NHS England

Biosimilar medicines workshops report

March 2016

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National Biosimilars Programme:

The following organisations, listed alphabetically, have partnered with NHS England in developing this document and are members of the National Biosimilar Medicines Programme Board, which will be considering how to prioritise and advance the proposed next steps arising from the workshops.

- Association of the British Pharmaceutical Industry (ABPI)
- BioIndustry Association (BIA)
- British Biosimilars Association (BBA)
- Medicines and Healthcare Regulatory Agency (MHRA)
- The National Institute for Health and Care Excellence (NICE)
- Royal Pharmaceutical Society (RPS)

Contents

1 Executive summary

Biological medicines have transformed patients' lives across a number of therapy areas, from rheumatoid arthritis to cancer; and have become an increasingly significant component of the European medicines cabinet. By 2014, eight out of the top ten medicines sold in Europe were biological medicines[1].

Although biosimilar medicines[2] have been used in the NHS for many years, further biosimilar medicines are in development or under review for approval as originator biological medicines come off patent.

Increased competition in the biological medicines market presents a significant opportunity for the NHS. The financial headroom generated from competition between originator biological medicines and biosimilar medicines can support the treatment and care of an increasing number of patients, including the utilisation of innovative, NICE approved clinical and cost effective medicines.

It is important that the NHS makes the most of this opportunity, whilst ensuring that patients are at the heart of what we do and that the medicines optimisation framework[3] and the seven medicines optimisation principles within it, are embedded in local approaches. This patient-centred, outcome based and value driven approach to medicines use will help ensure the safe, effective and consistent use of all medicines, including biosimilar medicines, across the NHS; and a sustainable market for biological medicines.

NHS England is working collaboratively with national and local stakeholders, from patient representatives and clinicians, to commissioners, medicines regulators and the pharmaceutical industry, to support consistent messaging and appropriate levels of understanding and awareness of biological medicines, including biosimilar medicines. Clinicians, in consultation with their patients, should always have a choice of what medicines to use and must have the confidence to choose biosimilars where appropriate. In this rapidly developing area, it is essential we continue to review the emerging evidence and carefully consider the implications of future developments, such as the increasing complexity of the biological medicines market, as the number of available products grows.

By producing national commissioning guidance and template materials, NHS England hopes to reduce duplication and give local decision makers the tools they need to decide the appropriate approach for their area and ensure that it is implemented appropriately whilst allowing commissioners and providers to share the benefits accordingly.

I look forward to working with you all to ensure the NHS makes the most of this opportunity.

Dr Keith Ridge, Chief Pharmaceutical Officer
Supporting NHS England, the Department of Health and Health Education England

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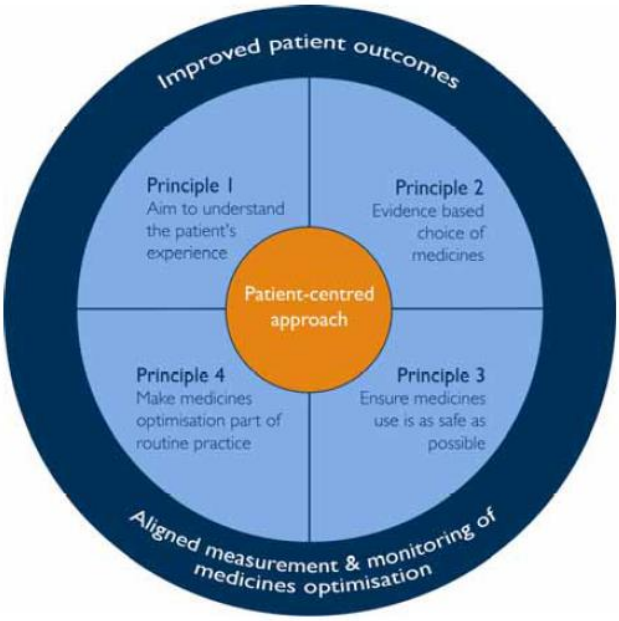
[1] *IMS Health, MIDAS, MAT June 2014. Rx bound. Europe doesn't include Russia and Turkey*
[2] Biosimilar medicine: a biological medicine that has been developed to be highly similar to an existing biological medicine.
[3] NHS England. Medicines optimisation dashboard. Accessed 7 June 2016.

2 Background

In March 2016, NHS England hosted two workshops on biosimilar medicines for local stakeholders with decision-making responsibility for commissioning, prescribing, dispensing and monitoring biological medicines, and, importantly patient representatives too.

Each workshop provided an opportunity for peer to peer discussion, debate and learning, with presentations on national and international biosimilar developments, panel discussions with local healthcare professionals and 'world café' style breakout sessions, through which information was collected on local approaches to the introduction of biosimilars.

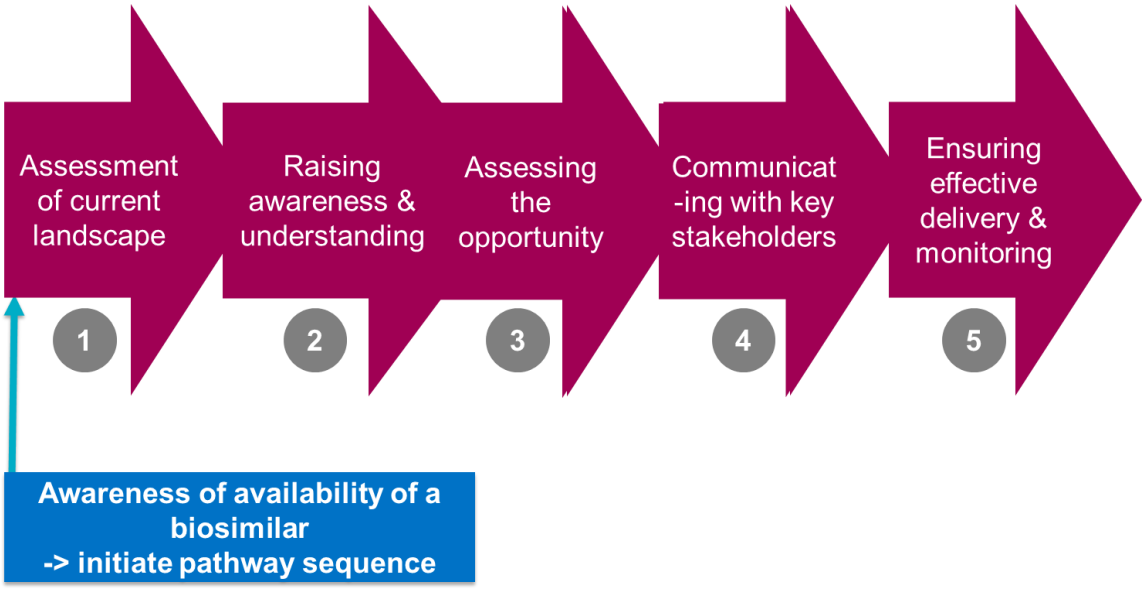
Whilst making the most of the opportunity presented by increased competition amongst biological medicines, including biosimilar medicines; medicines optimisation should underpin local approaches. With this in mind, workshop discussions were guided by medicines optimisation framework[4] and the seven medicines optimisation principles within it, outlined in the diagram below: a patient-centred approach, understanding the patient experience; ensuring medicine use is as safe as possible; promoting evidence based choice of medicine; improved patient outcomes; aligned measurement and monitoring; and making medicines optimisation part of routine practice.



