedures (SOPs) for switch/change process of medicinal product (e.g. reduce stock/minimum levels)
- Risk assess if reference and biosimilar are both to be used in the hospital, and take appropriate steps to minimise risk at both pharmacy and ward level
- Advertise the information in relation to the switch/change in all affected clinical areas of impending change of molecule, highlighting same/similar name risk (including photos of product if available)
- Complete patient information

**Timeframe:** Around 2 weeks prior to availability

**Task:** Finish preparations in advance of biosimilar use

**Lead:** Pharmacy

**Involved:** IT Leads, Pharmacy, Procurement

**Resource:** Checklist, Service Impact Study
Introduce Biosimilar

This is the agreed, pre-determined day of first administration of the biosimilar. This day should be in line with the locally agreed implementation plan in the adoption process of the individual biosimilar.

If all preparations have gone well, this day should go smoothly.

Checklist:

- Activate changes to prescribing and dispensing software in live environment
- Re-advertise the information in relation to the introduction in all affected clinical areas of impending change of molecule, highlighting same/similar name risk (including photos of product if available), including pharmacy contact details
- Ensure patient support materials are available. Click on link below for access to patient information leaflet
- Ensure dispensary and medicines information staff are fully briefed
- Consider allocating additional support, identified as a need, to units with e-prescribing systems to assist staff in affected clinical areas with any initial prescribing difficulties

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Timeframe: At time of availability
Task: Initiate biosimilar usage
Lead: Pharmacy
Involved: Clinical Leads, Specialist Pharmacist, Pharmacy Technical Services (if applicable)
Resource: Checklist, Service Impact Study, Patient Information Leaflet

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Patient Information Leaflet
Service Impact Study
Monitoring

In common with reference biologics, collecting clinical data for patients on biosimilars for submission to central registries (e.g. BSR-BR or British Association of Dermatologists Biologics Intervention Register (BADBIR) may be mandated under a pharmacovigilance condition of the drug’s licence. Every effort should be made to comply with those obligations. For those who do not have this requirement, monitoring of patient data may be considered within the Trust and should be agreed as part of the formulary application, including identification of those who would be responsible for collecting and analysing the data, and timeframe over which the data should be collected.

Checklist:

✓ Review agreed clinical outcomes:
  • Standard response criteria
  • Adverse event monitoring e.g. infusion related reactions (IRRs)
  • If sub-groups were selected for initial biosimilar use, does this data provide justification for expanding use to a wider population?

✓ Assess patient satisfaction
✓ Assess staff perceptions post training/launch
✓ Share learning

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Timeframe: At time of availability
Task: Set up for safe biosimilar use
Lead: Clinical Team
Involved: Locally dependent
Resource: Checklist, Service Impact Study
Calculate Actual Budget Impact

Now the biosimilar is in use, it is important to check the impact on the budget is occurring as expected and to look for variation in practice of biosimilar adoption within the trust. While still early, this is a time to identify where concerns are and work to address them, e.g. ensuring patients are on the correct regimens prior to the switch.

**Checklist:**

- ✔ Monitor expenditure and savings against projections
- ✔ Ensure biosimilar reimbursement is correct
- ✔ Review wastage
- ✔ Identify clinical areas with slow uptake
- ✔ Benchmark uptake against similar providers

**Timeframe:** Approximately 3 months after adoption
**Task:** Assess viability and impact of adopting a biosimilar
**Lead:** Pharmacy
**Involved:** Lead only
**Resource:** Checklist, Service Impact Study
Review Monitoring Data

If it is agreed to collect data in the monitoring task, data must be reviewed periodically. It should be agreed at the commencement of the data collection who should review the data and how often. This task serves as a reminder that collected data must be reviewed, not only to ensure patient safety but also to check that biosimilar adoption is proceeding as anticipated.

Checklist:

- Incorporate data collection requirements under CQUIN and other mandatory monitoring such as Medicines Optimisation dashboard metrics or bespoke gainshare data requirements, as made available
- Review agreed clinical outcomes
- Standard response criteria
- Adverse event monitoring e.g. IRRs
- If sub-groups were selected for initial biosimilar use, does this data provide justification for expanding use to a wider population?
- Assess patient satisfaction
- Assess staff perceptions post training/launch
- Share learning

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Service Impact Study

Timeframe: Approximately 3 months after adoption
Task: Monitor agreed clinical outcomes
Lead: Clinical Team
Involved: Locally dependent
Resource: Checklist, Service Impact Study
Review Resource Impact

Once biosimilar use is underway, it is important to monitor the impact of their use and compare this against what was projected, not only financially, but also on the wider service resource. This is central to understanding the whole picture of biosimilar implementation and their value.

