Biosimilar Medicines
A National Prescribing Framework

March 2018
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1. Introduction

Eight of the top 10 medicines by expenditure used in the hospital setting in Scotland in the year to 31 March 2017 were biological medicines (adalimumab, aflibercept, normal immunoglobulin human, trastuzumab, etanercept, rituximab, infliximab and ranibizumab) some of which have lost patent protection within the last 3 years, with others soon to expire in coming years. The availability of biosimilar medicines has enhanced competition within the marketplace.

£46m of current biological medicine spend is expected to face biosimilar competition for the first time within the next 3 years.

**Biosimilar medicines** are medicines that are made by or derived from a biological source, such as a bacterium, yeast or blood. They can consist of relatively simple molecules, such as human insulin or erythropoietin, or complex molecules such as monoclonal antibodies.

A biosimilar medicine is a biological medicine that is similar to another biological medicine which has already been granted marketing authorisation. The standard approach to licensing of a generic medicine, where the medicine must demonstrate bioequivalence (that is the bioavailability of the generic medicine must not differ significantly when given at the same dosage under similar conditions), is not sufficient for biosimilar medicines. For licensing in the European Union, the manufacturer of the biosimilar medicine must demonstrate that the medicine is:

1. similar to the original reference product, and
2. does not have any meaningful differences from the original reference product in terms of quality, safety or efficacy.

However, if biosimilarity has been demonstrated for one indication or clinical situation, the licence may be extrapolated to a broader range of therapeutic indications established by the reference medicine if appropriate scientific justification is provided. More detailed information on biosimilar medicines can be found in the European Medicines Agency questions and answers on biosimilar medicines (similar biological medicinal products) document [www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_001832.jsp&mid=WC0b01ac0580bb8fda](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_001832.jsp&mid=WC0b01ac0580bb8fda)

**Managed introduction of biosimilar medicines in Scotland**

In NHSScotland, all new medicines are routinely assessed by the Scottish Medicines Consortium (SMC) followed by local consideration by Area Drugs and Therapeutic Committees (ADTCs). However, SMC policy is that biosimilar medicines are considered ‘out of remit’ where the reference product has been accepted by SMC for the same indication(s) and in the same population or was initially licensed and available prior to 31 January 2002. Full submissions continue to be required for indication(s)/populations where the reference product is not recommended by SMC.

SMC also carries out horizon scanning for emerging biosimilar medicines and reserves the right to request a full submission in the event that it is anticipated that the biosimilar medicine will have an impact on NHSScotland resources. SMC’s Policy Statement on Biosimilar Medicines came into effect on May 2015 and can be accessed at [www.scottishmedicines.org.uk/About_SMC/Policy_statements/Biosimilar_Medicines](http://www.scottishmedicines.org.uk/About_SMC/Policy_statements/Biosimilar_Medicines)

Business as usual in Scotland for the managed introduction of biosimilar medicines is that National Procurement and the ADTCs work together in the anticipation and planning for all new biosimilar medicines in order to support NHS boards to consider their place in therapy,
secure the best price for the biological medicine and support NHS boards to manage the introduction of biosimilar medicines into practice safely and quickly.

Several small molecule biosimilar medicines (including erythropoietin, somatropin and filgrastim) have been licensed for a number of years and are in use in some NHS boards. A number of originator biological medicines have been licensed as biosimilar medicines. These include anti-TNF agents infliximab and etanercept with adalimumab biosimilar also expected to be licensed in 2018. Moreover, the intravenous formulation of rituximab has become available in a biosimilar medicine.

**Biosimilar Medicines: A National Prescribing Framework**

This updated prescribing framework builds upon the principles of our previously developed national prescribing framework (published May 2015).³

The prescribing framework contains prescribing principles to:

- promote the safe use of biosimilar medicines
- promote prescriber confidence
- ensure a shared decision-making approach between clinician and patient.
- encourage a consistent approach across NHSScotland
- support National Procurement
- recognise the potential savings that can be achievable within NHSScotland by the use of biosimilar medicines, and
- provide guidance on implementing the use of biosimilar medicines.