Delegates were asked to consider their experiences so far and how these might inform the approach taken by others and to identify materials that would be helpful to include in a biosimilar implementation framework. The biosimilar implementation framework is a toolkit which will be developed by NHS England and members of the

[4] NHS England. Medicines optimisation dashboard. Accessed 7 June 2016.

National Biosimilars Group following the workshops to help support local decision makers decide on the best approach for their area. The pathway that the framework will cover is set out in the diagram below. This framework will be informed by the comments and reflections of delegates and will provide practical materials and guidance for use locally on the introduction and appropriate use of biological medicines, including biosimilar medicines.



The discussions, which took place at the workshops, have been summarised in this report. They centred on five key themes:

- A thorough assessment of each situation;
- Patient communication and involvement;
- Mechanisms for sharing the benefits of increased competition;
- Consistent understanding of the key considerations related to the commissioning and use of biological medicines, including biosimilar medicines; and
- Standards for appropriate monitoring and real world evidence collection.

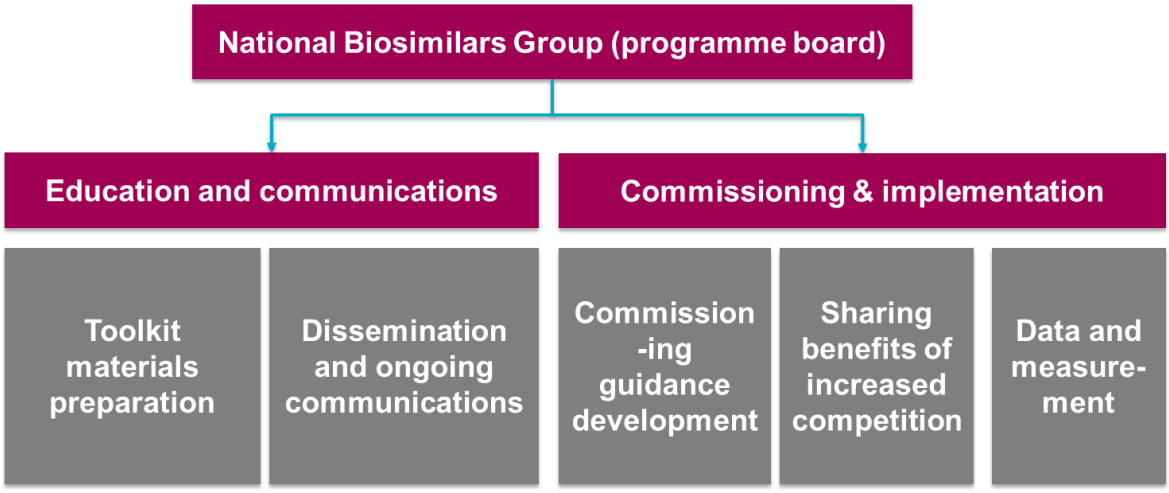
Next Steps:

NHS England is grateful to attendees for their contributions on the day and is committed to driving forward many of the suggestions made during the workshops, in collaboration with national, regional and local stakeholders.

There are a number of proposed next steps in the report below. These are intended to reflect what workshop attendees considered might help colleagues as they seek to decide what approach to take in their local area. In particular, many of the suggestions focus on demystifying a complex topic and ensuring that local decision

makers have the information they require in easily understandable and accessible formats.

The next steps of the national biosimilars work programme are intended to ensure that the NHS is in the best possible position to realise the benefits of increased competition amongst biological medicines. The proposals made in this report will be considered and prioritised through the recently restructured National Biosimilars Group and its work streams, set out in the diagram below.



The programme board will be led by NHS England in collaboration with the National Institute for Health and Care Excellence (NICE), the Medicines and Healthcare products Regulatory Agency (MHRA), NHS Clinical Commissioners, Department of Health Commercial Medicines Unit, the Royal Pharmaceutical Society, patient organisations and industry (the Association of the British Pharmaceutical Industry (ABPI), the British Biosimilars Association (BBA) and the BioIndustry Association (BIA)). This group will oversee delivery of a programme of work intended to ensure the appropriate use of biosimilar medicines in England, in line with the principles of medicines optimisation.

Although the details of the work programme are yet to be finalised, NHS England is keen to work with stakeholders from across the NHS to make the most of this opportunity.

NHS England has set up a biosimilars NHS Network to continue the discussion with local stakeholders and keep delegates updated on progress made towards delivery of the work programme. There will also be plenty of opportunities for local stakeholders to get involved as the programme develops. In particular, we are looking for clinical and patient NHS pathfinders to contribute to the ongoing work programme.

If you wish to join the NHS Network or get involved as a clinical or patient NHS pathfinder, please email: england.biosimilars@nhs.net

3 Workshop summary

3.1 A thorough assessment of each situation is required

3.1.1 Key themes

- Experience with biosimilar medicines so far is helpful but it is important to assess the approach to each new molecule on its own merits.
- Local approaches to biological medicines, including biosimilar medicines, should be informed by a thorough assessment of the opportunity.
- The appropriate use of biosimilar medicines should take variable factors such as different care settings, mode of action and method of administration into account to ensure that a patient centred approach is delivered consistently.
- The biological medicines market will become increasingly complex as additional biosimilar medicines become available. The implications of this complexity have not yet been adequately considered.