**Checklist:**

- **✓** Quantify actual costs associated with switching:
  - Formulary application process
  - Update to pharmacy systems
    - Dispensing, prescribing, production unit
  - Staff education/training
  - Update local guidelines
  - Development of patient information

- **✓** Quantify ongoing change in resources post implementation:
  - Reconstitution, site of administration, chair time, monitoring

- **✓** Monitoring of financial targets

- **✓** Share learning

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**Timeframe:** Approximately 3 months after adoption

**Task:** Monitor agreed clinical outcomes

**Lead:** Clinical Team

**Involved:** Locally dependent

**Resource:** Checklist, Service Impact Study
Background:
Biosimilars are approved by the EMA if they are shown to be equivalent to their reference molecule in terms of safety, efficacy and quality. Due to the differences in their development program, biosimilars are able to be marketed at a cost significantly less than their reference product. To understand the impact of the reduced drug acquisition cost on total expenditure for that given treatment, it is necessary to fully characterise the areas of expenditure from vial to patient both prior to and after a decision to use a biosimilar has been made. This must account for one-off costs associated with implementing biosimilar usage, such as additional patient counselling requirements and also evaluate the impact of this biosimilar implementation on outcome measures such as patient satisfaction.

Hypothesis $H_A$:
Biosimilar use has a net reduction on overall expenditure compared to their reference molecule and has no impact on patient satisfaction measures

Aim:
To fully characterise total costs and services associated with delivery of a cancer treatment with a biosimilar equivalent and re-evaluate once a biosimilar is in use.

Methods:
Assess associated costs in terms of the following factors as detailed below.

Items highlighted in green require prospective consideration and need input prior to the adoption of the biosimilar.

<table>
<thead>
<tr>
<th>1. Eligible patients</th>
<th>Evaluate before biosimilar introduction</th>
<th>Evaluate after biosimilar introduction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Task</td>
<td>Time frame</td>
</tr>
<tr>
<td>a. Total number of patients prescribed biologic under review</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>i. Patients on IV and SC</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>ii. Patients eligible for biosimilar usage according to Trust policy (all patients without indication protected by patent or research protocol)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>iii. Patients receiving biosimilar</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>b. Clinical trial patients on biologic under review</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>i. Patients on commercial stock</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>ii. Patients on sponsor funded trial stock</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>iii. Patients receiving biosimilar</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Drug acquisition costs</th>
<th>Evaluate before biosimilar introduction</th>
<th>Evaluate after biosimilar introduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Drug cost (actual spend- vial cost or mg costs)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>b. Service delivery model</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>i. % (near patient vs. SC vs. compounder (3rd party) vs. aseptic vs. at home)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>ii. Costs (near patient vs. compounder (3rd party) vs. aseptic vs. at home)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>c. Costs associated with additional stock</td>
<td>✓</td>
<td>✓</td>
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</table>
## 3. Service costs

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<table>
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<tr>
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</thead>
<tbody>
<tr>
<td><strong>a.</strong> Counsel +/- consent patients</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>b.</strong> Preparation of patient materials and education</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td><strong>c.</strong> Time associated with clerking patient</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td><strong>d.</strong> Administration costs</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>i. Chair time (Vs. total capacity)</td>
<td></td>
<td></td>
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<tr>
<td>ii. Monitoring</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>e.</strong> Resources associated with ensuring reimbursement from commissioners</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td><strong>f.</strong> Costs associated with prescribing or administration errors</td>
<td></td>
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</tbody>
</table>

### Across 20 sequential patients

- Is monitoring or chair time requirement expected to change?
- Did monitoring or chair time change?

### Across 20 sequential patients in first and second month of use

- Do you anticipate use of biosimilars changing your reimbursement process?