It should be noted that the prescribing framework complements the existing NHS boards' governance processes for the managed introduction of new medicines.

The prescribing framework aligns with the ambitions of the NHSScotland Healthcare Quality Strategy⁴ which aims to ensure “the most appropriate treatments, interventions, support and services will be provided at the right time to everyone who will benefit, and wasteful or harmful variation will be eradicated.”

The prescribing framework may be reviewed as clinical experience with the use of biosimilar medicines evolves.
2. **Biosimilar Medicines: A National Prescribing Framework**

The aim of the prescribing framework is to inform clinical decision-making and support the safe, effective and consistent use of biological medicines, including biosimilar medicines in NHSScotland.

The prescribing framework is presented in the format of frequently asked questions which are summarised in Table 1. Additional underpinning supportive detail is provided for each of the frequently asked questions.

This updated prescribing framework has been developed using experience to date and expertise from ADTCs and the NHSScotland expert advisory group (for development process and membership, see appendices 2 and 3).

The original prescribing framework document, which includes the development process and membership of the expert advisory group, can be accessed at www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/programme_resources/biosimilar_medicines_framework.aspx

**Table 1: Summary of the frequently asked questions**

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<thead>
<tr>
<th>Frequently asked question</th>
<th>NHSScotland advice</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.1</strong> What is NHSScotland’s policy on the use of biosimilar medicines?</td>
<td>NHSScotland encourages the use of biosimilar medicines and recommends that they should be considered as a treatment option for patients for whom a biological medicine is being considered as part of their treatment pathway.</td>
</tr>
<tr>
<td><strong>2.2</strong> Can patients established on a biological medicine be switched to another biological medicine, for example a biosimilar medicine?</td>
<td>Individual patients or groups of patients may be switched to another biological medicine, including a biosimilar medicine, as part of a clinician-led management programme which has appropriate monitoring in place.</td>
</tr>
<tr>
<td><strong>2.3</strong> Are different approaches to the use of biosimilar medicines required in different clinical specialties?</td>
<td>There are differing clinical and operational factors within specialties which may be important to consider when using biosimilar medicines. National specialty guidelines have supported the use of biosimilar medicines and should form the basis of prescribing.</td>
</tr>
<tr>
<td><strong>2.4</strong> Are there any specific efficacy or safety concerns associated with the use of biosimilar medicines?</td>
<td>There are no specific efficacy or safety concerns identified for biosimilar medicines. As for all biological medicines, clinical experience with biosimilar medicines is still growing and will continue to guide their use. As for all new medicines, adverse drug reactions to biosimilar medicines should be reported through the Yellow Card Scheme.</td>
</tr>
<tr>
<td>2.5</td>
<td>How should biological medicines, including biosimilar medicines, be monitored?</td>
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<tr>
<td>2.6</td>
<td>How should biological and biosimilar medicines be prescribed and product details recorded?</td>
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<td>2.7</td>
<td>What information should be provided to patients?</td>
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<tr>
<td>2.8</td>
<td>How do I switch from an original biological medicine to a biosimilar?</td>
</tr>
</tbody>
</table>
2.1 What is NHSScotland’s policy on the use of biosimilar medicines?

NHSScotland encourages the use of biosimilar medicines and recommends that they should be considered as a treatment option for patients for whom a biological medicine is being considered as part of their treatment pathway.

Biosimilar medicines are licensed medicines which have met the regulatory requirements for quality, efficacy and safety. NHSScotland recognises the benefits that increased availability of biosimilar medicines can bring.

Clinicians agree that biosimilar medicines are a useful treatment option for patients for whom a biological medicine is being considered as part of their treatment pathway.