3.1.2 Discussion summary

Overarching advice and guidance is helpful to support local decision makers as they agree on the approach they wish to take locally in response to the increasingly competitive biological medicines market.

Each situation should be assessed on a case by case basis taking into account factors such as: the value proposition of each individual medicine; costs and benefits of making changes to existing patients' medication; and the care setting where the medicine will be prescribed and administered. Stakeholders from across the care pathway should be involved in decision making and patients should be represented from the outset.

The majority of experience so far is based on biosimilar medicines that are prescribed and administered in secondary care. The implications of different care settings, such as homecare and primary care; as well as changes to the market environment, as more biosimilar products are launched, require additional consideration. It was considered important that patients should be able to expect a consistent, patient-centred approach.

Delegates noted a key challenge as being the increased number of stakeholders who would need to be engaged, informed and knowledgeable about biosimilars going forward. GPs, community pharmacists and homecare professionals were added to the key stakeholder list which already included doctors, nurses, hospital pharmacists, finance directors and patients.

With homecare delivery, patients might be seen less frequently and depending on whether a nurse or pure delivery service was provided, there might be less opportunity for monitoring, answering questions or gathering feedback from patients.

These challenges may be even greater for self-managed patients and could be compounded by the multitude of providers that a single hospital might work with, all of which is important to consider. Setting out service level agreements and key performance indicators for homecare companies in relation to biological medicines, including biosimilar medicines (particularly in relation to switch programmes) would help to ensure a consistent and safe approach regardless of care setting.

More biosimilar medicines are expected to come to market in the coming months and years. Multiple products are likely to exist for a particular molecule and delegates questioned whether the implication that this complexity might have had been considered adequately. Questions were raised about the potential for multiple switches between different biological medicines: how this might affect patients and whether it would be worthwhile or appropriate to take this approach. Delegates were keen to understand how the prospect of an increased number of medicines should affect their behaviour today. Although no conclusions were drawn at the workshops, the imperative was clear that greater understanding and guidance on this issue is needed.

3.1.3 Proposed next steps

Support local decision makers to conduct a thorough assessment to inform their local decision making

Suggested actions for consideration
Biosimilars implementation framework to provide guidance on key considerations and the types of evidence needed for local decision makers.

Clarify how appropriate use of biosimilar medicines can be ensured in non-hospital settings, such as home care and primary care

Suggested actions for consideration
Engage with primary and secondary care doctors, pharmacists and nurses to explore how the appropriate use of biosimilar medicines, can be secured in primary care.
Liaise with homecare companies to establish template service level agreement and key performance indicators related to their role in supporting the appropriate use of biosimilar medicines.

Assess impact of increasing complexity of biosimilar medicines market, continuing to dialogue with key stakeholders to ensure national guidance remains fit for purpose

Suggested actions for consideration
Include information on the increasing complexity of the biological medicines market in any national commissioning guidance, as well as how any implications should be addressed.
Convene regular meetings with national stakeholders to continue discussions on the evolving landscape.
Provide timely updates to guidance to ensure ongoing safe and effective use of biological medicines, including biosimilar medicines.

3.2 Patient communication and involvement

3.2.1 Key themes

- A patient centred approach to the use of biological medicines, including biosimilar medicines, is essential and should always ensure that the well-being of the patient is a priority.
- The decision regarding the choice of biosimilar or originator biological medicine for an individual patient rests with the responsible clinician in consultation with the patient.
- Patients should be involved in decisions about their medication, including any changes to their current medication. Information provided needs to be clear, balanced and transparent. Patient representative organisations have a key role.
- Individual patients require different approaches to communication, but simply writing to patients to announce a switch in biological medicine, without offering an opportunity for discussion is not recommended.
- Collecting feedback on patient experiences of a switch programme would help to ensure that a patient centred approach had been taken and provide intelligence to inform future programmes.

3.2.2 Discussion summary

Patients being initiated on a biological medicine would require similar information whether they were being initiated on an originator biological medicine or a biosimilar medicine. However, being changed from one medication to another can be an anxious time for patients, potentially exacerbated if that patient has been stable on a particular medicine for a long time. In this scenario, communication and meaningful consultation are of vital importance to ensuring a patient-centred approach in line with the medicines optimisation principles.

Appropriate communication should be open and transparent and must recognise and seek to cater to the varying needs and preferences of individual patients. Having a

central suite of materials that can be tailored to local circumstances and accessed through different channels would avoid duplication and help ensure optimal patient communication across the country. Workshop participants suggested a number of materials and channels that could support consistently high quality communication with patients, including:

- Exemplar patient letter and information leaflet;
- Information video to be played in waiting rooms and made available online;
- Greater use of social media hubs, such as Facebook, to share information and provide support; and,
- Group sessions, including with patient representative organisations, to provide information and an opportunity for multiple patients to ask questions of their clinicians.

Patient representatives at the workshops stressed the importance of patients being given a choice in decisions about their medication. Although opt in patient consent was not necessarily required, patients should be given the opportunity to opt out of making a change if this was something they felt strongly about. That said, there was broad agreement that most patients would be willing to consider a change to their medication if they were given all the information they needed and the reason for any change was clearly communicated.

Collecting feedback on patient experiences of a switch programme would help to ensure that a patient-centred approach had been taken and provide intelligence to inform future programmes. To reduce administrative burden for clinical teams, a centralised self-reporting mechanism might be developed, such as a mobile phone app. This kind of approach would support a holistic view of patient experience across the country and help to identify best practice.

The workshop participants also discussed the need to be pragmatic. Whilst it is always important to discuss the choice of any medicine with the patient, there was also a need to develop local policy in a manner which does not inhibit access to biosimilar medicines. For example, some clinics serve a large population, and engaging each individual patient on the development of a biosimilar programme could take a very long time. Therefore it was considered important that there should be a degree of informed patient representation in local decision-making about potential approaches to the introduction of new biosimilar medicines. Well informed patient organisations would be able to fulfil this function effectively. Patients who had already been initiated or switched onto a biosimilar medicine might also play an active role in supporting other patients. The biosimilars implementation framework (toolkit) should provide clarity on:

- How to involve patients in local decision-making about the use of biological medicines, including biosimilar medicines;
- What considerations prescribers should account for when assessing whether to switch patients from one biological medicine to another; and,
- How patients already using biosimilar medicines might support others making the transition from one biological medicine to another.