### Across 20 sequential patients in first and second month of use and second month of use

## 4. Costs associated with biosimilar introduction

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<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>a.</strong> Preparation and validation of aseptic worksheet</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>b.</strong> Preparation for formulary application</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>c.</strong> Development/adaption of biosimilar policy and guidance</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>d.</strong> Development and delivery of patient focused and staff educational material</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>e.</strong> Costs of further education of staff (initial and ongoing)</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>f.</strong> Updating electronic prescribing and dispensing software</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>g.</strong> Costs due to lack of stability data/validated method</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>h.</strong> Costs associated with changes to prescribing activities and uncertainty</td>
<td></td>
<td>✓</td>
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</tbody>
</table>

### One-off measurement and calculation

- Costs associated with changes to prescribing activities and uncertainty

## 5. Patient satisfaction survey

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</thead>
<tbody>
<tr>
<td><strong>a.</strong> Costs to perform patient satisfaction survey</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>b.</strong> Assessment of patient global satisfaction with treatment</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

### 100 patients in same and second month as 1

### 100 patients in same and second month as 1

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The Cancer Vanguard is a partnership between
Greater Manchester Cancer Vanguard Innovation, RM Partners and UCLH Cancer Collaborative

UK/MKT/SDZ/17-0027b March 2017
Biosimilars Education Impact Assessment Questionnaire

Before Training

What do you know about biosimilars?

Q1a. Before this training, had you heard the term “biosimilar/biosimilarity” in the last month? No Yes

Q1b. How well do you understand how biosimilar medicines are developed?

I know nothing I have extremely good knowledge

0 1 2 3 4 5 6 7 8 9 10

Q1c. How well do you understand how biosimilars are licensed in the UK?

I know nothing I have extremely good knowledge

0 1 2 3 4 5 6 7 8 9 10

Q1d. How well do you understand the concept of extrapolation in regards to biosimilars?

I know nothing I have extremely good knowledge

0 1 2 3 4 5 6 7 8 9 10

Biosimilars in your practice:

Q2a. How would you expect patients to respond clinically to biosimilars compared to the reference/original medicine?

Very much differently Somewhat differently Somewhat the same Very much the same Not Sure

Q2b. How confident would you be in using biosimilars in your patients?

Not at all confident Very confident

0 1 2 3 4 5 6 7 8 9 10

Q2c. How easy do you think it will be to introduce biosimilars into your department?

Impossible Straightforward

0 1 2 3 4 5 6 7 8 9 10

Q2d. What issues do you expect to arise if biosimilars are introduced into your department?

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About you

Q5a Role: Nurse Doctor Pharmacist Other (please state) ___________________

Q5b Therapy Area:

Q5c Year of registration as a healthcare professional:
Talking about biosimilars:

Have you ever had a discussion about biosimilars with:

Q3a. Clinical colleagues: No Yes

How confident were you at explaining what a biosimilar is:

<table>
<thead>
<tr>
<th>Not at all confident</th>
<th>Very confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
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</tbody>
</table>

Q3b. Patients: No Yes

How confident were you at explaining what a biosimilar is:

<table>
<thead>
<tr>
<th>Not at all confident</th>
<th>Very confident</th>
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<tbody>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
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</table>

Biosimilar training

Q4a. Have you previously received any training on biosimilars? No Yes

Q4b. If yes, was it provided by:

Someone in your Trust Professional Body Pharmaceutical Industry Other

Q4c. When did you have the training? Less than 1 month, 1-3 months ago, 3-6 months ago, more than 6 months

Q4d. How useful was it?

<table>
<thead>
<tr>
<th>Not at all useful</th>
<th>Very useful</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
</tbody>
</table>

Q4e. If less than 10, why?

Too brief Not enough detail Too detailed Not relevant to my role Too biased

Other:........................

About you

Q5a Role: Nurse Doctor Pharmacist Other (please state) ___________________

Q5b Therapy Area:

Q5c Year of registration as a healthcare professional:
About the way you learn

Q6a. How do you prefer to learn new information?

Please select 3 in order of preference where 1=first, 2=second and 3=third

<table>
<thead>
<tr>
<th>Learning format</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation/Lecture</td>
<td></td>
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<tr>
<td>Online training</td>
<td></td>
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<tr>
<td>Ward-based teaching</td>
<td></td>
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<tr>
<td>Self-directed reading/training</td>
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<tr>
<td>Attending meetings/congresses</td>
<td></td>
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<tr>
<td>Webinar</td>
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<tr>
<td>Interactive training session</td>
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<tr>
<td>Other (please describe)</td>
<td></td>
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</tbody>
</table>

Q6b. On average, how much time do you spend in total on role specific learning each week? Please circle most appropriate.