The decision to prescribe a biological medicine, including a biosimilar medicine, for an individual patient is the responsibility of the prescribing clinician in consultation with the patient. The frequently asked questions in this prescribing framework provide additional information to support clinical decision-making on the use of biosimilar medicines.

Strategically, the NHSScotland Medical Directors and Directors of Pharmacy have recommended two key principles in the introduction of biosimilar medicines. All NHS boards should:

- where no clinical reason exists for a specific biological preparation, use the most cost-effective biological medicine in new patients.
- consider implementing a plan for the managed switching of existing patients to a biosimilar medicine where the biosimilar offers a significant cost advantage in comparison to the reference product. This should include consideration of how switching will be adequately resourced, for example through ‘Invest to Save’ arrangements. More advisory information can be accessed at www.rheumatology.org.uk, www.bsg.org.uk, www.bad.org.uk and www.bopawebsite.org.
2.2 Can patients established on a biological medicine be switched to another biological medicine, for example a biosimilar medicine?

Individual patients or groups of patients may be switched to another biological medicine, including a biosimilar medicine, as part of a clinician-led management programme which has appropriate monitoring in place.

The evidence base for the safety and efficacy of biosimilar medicines has been established through the medicines regulatory process. There has been a rapid growth in biosimilar prescribing recently with growing prescriber and patient confidence, albeit experience with their use is still being built. Emerging evidence on switching a biological medicine to a biosimilar medicine will continue to guide decisions on interchangeability in the future.

NHS boards should work with multidisciplinary teams and other stakeholders to agree switching programmes. Section 2.8 provides biological case studies detailing how to switch and the most efficient approaches to switching.
2.3 Are different approaches to the use of biosimilar medicines required in different clinical specialties?

There are differing clinical and operational factors within specialties which may be important to consider when using biosimilar medicines.

Differences in approach to prescribing in new patients and switching existing patients would include how the medicines are used, e.g. treatment length, route of administration subcutaneous vs intravenous, maintenance vs acute and whether hospital, homecare or primary care medicines.

Individual clinical specialties are at different stages in their experience in the use of biosimilar medicines.

Gastroenterology, rheumatology and dermatology

Patients treated with biological medicines within gastroenterology, rheumatology and dermatology are generally treated long term. Where an equivalent biosimilar medicine is available for a specific anti-TNF agent, the most cost-effective preparation should be used in both new patients and those switching from another biological medicine. Treatment choice should be at the discretion of the treating clinician in consultation with the patient.

Oncology and haemato-oncology

The place of biosimilar medicines in oncology and haemato-oncology is still emerging. The route of administration is a key factor when deciding whether use of a biosimilar is feasible. This is due to the impact it can have on patient experience, service capacity and infrastructure (physical capacity). NHS England has produced a toolkit which can be accessed at http://cancervanguard.nhs.uk/biosimilars-adoption6.

The Cancer Vanguard Trusts1 in England:

- actively support the appropriate use of licensed biosimilar medicines in cancer patients
- recognise the benefits to the health economy of the appropriate use and managed introduction of biosimilar medicines in cancer, and
- for rituximab, the first biosimilar medicine available for use in oncology supports the appropriate use for its licensed indications, including transferring patients previously on the originator to the biosimilar.

Diabetes

Biosimilar insulins are smaller less complex molecules and clinicians describe some concerns about switching. Switching patients between any insulin has service workload implications and requires careful planning. Patient suitability may influence decision-making where there is a difference in the device, preparation or formulation between the original reference product and biosimilar medicines. Treatment choice should be at the discretion of the treating clinician in consultation with the patient.

As insulins are predominantly managed in primary care, consideration needs to be given as to how the product details of the biosimilar medicine will be recorded (see Section 2.6).

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1 The Cancer Vanguard has partnered with Sandoz in a Joint Working Project to share biosimilar knowledge and experience, for the benefits of patients and the NHS.
2.4 Are there any specific efficacy or safety concerns associated with the use of biosimilar medicines?