3.2.3 Proposed next steps

Ensure that meaningful patient consultation is an integral part of any programme that seeks to switch patients from one biological medicine to another

Suggested actions for consideration
Provide information on what constitutes meaningful patient consultation and how this can be achieved in a cost-constrained environment.
Clearly specify in the biosimilars implementation framework (toolkit) when patients and/or patient representative organisations, should be engaged in decision making about biological medicines, including biosimilar medicines.
Agree how best to capture patient experience during and after any changes to their biological medicine.

Ensure consistently high standards of communication with patients about potential changes to their biological medicine ensuring each individual has access to the information and advice they require to make informed decisions about their treatment

Suggested actions for consideration
Prepare a set of communication materials to support local switch programmes, which take different levels of health literacy and desire for information to be provided using different channels/formats into account.

3.3 Mechanisms for sharing the benefits of increased competition

3.3.1 Key themes

- The appropriate use of biosimilars will drive greater competition to release cost efficiencies to support the treatment of an increasing number of patients and the uptake of new and innovative medicines.
- More needs to be done to ensure that the financial headroom generated through increased competition amongst biological medicines contributes directly to increased patient access.
- At a local level, gain share agreements can be effective mechanisms for ensuring that savings generated through increased competition are shared between local decision makers responsible for implementing any changes.
- However, gain share agreements can be time consuming to put in place; the process should be streamlined where possible.

3.3.2 Discussion summary

Increased competition between biological medicines, including biosimilar medicines, was seen as essential to generate savings for the NHS through lower prices and enhanced value propositions for individual medicines.

There was a common desire amongst those attending the workshops to make the most of this opportunity, whilst ensuring that at least some of the value delivered was transferred back to the departments facilitating the appropriate implementation of any changes to patients' medication; and to patients themselves in the form of improved outcomes through increasing access to biological medicines.

Increased patient access had been used to justify some switch programmes but there was a lack of clarity on exactly how this had been delivered. It was considered important to be transparent with patients about how the financial benefits of any switch programme were to be used. If savings were used to contribute to general NHS or provider finances, rather than supporting a particular department or improving patient access, this should be made clear.

It was noted that improved patient access was often dictated by NICE guidance. Although NICE guidance was intended to mandate a minimum threshold for treatment, this may be used by commissioners as a maximum threshold for reimbursement, helping to manage demand. In practical terms, patient access was considered unlikely to increase unless treatment thresholds are reviewed and expanded by NICE.

There was support for NICE updating the average cost of treatment used in its calculations to account for reductions generated following increased competition amongst biological medicines. The specific example of rheumatoid arthritis disease activity scores (DAS) thresholds was provided, where lower average cost of treatment resulting from greater competition would provide an opportunity to align treatment thresholds more closely with levels in Europe.

Other mechanisms might be used to improve patient access and these should also be considered. For example, if a hospital department was able to retain some of the savings from increased competition, they might choose to provide access to patients who might not otherwise have been treated with a biological medicine at their stage of disease progression. It was also noted that a range of hospital departments are likely to contribute to making the most of biosimilars. For example, a hospital pharmacy department may have to change its approach to preparing the biosimilar for administration, or would need to deploy clinical pharmacy staff to encourage doctors to use biosimilars.

Being able to demonstrate improved patient access to biological medicines was likely to be a significant motivating factor for clinicians to support and drive forward switch programmes. Ensuring the financial headroom created by increased competition is reinvested in medicines was also seen as essential to supporting a sustainable biological medicines market.

For clinicians, having the opportunity to improve outcomes by treating more patients with biological medicines was an attractive prospect, but being able to make other

investments in the department was also considered important. For example, departments might wish to use savings recouped by their department to fund an additional nurse post or administrative assistant to support better patient care and appropriate monitoring of their switch programme. For any additional investments, departments would need to consider funding longevity if there were a fixed term on the savings being granted to the department.

Savings generated by biosimilar or originator medicines that are shared directly with the department are typically granted through a gain share agreement with the local commissioner. However, specific departments are not always party to a gain share agreement, which can also be settled between commissioners and the provider only. Given the efforts involved in administering a responsible switch programme, there was broad agreement at the workshops that three way gain shares between commissioners, providers and the specific department were desirable.

The process of putting a gain share in place was considered challenging and would benefit from being streamlined. The majority of gain share agreements related to biosimilar medicine usage had been negotiated with clinical commissioning groups to date, given the nature of the products currently on the market. This could often involve multiple parties and might impede implementation of a switch programme.

Although gain share agreements typically involved percentage splits of savings between those involved, other approaches were discussed and favoured by some. For example, there might be a fixed sum agreement (e.g. capped total budgets) or, to encourage swift action, gain shares might be proposed with a fixed timeframe, over the course of which the percentage or sum on offer to providers and departments would diminish.

In the event that an area had decided to switch patients from one biological medicine to another, local decision makers would need to agree the best gain share approach for their specific local circumstances. A national model gain share agreement, alongside examples of current gain share agreements and national guidance and support would facilitate more streamlined local approaches.

3.3.3 Proposed next steps

Ensure that financial headroom generated through increased competition delivers increased access to biological medicines for patients

Suggested actions for consideration
Consider whether treatment thresholds should be revisited to reflect reduction in average treatment costs for particular conditions following increased competition in biological medicines.
Consider other mechanisms for ensuring financial headroom supports increased access to medicines.

National guidance should support a more streamlined, 'model' approach to gain share agreements

Suggested actions for consideration
Collect national examples and provide model template gain share agreements to inform and support local approaches to biological medicines, including biosimilars.
Include guidance on how to put a gain share in place in national commissioning guidance.
Provide practical support to commissioners, providers and departments with agreement of local gain shares.

3.4 Consistent understanding of the key considerations related to biological medicines, including biosimilar medicines

3.4.1 Key themes

- In addition to patient information requirements, it was seen as important that clear, concise and unbiased information is available to all those involved in prescribing, administering, procuring and monitoring the usage of biological medicines, including biosimilar medicines.
- Lack of clarity on key issues should be addressed to improve confidence in biological medicines, including biosimilar medicines.
- An agreed way of information sharing and provision of peer-to-peer support would be beneficial.
- Further awareness raising and education on biosimilar medicines across a range of stakeholders remains necessary.