<table>
<thead>
<tr>
<th>Less than 15min</th>
<th>30min</th>
<th>1hr</th>
<th>2hrs</th>
<th>3hrs</th>
<th>4hrs</th>
<th>5hrs</th>
<th>6hrs</th>
<th>1day</th>
</tr>
</thead>
</table>
Please note that the following pages are to be used after completion of the training to measure success against the baseline measurements in pages 1, 2 and 3.
Cancer Vanguard

Biosimilars Education Impact Assessment Post-Training Questionnaire

After Training

**What do you know about biosimilars now?**

Q7a. How well do you understand how biosimilar medicines are *developed*?

I know nothing  I have extremely good knowledge

0 1 2 3 4 5 6 7 8 9 10

Q7b. How well do you understand how biosimilars are *licensed in the UK*?

I know nothing  I have extremely good knowledge

0 1 2 3 4 5 6 7 8 9 10

Q7c. How well do you understand the concept of *extrapolation* in regards to biosimilars?

I know nothing  I have extremely good knowledge

0 1 2 3 4 5 6 7 8 9 10

**Biosimilars in your practice:**

Q8a. How would you expect patients to respond *clinically* to biosimilars compared to the reference/original medicine?

Very much differently  Somewhat differently  Somewhat the same  Very much the same  Not Sure

Q8b. How confident would you be in using biosimilars in your patients?

Not at all confident  Very confident

0 1 2 3 4 5 6 7 8 9 10

Q8c. How easy do you think it will be to introduce biosimilars into your practice?

Impossible  Straightforward

0 1 2 3 4 5 6 7 8 9 10

The Cancer Vanguard is a partnership between
Greater Manchester Cancer Vanguard Innovation, RM Partners and UCLH Cancer Collaborative

UK/MKT/SDZ/17-0027c March 2017
Talking about biosimilars:

How confident do you feel now at explaining what a biosimilar is to...

Q9a. Clinical colleagues:

Not at all confident

0 1 2 3 4 5 6 7 8 9 10

Very confident

Q9b. Patients:

Not at all confident

0 1 2 3 4 5 6 7 8 9 10

Very confident

For your role, please list the three biosimilars topics you would like to learn more about?

1. ________________________________

2. ________________________________

3. ________________________________
The following slide set is available from the Resource Gallery.
An introduction to Biosimilars
Cancer Vanguard Overview

• The Cancer Vanguard comprises
  • RM Partners
  • UCLH Cancer Collaboration
  • Greater Manchester Cancer Vanguard Innovation

• These three local delivery systems are transforming the clinical model of cancer care delivery by providing evidence based solutions that can be replicated nationally.
The Cancer Vanguard is about driving innovation

- One innovation coming to cancer treatment in the NHS is a group of medicines called biosimilars

- Sandoz, a Novartis Division, pioneered the science of biosimilars and its biosimilars have been used in the NHS for over ten years

- The Cancer Vanguard have partnered with Sandoz to develop a process for evaluating biosimilars through education and research
Agenda

• What are biologics?

• What are biosimilars?

• How are biosimilars developed?
What are biologics?
What are biologics?

**Paracetamol**
- Small molecule
- Chemical synthesis
- Single substance
  - 151 Da
- MoA ambiguous

**Filgrastim (a growth factor)**
- Protein (without sugars)
- Made using bacteria
- Single main substance
  - One chain, 175 amino acids
    - 18,803 Da
- Receptor binding only

**Antibody (mAb)**
- Glycoprotein (with variable sugars)
- Made using mammalian cells
- Mixture of variants
- Four chains, 1330 amino acids
  - 144,000 Da
- Receptor binding, effector functions

Note: Illustrations not to scale.

Biologic manufacture

- Biologics are produced from living organisms

Modify host cells (e.g. bacteria, yeast, mammalian) to produce recombinant proteins

Grow cells Under controlled conditions (fermentation, upstream process)

Extract, refold, purify To generate drug substance (downstream process)

Formulate to stable finished drug product Vial, syringe, cartridge

Adapted from EGA Handbook on biosimilar medicines; available from http://www.egagenerics.com/index.php/publications

UK/MKT/SDZ/17-0027d Mar 2017
Impact of manufacturing changes

- Manufacturing changes can create variability in the biologic molecule

Higher risk changes require greater amounts of supporting data

Adapted from Lee J, Litten J and Grampp G, CMRO, 2012; 28:1053-1058
Vezér B, Zrubka Z et al; CMRO, 2016, 32:829-834

UK/MKT/SDZ/17-0027d Mar 2017

Variability is in the nature of biologics

- Manufacturing changes are tightly regulated
What are biosimilars?
Biosimilars are nothing new

- In 2006 the first biosimilar became available in the UK
- Since this time the safety profile of biosimilars has been consistent with the reference products and the product class\(^1,2,3\)
- Biosimilars are now in routine use in the NHS, particularly in rheumatology and gastroenterology

3. For full adverse event profiles, please refer to Zarzio and Omnitrope SPCs available at: www.medicines.org.uk/emc

UK/MKT/SDZ/17-0027d Mar 2017
Biosimilar-a regulatory term

• A biosimilar is “essentially the same” as the reference biologic medicine with some natural variability.