There are no specific efficacy or safety concerns identified for biosimilar medicines. As for all biological medicines, clinical experience with biosimilar medicines is still growing and will continue to guide their use.

As for all new medicines, adverse drug reactions to biosimilar medicines should be reported through the Yellow Card Scheme.

The evidence base for the safety and efficacy of biosimilar medicines has been established through the EU medicines regulatory process. A biosimilar medicine is similar, but not identical, to the original reference product.

All biological medicines can display a degree of minor variability. A biosimilar medicine may have minor differences from the original reference product or another related biosimilar medicine. Small changes to the manufacturing process of biological medicines may also modify the medicine over time and this applies to both the reference biological medicine and the biosimilar medicine. No clinical difference has been noted in practice.

As for all new medicines with black triangle status, adverse drug reactions to biosimilar medicines should be reported through the Medicines and Healthcare Products Regulatory Agency (MHRA) Yellow Card Scheme. When reporting adverse drug reactions to biosimilar medicines, it is important to include details of the brand name and batch number (see Section 2.5).
2.5 How should biological medicines, including biosimilar medicines, be monitored?

Clinical outcomes for individual patients on any biological medicine should be measured using established recognised systems for monitoring disease activity and response to treatment.

Measuring clinical outcomes is equally important for all medicines and NHSScotland is actively exploring ways to achieve this. However, specifically for biological medicines, there are two aspects to measurement:

1. monitoring clinical outcomes in individual patients, and
2. establishing a population-based clinical registry.

Monitoring clinical outcomes in individual patients

Frequent monitoring of clinical efficacy and safety outcomes is required when treatment is initiated with any biological medicine, including a biosimilar medicine. Similarly, monitoring will also be required when patients are switched between treatments.

Patient response to treatment and side effects should be measured, where possible, using established systems for monitoring disease activity and documented in case records and clinical letters.

Suspected adverse drug reactions, medicines defects and significant drug interactions for biological medicines, including biosimilar medicines, should be reported through the Yellow Card Scheme in line with the criteria for reporting. Specifying the brand name and batch number allows the specific biosimilar medicine implicated in the adverse drug reaction to be clearly identified.

Therapeutic drug monitoring

Therapeutic drug monitoring (TDM) has now evolved and provides information that assists in optimising therapy and clinical outcomes.

A national therapeutic drug monitoring service is available as one tool to monitor some biological medicines. Protocols for use in rheumatology and gastroenterology are available. This is beneficial in ensuring optimal use of biological therapies and primarily advises on undertreatment, dose reduction and potential switching to alternative medicines.

Establishing a population-based clinical registry

Some clinical specialties contribute to existing, national or international, registries for biological medicines. It is important that biosimilar medicines are included in these clinical registries as they are beneficial in gathering intelligence and building confidence over the longer term by establishing experience beyond what is already known from clinical trials or anecdotal experience.

There is strong clinical support for the continuation and development of registries for biological medicines to monitor population outcomes. Registries should enhance quality and capture patient clinical data and patient satisfaction to optimise clinical management. There are current challenges around the sustainability of the existing registries and supporting registries in clinical specialties where they do not currently exist. Further assessment is required of the current use and benefits of registries to inform policy and strategy for future development.
2.6 How should biological and biosimilar medicines be prescribed and product details recorded?

Biological medicines, including biosimilar medicines, should be prescribed by both the approved and brand name and the brand name and batch number should be recorded on the patient’s case record or other appropriate clinical system.

It is good practice to prescribe biological medicines, including biosimilar medicines, by brand name.\(^6\)\(^7\) Brand prescribing has been recommended to avoid confusion and mixing of products in patients sequentially. This will ensure that patients remain on the same product unless a change in product is considered necessary. This is in line with good practice guidance from the MHRA.