3.4.2 Discussion summary

Whilst a growing number of doctors, pharmacists and others have a good understanding of the key considerations outlined in the 'What is a biosimilar medicine?' document this understanding was not felt to be widespread. Furthermore, authoritative, high quality information was seemingly dispersed and difficult to identify and access.

Several topics which should underpin confidence in biological medicines, including biosimilar medicines, would benefit from clearer and more consistent explanations. In particular, additional information on the regulatory process was considered desirable by workshop attendees. The explanations about how biosimilarity was confirmed, provided by Professor Peter Taylor and Professor Maya Buch at the London and Leeds workshops respectively, were regarded as constructive and informative. Several attendees commented that the slides used had not been seen before and were clear and helpful.

Bio-manufacturing, including batch-to-batch variation and planned manufacturing changes, was presented in different ways by different people at the workshops, which had led to some confusion. A jointly agreed factsheet on this topic would

facilitate more consistent communication and would be a helpful resource for those with an interest. The format of these additional materials would be important as the complexity of the issues would need to be made accessible.

Definitions of interchangeability and switching were also inconsistent and more could be done to provide clarity. It was highlighted as important to ensure that those involved in the use of biological medicines, including biosimilar medicines across the

NHS have a robust understanding of these terms and any associated considerations which might affect their approach in practice.

Ensuring greater understanding would also rely on appropriate networks being in place to support sharing of information and provision of support to those who need it.

The opportunity for discussion between peers was considered valuable at the workshops and a more permanent mechanism for facilitating this kind of communication would be helpful.

Having a network of champions with experience of biological medicines, including biosimilar medicines, would also be a useful way of improving levels of understanding across the country. Several of these champions have been identified through the workshops. These champions might work closely with the proposed Regional Medicines Optimisation Committees or within an AHSN geography to ensure appropriate sharing of information and expertise.

3.4.3 Proposed next steps

To provide easily accessible information and education on the key considerations related to biological medicines.

Suggested actions for consideration
Collate existing materials on biological medicines, including biosimilar medicines.
Set up website repository for key materials related to biological medicines, including biosimilar medicines.
Consider additional formats for delivery of key information and facts, such as infographics, videos and webinars.

Prepare additional materials and consistent guidance to address specific areas of confusion or misunderstanding, such as the regulatory pathway and bio-manufacturing

Suggested actions for consideration
Provide additional information resources to doctors and other clinical staff explaining the regulatory process.
Consider recording a webinar on the regulatory process including medical speakers from the workshops.
Prepare a short factsheet on bio-manufacturing issues to set an agreed narrative that reduces confusion.
Include factual information on the difference between switching and interchangeability, and related considerations in the national commissioning guidance.

Ensure that pathways are in place to support the appropriate and timely dissemination of information

Suggested actions for consideration
Establish an NHS network to support peer-to-peer conversation and information sharing on biological medicines, including biosimilar medicines.
Establish a network of NHS and patient champions to support local stakeholders as they seek to decide and implement the appropriate approach for their area.

3.5 Standards for appropriate monitoring and real world evidence collection

3.5.1 Key themes

- Appropriate data and evidence to underpin decision making in relation to biological medicines, including biosimilar medicines would be helpful.
- Regulatory guidance is already in place regarding the reporting of adverse events by brand name and batch number for biological medicines. There are also recommendations for brand name prescribing, which supports ongoing pharmacovigilance; however, these should be adhered to more rigorously.
- Real world data collection as vital for understanding the evolving biological medicines landscape. It would be helpful to address the current lack of clarity around what, where and how to collect data and monitor outcomes at the individual patient level.
- A central repository for key information and data would be beneficial.

3.5.2 Discussion summary

Data and evidence play a vital role in decision making about biological medicines, including biosimilar medicines. This includes safety monitoring of all biological medicines, including biosimilar medicines, and collection of real world evidence. The information collected can help support clinical and patient confidence and understanding; identify and isolate any potential issues; and inform policy development and future decision making.

ADR reporting is important for all medicines but particularly more newly authorised medicines that fall under the black triangle scheme. From a regulatory perspective, there is already guidance in place about the need to report suspected adverse drug reactions (ADRs) for biological medicines, including biosimilar medicines and the importance of reporting brand name and batch number whenever possible[5]. Despite general awareness of the Yellow Card Scheme, discussion at the workshops suggested that suspected ADR reporting to the Medicines and Healthcare Products Regulatory Agency (MHRA) Yellow Card Scheme is inconsistent.

Barriers to consistent ADR reporting included a lack of time to submit the form and limited availability of the relevant information needed to produce complete forms. There was also discussion of an inability to correctly report the specific product concerned due to the prevailing use of international non-proprietary name (INN) prescribing and lack of recording of the brand and batch number of the product dispensed which hampers accurate attribution of adverse drug reactions and could also lead to unintended substitution at dispensing. Greater promotion of the importance of reporting all ADRs for biological medicines, including biosimilar medicines, was considered important for patients and healthcare providers alike. In addition, further information on how ADRs were monitored following a yellow card report would help stakeholders better understand the wider benefits of the scheme.

Satisfactory adherence to brand name prescribing for biological medicines would rely heavily on a clinical cultural shift and retraining to move away from INN prescribing which is normally used for medicines. Delegates noted a significant trend towards electronic prescribing, which was considered a helpful route for ensuring better adherence to brand name prescribing. If those inputting prescriptions for a biological medicine into the electronic prescribing system were mandated to prescribe that medicine by brand name only, this would reduce reliance on individual prescribers to remember to use the biological medicine's brand name. It would be important to ensure that electronic prescribing systems included all of the product names available to prescribers, which is not the case currently. Concerns were raised during the discussions about the potential for medication errors by inadvertent prescription of the wrong product once a large number of biosimilars are available for a particular molecule. Prescribers would still need to take responsibility for prescribing the correct brand but the electronic prescribing systems could support this choice through built in reminders.