“The active substance of a biosimilar and its reference medicine is essentially the same biological substance, though there may be minor differences due to their complex nature and production methods. Like the reference medicine, the biosimilar has a degree of natural variability. When approved, its variability and any differences between it and its reference medicine will have been shown not to affect safety or effectiveness.”

How are biosimilars developed?
Biosimilars are highly similar to reference biologic

- Biosimilars are approved biologics that have been demonstrated to be highly similar to a reference product

**Key requirements for comparability**

- Highly similar structure and function
  - Same primary structure (amino acid sequence)
  - Similar higher-order structure
  - High quality
  - Same biological functions

- Equivalent PK/PD
- Comparable clinical efficacy and safety
- Same presentation, dose (strength) and administration mode

---


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Biosimilars are made to match

• Biosimilars are systematically developed to match the reference product

Differences in development

Originator

Clinical
PK/PD
Non-clinical
Analytical

Biosimilar

Clinical
PK/PD
Non-clinical
Analytical

Major goal is to determine the clinical effect

Major goal is to determine similarity;
• Establishment of the scientific bridge to the clinical experience of the reference molecule
• Analytical methods provide the most sensitive tools to establish this scientific bridge

Adapted from:

UK/MKT/SDZ/17-0027d Mar 2017
**Cancer Vanguard**

**Development approach for biosimilars is closer to originators than to generics**

<table>
<thead>
<tr>
<th></th>
<th>Generic</th>
<th>New biologic</th>
<th>Biosimilar</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time to market</strong></td>
<td>2–3</td>
<td>8–10</td>
<td>7–8</td>
</tr>
<tr>
<td>(years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Clinical studies</strong></td>
<td></td>
<td>Bioequivalence</td>
<td>Comparative phase</td>
</tr>
<tr>
<td></td>
<td></td>
<td>studies in</td>
<td>I pharmacokinetic</td>
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<tr>
<td></td>
<td></td>
<td>healthy volunteers</td>
<td>and Phase III</td>
</tr>
<tr>
<td><strong>Patients</strong></td>
<td>20–50</td>
<td>800–1000</td>
<td>~500</td>
</tr>
<tr>
<td>(n)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Post-approval</strong></td>
<td>Pharmacovigilance</td>
<td>Phase IV, Risk</td>
<td>Phase IV, Risk</td>
</tr>
<tr>
<td>activities</td>
<td>Risk Management Plan in special situations</td>
<td>Management Plan including Pharmacovigilance</td>
<td>Management Plan including Pharmacovigilance</td>
</tr>
</tbody>
</table>

Development process

- Focus of biosimilar development is to establish similarity to the reference product

**TECHNICAL DEVELOPMENT**
- Fully characterise reference product
- Match molecule profile of biosimilar with reference product (structure & function/biological activity)
- Match final dosage form to reference product

**PRECLIN | PHASE I | PHASE III**
- Demonstrate PK/PD equivalence
- Confirm efficacy and safety via tailored Phase III studies
- Support extrapolation to non-studied indications and interchangeability

**PHASE IV | REGISTRIES**
- Additional data following the product long-term

**Develop highly similar product**

**Confirm biosimilarity**

**Post-approval**


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**Understanding the molecule**

- Integration of data from multiple analytical and biological tests provides complete understanding.

- Combined data from ~45 different methods provide **information on multiple attributes** (orthogonality).

- Every attribute is evaluated more than once (redundancy).