At the time of dispensing or administration, a biosimilar medicine should not be substituted for the original reference product or another biosimilar medicine.\(^7\) NHSScotland recommends that both the approved and brand name and batch number of all biological medicines, including biosimilar medicines, is recorded on the patient’s case record or other appropriate clinical system.

Should an adverse event occur, recording the brand name and batch number facilitates traceability of the medicine and post-marketing surveillance.

However, the challenge of recording these details in primary care is recognised and a practical solution remains to be determined.

The introduction of electronic prescribing and administration systems and electronic health records changes the complexity of recording these details. If, after a full risk assessment, it is determined that electronic prescribing by brand name is not sustainable, an alternative, robust method of capturing brand name must be implemented.
2.7 What information should be provided to patients?

The manufacturer’s patient information leaflet should be supplied to all patients receiving any medicine, including a biosimilar medicine.

As with all medicinal products, a patient information leaflet should be supplied to patients receiving a biological medicine, including a biosimilar medicine. Since 1999, it has been a legal requirement for all medicines to have a patient information leaflet. In some specialties, the manufacturer’s patient information leaflet may be supplemented by locally-developed information about the disease and medicines being prescribed. It would be good practice to update locally-developed information to highlight that, in some cases, patients may receive a biosimilar medicine rather than the original reference product. A template ‘switch letter’ has been produced and a copy of this is included in Appendix 1.

Patients should be kept informed about their medications and any changes to their treatment discussed with them.

Patients should also be made aware that they should always receive the same brand of their biological medicine unless they are switching to another biological or biosimilar medicine as part of a managed programme.
2.8 How do I switch from an original biological medication to a biosimilar medicine?

Case studies provide examples of good practice and key drivers involved in implementing quality improvement in the use of biological medicines.

The case studies outline the experiences, challenges and lessons learned to date by NHS boards that have invested in review clinics in rheumatology and gastroenterology to:

- switch existing patients from an originator biological medicine to the biosimilar version (NHS Grampian and NHS Highland), and
- optimise biological dose in stable patients (NHS Greater Glasgow and Clyde, and NHS Lothian).

Their experiences demonstrate that it is possible to maintain the highest level of care for the patient and make financial efficiencies by adopting a shared decision-making approach between clinician and patient.

Each case study is unique; however, they include the following key learning points.

- Clinical and service engagement with key stakeholders and decision makers is essential. This can support the initial case for management and agreement of the approach for the service. Success requires strong buy-in from senior management and clinical teams.
- Securing additional staffing resource has been central. A small amount of investment has been required in most cases in order to review, counsel and monitor patients.
- Capacity and logistics are a key issue for NHS boards. It can be challenging to free up clinician time – be that consultant, nurse or pharmacist time – clinic space or physical rooms.
- Sustainability of the service requires robust structures in place. Currently, systems can be person dependent and, therefore, vulnerable.
- A shared decision-making approach between clinician and patient: patients have been supportive of the switch to biosimilar medicines where there has been good communication and engagement with the healthcare team. Drug trough levels have guided clinicians as a marker of response and helped reduce patient exposure to unnecessary drug dosage.

Full case studies can be accessed from our website:

Appendix 1: Biosimilar medicines switch letter template

Infliximab and biosimilars

Information for patients on switching from Remicade® to___________

Why have I been given this leaflet?
You have been given this leaflet because you are being treated with a medicine called Remicade® (infliximab) for ____________________.

This leaflet gives information about your medicine and our plans to change the brand of your medicine from Remicade® to ____________. Both of these medicines contain infliximab.

Why is my medicine being changed?
Infliximab belongs to a group of drugs called biological medicines.

At first biological medicines are produced by only one pharmaceutical company under patent. The first manufacturer of infliximab called their medicine Remicade®. Now that the patent for Remicade® has run out, other pharmaceutical companies can produce infliximab. Copies of infliximab are called biosimilar medicines (or biosimilars).