There was consensus about the importance of real world data and evidence but an apparent lack of clarity around what data should be collected, where it should be input and stored and how it should be assessed and fed back to relevant

[5] Drug Safety Update November 2012, vol 6, issue 4: H1; https://www.gov.uk/drug-safety-update/reporting-suspected-adverse-drug-reactions-to-vaccines-and-biological-medicines ; accessed 15 April 2016

stakeholders to inform decision making. The value of real world data would come through the development of a collective understanding, but the mechanisms to facilitate this were not currently considered to be in place. Encouraging data input and collection was necessary and could potentially be incentivised, for example through gain share agreements or by regular exchange of information and sharing of data insights.

Helpful evidence could be generated through a number of different means ranging from international studies, national databases and data collection programmes; through to disease specific registries and local hospital databases. A more coordinated approach was needed to avoid duplication and ensure the collection of coherent, comparable data. There was particular confusion about the role of registries as opposed to local databases, which registries existed, and how these could be used to best effect. Registries are typically funded by industry but some commissioners considered that it was sometimes hard to justify the value of a registry, as data insights from the wider database were not shared systematically.

At a basic level, it was felt that stakeholders would find it helpful to have access to, or summaries of, data on factors including: patient outcomes, patient experience of switch programmes, and reasons for patients choosing to switch back to their original medicine (clinical and non-clinical). Data that would allow an assessment of medicines use based on factors such as age, disease severity and comorbidities, might also be helpful.

The proposed indicators being collected through national programmes such as the medicines optimisation dashboard and the Lord Carter hospital pharmacy and medicines optimisation programme (HoPMOp), could provide a useful set of measures regarding whether the NHS was making the most of the opportunity of increased competition amongst biological medicines. This could be achieved by looking at an indexed measure of enhanced value, the use of biosimilar medicines by trust and, in the longer term, an assessment of overall patient access to biological medicines. This data could also indicate whether the market was becoming over-reliant on a particular supplier, which would not support a sustainable biological medicines market.

A guide to what information is currently available and where it can be found would be a helpful resource in the immediate term; with a central repository for all relevant data, an appropriate ambition for the future. Blueteq was mentioned as a possible system for facilitating data sharing. Care would need to be taken to ensure commercial confidentiality was retained, whilst still providing an overview of helpful trends and information. A data roadmap would help to set out the steps needed to improve the collection of consistent and shareable data.

3.5.3 Proposed next steps

Support improved pharmacovigilance

Suggested actions for consideration
Continue to publicise the Yellow Card Scheme in the context of the UK's pharmacovigilance system, mentioning biological medicines, including biosimilar medicines, where relevant to raise awareness about the importance of the Scheme and encourage the reporting of suspected ADRs.
Develop educational materials for clinicians and training clinicians highlighting the importance of recording brand name for monitoring.
Request all electronic prescribing data feed and interface companies to mandate brand name prescribing for all biological medicines.

Provide greater clarity on real world data requirements and insights

Suggested actions for consideration
Include section on data collection and sharing in NHS England biosimilar medicine commissioning guidance to include information on what data should be collected and how.
Expedite work on national indicators to demonstrate impact of increased competition amongst biological medicines.
Explore how national data insights can be developed, agreed and shared with local stakeholders.

4 Conclusion

NHS England is grateful to all those attendees whose experiences, comments, suggestions and questions are reflected in the above summary. The workshops provided exceptional insight into the local considerations on biological medicines, including biosimilars and the topics raised and proposed next steps are being considered carefully by NHS England.

Over the next year, NHS England will work collaboratively with national and local stakeholders, from patient representatives and clinicians, to commissioners, medicines regulators and the pharmaceutical industry, to support consistent messaging and appropriate levels of understanding and awareness of biological medicines, including biosimilar medicines. NHS England welcomes workshop participants continued engagement with this programme and looks forward to working together to ensure the NHS makes the most of the opportunity at hand and, in the process, ensuring the seven medicines optimisation principles are embedded in local approaches.

5 Appendix

5.1 Workshop programme

OVERALL AIM:
NHS England is hosting two workshops on biosimilar medicines, which have been developed in coordination with a number of AHSNs. The workshops have been designed to ensure that local stakeholders are equipped with the information and materials needed to support appropriate use of biological medicines, including biosimilar medicines across the NHS. This will include drawing on local experiences and understanding to inform development of a biosimilars implementation framework containing practical materials and guidance. Delegates will hear about national and international developments in biosimilar medicines, as well as local insights from clinicians, pharmacists and commissioners.

DELEGATE OBJECTIVES:

- To increase awareness and understanding of biosimilar medicines and the unique considerations related to their appropriate use amongst decision makers at a local level of the NHS
- To clarify how biosimilar medicines fit in with the wider medicines optimisation agenda and to ensure medicines optimisation principles are embedded in local approaches
- To assess where you are today in your area and learn how you might make the most of the availability of biosimilars to increase competition in the biological medicines market for the benefit of patients
- To understand which data and metrics are available and how to use them to inform decision-making
- To hear from your peers about the approaches they have taken to date
- To contribute to the development of a biosimilars implementation framework that will support people across the NHS to make appropriate use of biological medicines, including biosimilars

DELEGATES: Local stakeholders with decision-making responsibility for commissioning, prescribing, dispensing and monitoring biological medicines, including biosimilar medicines are invited to the workshops, alongside patient representatives.

As we will be developing materials to support local approaches to biological medicines, it is expected that attendees will have a range of experience related to biosimilar medicines to ensure that the materials agreed are well targeted and of practical use to local stakeholders.
The workshops will be interactive and attendees are asked to commit to remaining until the end of the day.

Delegates will also have the opportunity to volunteer as NHS pathfinders to help cascade information using the biosimilars implementation framework across their localities to ensure good levels of understanding, awareness and confidence in biosimilar medicines.

APPROACH: Each workshop will provide an opportunity for peer to peer discussion, debate and learning, while helping participants enhance their understanding of biosimilar medicines within the context of medicines optimisation.
Delegates' comments and reflections throughout the day will inform the ongoing development of a biosimilars implementation framework which will be used around the country to support stakeholders in considering how to make the most of the opportunity of increased competition in the biological medicines market, driven by the introduction of new biosimilar medicines.
The morning sessions will feature a brief overview of the evolving biological medicines market and related considerations, as well as presentations from local healthcare professionals who will share their experiences of biosimilar medicines, including the challenges they have faced and how these have been overcome.