---


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Understanding the molecule

- Integration of data from multiple analytical and biological tests provides complete understanding

**Primary Structure**
- LC-MS intact mass
- Peptide mapping
- LC-MS subunits

**Higher-Order Structure**
- NMR
- CD spectroscopy
- FT-IR

**Post Translational Modifications**
- NP-HPLC-(MS) N-glycans
- AEX N-glycans
- MALDI-TOF N-glycans
- HPAEC-PAD N-glycans
- MALDI-TOF O-glycans
- HPAEC-PAD sialic acids
- RP-HPLC sialic acids

**Impurities**
- CEX, cIEF acidic/basic variants
- Peptide mapping, mutation, oxidation, deamidation, glycation
- SEC/FFF/AUC aggregation
- LC glycation

**Biological Activity**
- Binding assay
- ADCC assay
- CDC assay

**Combination of Attributes:**
- MVDA, mathematical algorithms

- Combined data from ~45 different methods provide information on multiple attributes (orthogonality)

- Every attribute is evaluated more than once (redundancy)

**Totality of the evidence**

- Biosimilars must be highly similar at all levels

**Measures of drug activity are usually more sensitive than outcome endpoints evaluating patient benefit**


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Patient populations

• Choosing the right indication for the clinical data is a critical part of biosimilar development and is done in conjunction with the EMA

• The aim of the biosimilar regulatory study may be different to that of the originator biologic

EBG’s perspective on draft guidance on clinical/non-clinical issues. Available at:

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Patient populations

• Trial populations must be:
  – Sensitive
  – Homogenous

Sensitive populations have:
• Active disease
• Large effect size (drug effect)
• Immunocompetence

This makes it easier to determine the effect of the drug

Homogenous populations have:
• Fairly consistent disease activity
• Less disease/patient confounders
• Minimal interpatient variability

This means smaller sample sizes can be used

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Extrapolation of indication

- Extrapolation is based on the entire similarity exercise, including clinical experience with the reference product.

<table>
<thead>
<tr>
<th></th>
<th>Reference</th>
<th>Biosimilar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structural attributes</td>
<td>MATCH</td>
<td>MATCH</td>
</tr>
<tr>
<td>Biological functions</td>
<td>MATCH</td>
<td>MATCH</td>
</tr>
<tr>
<td>Human PK/PD</td>
<td>MATCH</td>
<td>MATCH</td>
</tr>
<tr>
<td>Sensitive indication</td>
<td>MATCH</td>
<td>MATCH</td>
</tr>
<tr>
<td>Less sensitive indications</td>
<td>JUSTIFIED</td>
<td>JUSTIFIED</td>
</tr>
</tbody>
</table>

‘SIMILARITY SPACE’

Post-authorisation activities

- As for any biopharmaceutical, the clinical safety of biosimilars must be monitored through continued pharmacovigilance

  - A pharmacovigilance plan must be adopted
    - Involves collection and assessment of AE data, post-approval studies and registries

  - The need for risk minimisation strategies must be evaluated
    - Assesses whether strategies are needed beyond the pharmacovigilance plan

  - A risk management plan must be submitted
    - Typically includes the same obligations and activities as for the reference medicine

---

Summary
Biosimilars: Summary

- Biologics can be thoroughly analysed and characterised
- Biosimilars are systematically developed to be highly similar to their reference biologic
- Clinical studies aim to confirm the characterisation work
- Extrapolation builds on the entire similarity exercise
- Post authorisation studies continue safety monitoring
- Biosimilars must meet the same quality standards as originator products
- Biosimilars may increase patient access to biologic medicines and contribute to savings for healthcare systems

Questions?
Patient Information Leaflet is under approval with relevant patient groups.

Please revisit to access leaflet soon.
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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.
The first biosimilar became available in 2006 (somatropin), since then a number of biosimilars have obtained license for originator medicines including filgrastim, infliximab and more recently etanercept. In 2017 the first biosimilars for use in the therapeutic treatment of oncology will be launched. The early adoption of which will provide economic benefit to the NHS through acquisition cost savings when brand originator patent expires whilst at the same time providing the same expected patient outcomes.

Prior to introduction the biosimilar will have received Marketing Authorisation from the EMA, where the biosimilar undergoes a robust regulatory approval process including detailed head to head comparison with the originator molecule to show no clinically significant differences.

**To note:** The EMA biosimilar regulatory pathway does not require comparative clinical data (phase III studies) in all indications for which the biosimilar has a licence. It will however, typically have all the therapeutic indications as the reference medicine based on the totality of the data package submitted and the EMA allows extrapolation to the additional indications. Additional data may be required in certain situations. For further information regarding this refer to EMA guidance.
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
  - Monitoring patient satisfaction.
  - Pharmacy Purchasing requirements
  - 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.
1. Background & scope

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  - 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

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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 throughout 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 timeline for further information).
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5. Bibliography

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


6. Linked documents

*This will be different for individual trust and may include:*

- Standard Operating Procedures for individual biosimilars
- Medicines Management Policy
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