Research shows that the different brands of infliximab are clinically identical. Biosimilar versions of infliximab are as safe and effective as Remicade®. There is also potential that they may cost less. We can use these savings to support services to our patients in other ways.

Like other centres in NHSScotland and in the United Kingdom, the ________________ team in NHS _______________ is moving patients on Remicade® to a biosimilar version of infliximab called _________________.

What does this mean for me?
Your treatment remains the same because both Remicade® and ________________ contain infliximab.

We do not expect you to have problems because you have changed to biosimilar infliximab. We will continue to monitor your response to treatment as we have always done.

What do I do if I have further questions?
You can speak to us at your next appointment or by contacting us on _________________ if you have any questions about the changes to your treatment.

Content of leaflet based on material initially produced by NHS Highland
Appendix 2: Development of Biosimilar Medicines: A National Prescribing Framework - update March 2018

Healthcare Improvement Scotland facilitated collaboration between ADTCs and an expert advisory group to develop the national biosimilar medicines prescribing framework published in May 2015.\(^3\)

A new expert advisory group was formed between July-November 2017 and consisted of representation from NHS boards, NHS National Services Scotland and Healthcare Improvement Scotland. NHS board representation included doctors and pharmacists from a variety of specialties that are expected to experience the introduction of biosimilar medicines in the next few years. These include rheumatology, oncology and gastroenterology. Membership of the new expert advisory group is outlined in Appendix 3. Declarations of interest were collected from members of the expert advisory group in relation to the development of the prescribing framework.

Drawing on national clinical practice and experience, the expert advisory group developed the updated prescribing framework outlining how biosimilar medicines should be introduced in clinical practice.
## Appendix 3: Membership of expert advisory group

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Name</th>
<th>Title</th>
<th>NHS board</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastroenterology</td>
<td>Jonathan Macdonald</td>
<td>Consultant Gastroenterologist</td>
<td>NHS Greater Glasgow and Clyde</td>
</tr>
<tr>
<td>Gastroenterology</td>
<td>Emma Nowell</td>
<td>Specialty Doctor in Gastroenterology</td>
<td>NHS Greater Glasgow and Clyde</td>
</tr>
<tr>
<td>Medicine</td>
<td>Alison Graham</td>
<td>Medical Director and co-chair of the expert advisory group</td>
<td>NHS Ayrshire &amp; Arran</td>
</tr>
<tr>
<td>National Procurement</td>
<td>Lindsay McClure</td>
<td>Pharmaceutical Advisor</td>
<td>NHS National Services Scotland</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>Christine Gilmour</td>
<td>Chief Pharmacist</td>
<td>NHS Lanarkshire</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>Joan Mackintosh</td>
<td>Senior Clinical Pharmacist</td>
<td>NHS Highland</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>Karen Patterson</td>
<td>Head of Pharmacy</td>
<td>NHS Lanarkshire</td>
</tr>
<tr>
<td>Rheumatology</td>
<td>Liz Murphy</td>
<td>Consultant Rheumatologist</td>
<td>NHS Lanarkshire</td>
</tr>
<tr>
<td>Rheumatology</td>
<td>Martin Perry</td>
<td>Consultant Rheumatologist</td>
<td>NHS Greater Glasgow and Clyde</td>
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</tbody>
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**Healthcare Improvement Scotland provided professional and secretariat support:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
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<tbody>
<tr>
<td>Laura McIver</td>
<td>Chief Pharmacist and co-chair of the expert advisory group</td>
</tr>
<tr>
<td>Sharon Pfleger</td>
<td>National Clinical Lead ADTC Collaborative</td>
</tr>
<tr>
<td>Mandy Mackintosh</td>
<td>Clinical Advisor ADTC Collaborative</td>
</tr>
</tbody>
</table>

The original membership of the expert advisory group can be found on page 20 of the framework dated May 2015.\(^3\)
Appendix 4: References