In the afternoon, participants will discuss biosimilar medicines in 'world café' style sessions. These dynamic discussions will be guided by the seven principles of medicines optimisation: a patient-centred approach, understanding the patient experience; ensuring medicine use is as safe as possible; promoting evidence based choice of medicine; improved patient outcomes; aligned measurement and monitoring; and making medicines optimisation part of routine practice. Each group will be led by an expert facilitator who will ensure that the conversation on their focus topic continues to evolve as the groups rotate over the course of the afternoon. Further details on the programme can be found below.

PROGRAMME:

Start	End	Session title	Session content	Presenters
09:30	10:00	Registration and coffee		
10:00	10:10	Welcome	• Welcome • Overview of event, attendees & ongoing biosimilars programme • Expectations of participants • Housekeeping (health and safety etc)	NHS England facilitator: **Barrie Sheppard**
10:10	10:30	Biosimilars: an NHS England perspective	• Biosimilars within the medicines optimisation programme • Opportunity of increased competition in biological medicines market for the NHS • Importance of focus on patient perspectives • Local vs NHS England activity (i.e. work of	**Keith Ridge**, Chief Pharmaceutical Officer, NHS England

			national group/ development of overarching commissioning guidance) • Objectives for the workshop	
10:30	11:00	What is a biosimilar medicine	• Key principles set out in "What is a biosimilar medicine" document	7th March: **Peter Taylor**, Norman Collisson Professor of Musculoskeletal Sciences, University of Oxford 11th March: **Maya Buch,** Professor of Rheumatology, University of Leeds
11:00	11:30	European experiences of biosimilar medicines	• The Impact of Biosimilar Competition	7th March**: Angela McFarlane,** Senior Principal, IMS Market Access 11th March: **Clare Foy** Principal, IMS Market Access
11:30	11:45	Coffee break		
11:45	12:30	Local insights	• Provide an overview of experience in their area • Reasons behind decisions ··What worked well ··What did not work well ··What would they change ··What support would have been helpful in the process	7th March: **Fraser Cummings**, Consultant Gastroenterologist, Southampton General Hospital, **Simon O'Neill**, Director of Health Intelligence and Professional Liaison, Diabetes UK and **Vanessa Burgess**, Assistant Director Medicines Optimisation, Lambeth CCG, and **Jonathan Battarbee**,Head of Finance, UCLH NHS Foundation Trust 11th March: **Anne Phillips**, Consultant Gastroenterologist and IBD Lead & **Stuart Parkes**, Deputy Chief Pharmacist, York Teaching Hospital NHS Foundation Trust

12:30	13:00	Q&A	• Opportunity for attendees to ask questions of panel • Includes five minutes for morning session wrap up and preview for afternoon activity	Local insight presenters joined by experts in the field from national biosimilars group including MHRA, NICE, NHS Commercial Solutions, and industry representatives
13:00	13:45	Lunch		
13:45	15:45	World Café 1: The patient perspective	**Medicines optimisation principle: Aim to understand patient experience** • Ensuring a person-centred approach • Shared decision making – providing helpful information and evidence and taking into account patients' needs, preferences and values • Patient consultation • Patient support and ongoing monitoring	7th March: **Ailsa Bosworth**, Chief Executive and Founder, NRAS & **Peter Taylor**, Norman Collisson Professor of Musculoskeletal Sciences, University of Oxford 11th March: **Clare Jacklin**, Director of External Affairs, NRAS & **Maya Buch**, Professor of Rheumatology, University of Leeds
		World Café 2: safe and effective use of biological medicines, including biosimilar medicines	**Medicines optimisation principle: Ensure medicine use is as safe as possible** • Clinician confidence • Biomanufacturing overview • Regulatory pathway • Brand name prescribing • Pharmacovigilance (inc ADR reporting) • Measuring patient outcomes • Extrapolation	7th March: **Anne Cook**, Senior Quality Assessor, MHRA **Alison Shaw**, Unit Manager, MHRA, **Marie-Christine Bielsky** Expert Medical Assessor, MHRA & **Zoe Cole**, Consultant Representative, BSR 11th March: **Anne Cook**, Senior Quality Assessor, MHRA **Alison Shaw**, Unit Manager, MHRA, & **Kath Watson**, Representative from the centre hosting the BSRBR-RA, BSR

		World Café 3: Evidence based choice	**Medicines optimisation principle: Evidence based choice of medicine** • Technology appraisal • Available evidence (e.g. NICE guidance) • New patients and switching • Using data to inform decision-making • Appropriate monitoring and metrics	**Andy Hutchinson**, Medicines Education Technical Adviser, NICE & **Ruth Garnett** Senior Medicines Adviser, Medicines and Prescribing Programme, NICE
		World Café 4: Operational considerations	**Medicines optimisation principle: Making medicines optimisation part of routine practice** • Contracting approach • Ensuring competition • What costs and benefits to consider • Engagement with local stakeholders to inform commissioning approach • Gain share • Implementation in primary, secondary and home care • Design of appropriate communications	7th March: **Maggie Dolan**, Regional Pharmacy Procurement Specialist, NHS Commercial Solutions & **James Kent**, Secondary Care Lead, PrescQIPP NHS Programme 11th March: **Maggie Dolan**, Regional Pharmacy Procurement Specialist, NHS Commercial Solutions & **David Cook**, Specialist Procurement Pharmacist, North East and North Cumbria
15:45	16:00	Close: facilitator feedback session	• Present top-line findings from each world café session • Discuss next steps, including expectation of attendees to identify local NHS pathfinders to take work forward at a local level	NHS England facilitator: **Barrie Sheppard**

5.2 Declarations of interest

Name	Title	Interests
Maya Buch	Professor of Rheumatology, University of Leeds	Research funding/support: Pfizer ltd, Roche-Chugai Honoraria/Consultancy: Abbvie, AstraZeneca, Bristol-Myers squibb, Roche-Chugai, Pfizer, Sandoz

Fraser Cummings	Consultant Gastroenterologist	Ad boards: Hospira, NAPP, AbbVie, Biogen, Takeda, Janssen Speaker fees: Hospira, NAPP, MSD, AbbVe, Biogen, Takeda Research collaboration: Hospira, MSD, AbbVie, Takeda, Janssen, GSK, Astra Zeneca Member of UK IBD Audit Biologics sub-committee
Stuart Parkes	Deputy Chief Pharmacist, York Teaching Hospital NHS Foundation Trust	Presentations for Napp/ Biogen Advisory board for Vifor Case studies sponsored by Napp/Biogen Contributed to a consensus statement on Biosimilar Infliximab sponsored by Napp
Anne Phillips	Consultant Gastroenterologist and IBD Lead	Nothing to declare
Peter Taylor	Norman Collisson Professor of Musculoskeletal Sciences, University of Oxford	Research grants to Oxford University: UCB, GSK, Celgene, Abide therapeutics. Consultation, and/or speaking: Roche, UCB, GSK, BMS, Lilly, MSD, AstraZeneca, Pfizer, Janssen, AbbVie, Baxalta, Epirus, Galapagos, Biogen, Sandoz

5.3 Workshop programme feedback

5.3.1 Feedback survey questions

Attendees at both workshops were asked to complete a feedback form with the following questions. The feedback from each event is pasted below each question.

1. Please indicate how well you feel the event's delegate objectives were met (1= not met at all –> 5 = completely met)

DELEGATE OBJECTIVES:	1	2	3	4	5
To increase awareness and understanding of biosimilar medicines and the unique considerations related to their appropriate use amongst decision makers at a local level of the NHS					
To clarify how biosimilar medicines fit in with the wider medicines optimisation agenda and to ensure medicines optimisation principles are embedded in local approaches					

To assess where you are today in your area and learn how you might make the most of the availability of biosimilars to increase competition in the biological medicines market for the benefit of patients					
To understand which data and metrics are available and how to use them to inform decision-making					
To hear from your peers about the approaches they have taken to date					
To contribute to the development of a biosimilars implementation framework that will support people across the NHS to make appropriate use of biological medicines, including biosimilars					

London responses:

1	2	3	4	5
0	0	5	26	13
0	3	9	24	8
1	4	15	21	3
1	11	21	11	0
0	1	12	21	10
0	1	14	21	8

Leeds responses:

1	2	3	4	5
0	2	3	40	12
0	5	15	24	13
0	4	20	21	10
3	12	23	14	4
1	2	8	25	21
1	3	13	24	16

2. Please indicate the degree to which you agree with the following statements (1= not met at all –> 5 = completely met)

Event components	1	2	3	4	5
The event was well structured					
The presentations were informative and interesting					
The world café sessions were informative and interesting					
The venue was well suited for the structure of the event					

London responses:

1	2	3	4	5
0	0	5	23	16
0	0	6	17	21
0	4	22	11	7
1	1	12	21	8

Leeds responses:

1	2	3	4	5
0	0	8	25	24
0	1	6	23	27
1	6	11	25	14
4	14	11	14	14

3. For which topic would it be most helpful to have additional national guidance?

_____

London responses

Gainsharing	15
Patient safety data	1
Reassurance around switching patients	2
National framework to manage the implementation of biosimilar medicines	5
Drug switching	2
Incentivising outcome data and establishing national KPIs	6
Patient info leaflets	10
Research and licensing summary	2
Data collection	7

Leeds responses

Patient information and engagement	8
Data collection	9
Gainsharing	22
Implementation and commissioning framework	18

4. Has your local area developed any materials which might inform the biosimilars implementation framework (toolkit)? (please tick one response)
   Yes_____ No_____

If 'yes' please send the materials to the following address or provide your details on this form and someone will get in touch with you: england.biosimilars@nhs.net

London responses

Yes	No	NA
10	29	5

Leeds responses

Yes	No	NA
9	41	7

5. Would you be interested in continuing to work with NHS England to ensure the appropriate use of biological medicines, including biosimilar medicines?
   Yes_____ No_____

London responses

Yes	No	NA
36	5	3

Leeds responses

Yes	No	NA
41	11	5

To register your interest in being an NHS pathfinder, please use the following address or provide your details on this form and someone will get in touch with you:
england.biosimilars@nhs.net

6. Do you have any other comments, questions or concerns? (please complete overleaf)

London responses:

- London specialised commissioning model for HIV has been very successful- can this be used for biosimilars?
- Would be good to get support in setting up pharmacist network to aid implementation and standardising practice
- Useful to share data with trusts who have already switched
- Some repetition in workshops (but people with some ideas where aspirational)
- It was very interesting but did not set this in the context of wider medicines optimisation to focus on developments in local areas except Southampton. I think a national framework is definitely needed and there were some important messages about the need for patient involvement, shared and effective systems for mentoring, re-investment of cost savings into the system, including specialist nursing, pharmacists and other priorities, as identified by local multi-stakeholders project group (including patients).

Leeds responses:

- If a national toolkit is being developed it needs to be imminent
- What mechanisms are in place to ensure the price of biosimilars don't increase after adoption? If multiple cheaper biosimilars become commercially available would we have to switch again?
- I have a very clear impression that CCG MO leads don't understand many of the issues around biosimilars. I don't think it is going to be possible to develop a practical implementation in primary and secondary care as there are great differences in the clinical scenarios.
- Would have been useful to have more examples of local implementation
- I'm surprised by the lack of consistency of approaches to switch to biosimilars across the country. An enforces change is in complete contradiction to the principals of optimisation we're suppo9sed to be guided by

- We need to be very careful that a national approach does not hold back or delay implementation through the introduction of low value additional steps in the process. No guidance or framework would be better than a bad framework
- As a patient I would like the ‘top 10 tips for biosimilars’
- Great and informative to have patient input into discussions. Lots of discussion re: data capture- there is a need to use existing data capture methods or resource data capture appropriately

5.3.2 Key findings overview

1. 66% of delegates in London and 72% of delegates in Leeds stated that their local areas had not developed any materials which might inform the Biosimilars implementation framework (toolkit).

2. More guidance on gain sharing was required for both London (30%) and Leeds (38%).

3. Delegates were asked whether they found the world café sessions information and interesting both London and Leeds answered fairly neutral with most of the delegates answering with a 3.

4. When asked whether they were Interested in working with NHS England London percentage was high with 82% say yes and Leeds 72% saying yes.

5. Overall both London and Leeds found the overall day informative and interesting with a number of positive comments prevailing around the whole event.