



# **Understanding patient needs in switching from biologic to biosimilar medicines**

**Final report of survey and focus group findings**

**December 2018**

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## Executive Summary

It is widely known that the NHS has been under considerable financial pressure for some time, with levels of patient need rising while its funding growth has consistently been below historical trends. As one consequence of this, it has sought to save money on medicines. NHS England has issued guidance to restrict the prescription of some 'low value' items and over-the-counter medicines, while elsewhere the NHS has encouraged the use of cheaper biosimilar medicines in place of more expensive biologics. The emergence of these biosimilars is a second important driver of this change.

The Patients Association wants reassurance that when patients are put on new medicines, good practice guidelines are followed in terms of patient-centred care. During September 2018 we undertook a survey with 262 responses and a focus group of seven people in Birmingham in order to gain patients' views about whether they are in fact receiving the support they should expect.

Conditions treated with biologic or biosimilar medications are complex, and patients have often had long and painful journeys to get to a level of daily living that most people take for granted. If changes in medication are required this should be done in discussion with the patient. Information regarding new medication should be clear and helpful to allay people's fears and make any change as positive an experience as possible. Additionally, if adverse effects are experienced, mechanisms must be in place to monitor and support patients.

What was clear from the work carried out in Part 1 of the project was the lack of good quality information and advice and a need for a set of tools which are easily accessible both for patients and staff so that patients are better equipped to understand their health condition and make decisions about their treatment.

It was noticeable that despite the enormous amount of knowledge held by patients there was still a lot of uncertainty about the impact of changing to a biosimilar. The following questions raised by patients were the most imperative:

- What could the impact be on my condition if required to change medication?
- Would there be known and unknown side effects?
- Could I become ill again?
- Would I be able to get help?
- What contingency plans or business continuity plans are in place if a batch of medication was faulty or if there was a lapse in supply?
- What would the impact of Brexit be?

From the concerns raised and the suggestions about need for better information, shared decision making and collaborative working between patients and clinicians it would seem helpful to co-produce a set of tools to assist patients in the journey they describe. The aim would be to better inform and empower patients to take control of their situation and be more equal partners in their treatment plan and choice of medication.

# 1. Introduction

The Patients Association is an independent charity with a mission to harness and promote the patient voice, improve services and support people to engage fully in their own care.

Each year we facilitate and manage a number of national and local projects, reports and training events. The range of this work is considerable, and varies from surveys and focus groups to supporting individual NHS Trusts and other organisations on how they work with patients.

This project was sponsored by a non-restricted grant from AbbVie – a biopharmaceutical company<sup>1</sup> - with the aim of reaching a better understanding of the views of patients, and their needs in the event that their doctor suggests they should switch to a biosimilar medicine.

The NHS Constitution<sup>2</sup> sets out certain rights that patients using NHS services should expect. Patients have the right to be given clear information regarding their treatment including any risks, benefits, choices and alternatives. More recently the Patient Information Forum<sup>3</sup> and NHS England<sup>4</sup> outlined certain quality standards for information, which required the NHS to provide high quality patient information that was accessible, informative and up to date. The standards also required the information to be easily understandable and delivered in a collaborative way in order to meet the patients' needs.

When considering the above factors, especially access to information, the issue of health literacy is also paramount. Health literacy<sup>5</sup> has been defined as the degree to which people have the capacity to obtain, process, and understand basic health information in order to access services and make appropriate health decisions. As systems grow ever more complex our reliance upon computers, apps and electronic means to access information increases. This places an additional burden on some to access and understand information, and is especially pertinent for elderly people, people without access to computers or smart devices, people who have low levels of literacy, and people for whom English is not their first language. This is compounded when considering the complexity of biologic and biosimilar medications and may result in the most vulnerable not receiving the same levels of treatment as those who are able to articulate and make a case for their needs<sup>6</sup>. The World Health Organisation<sup>7</sup> makes a

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<sup>1</sup> <https://www.abbvie.co.uk/>

<sup>2</sup> <https://www.gov.uk/government/publications/the-nhs-constitution-for-england>

<sup>3</sup> The Patient Information Forum (PiF) Making the case for information –the evidence for investing in high quality health information for patients and the public May 2013

<sup>4</sup> [www.england.nhs.uk/tis/about/the-info-standard/](http://www.england.nhs.uk/tis/about/the-info-standard/) Information Standard Principles Accessed 17/10/2018

<sup>5</sup> <https://www.hee.nhs.uk/our-work/health-literacy> Health Education England Accessed 18/10/2018

<sup>6</sup> Determinants of health literacy and health behaviour regarding infectious respiratory diseases: a pathway model Xinying Sun<sup>1</sup>, Yuhui Shi<sup>1</sup>, Qingqi Zeng<sup>1</sup>, Yanling Wang<sup>1</sup>, Weijing Du<sup>2</sup>, Nanfang Wei<sup>2</sup>, Ruiqian Xie<sup>2</sup> and Chun Chang<sup>1</sup> Sun et al. BMC Public Health 2013, 13:261 <http://www.biomedcentral.com/1471-2458/13/261>

<sup>7</sup> <https://www.who.int/healthpromotion/conferences/9gchp/health-literacy/en/>

case for all health organisations to consider the literacy age of those reading information to ensure it is truly accessible and a fundamental part of this is to support patients when dealing with complex decisions about their health.

## 2. Aims and Objectives

Continuing development of biological medicines, including biosimilar medicines, creates increased choice for patients and clinicians, increased commercial competition and enhanced value propositions for individual medicines.<sup>8</sup> However, there is also a need – a greater need, in our view – to ensure that patients have the treatment that is right for them, and that any change to their medication is both clinically justified and their choice. Patients should expect to be supported through any switch of medication, which could be a complex or difficult process. NHS England has outlined some good practice principles<sup>9</sup> to ensure that any change in patient medication is undertaken by a meaningful process of shared decision-making.

The Patients Association wants reassurance that these good practice guidelines are being adhered to and that patients are routinely enjoying the benefits of shared decision-making and comprehensive support in respect of any change of medicine from a biologic originator to a biosimilar. This report sets out the findings of our research into this topic.

## 3. Methodology

The project used a mixture of quantitative and qualitative approaches to obtain feedback.

### Survey Details

Initially an online survey was distributed to patients via the Patients Association's social media channels and weekly email newsletter. Respondents were also able to complete it by phone via our national helpline. The survey contained 17 questions using a mixture of open and closed responses.

### Focus Group Details

The questionnaire was followed by a focus group held in Birmingham, attended by patients. The information gathered during the focus group was not audio recorded, but

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<sup>8</sup> NHS England. *RMOC, Best Value Biologicals: Adalimumab Update 1. March 2018.*

<https://www.sps.nhs.uk/wp-content/uploads/2018/03/Adalimumab-RMOC-Briefing-Final-27-March.pdf>

<sup>9</sup> <https://www.england.nhs.uk/shared-decision-making/>

written notes were taken and permission was given by participants for this information to be used anonymously.

There were 262 responses to the survey and seven people attended the focus group.

#### Data protection

The General Data Protection Regulation (GDPR)<sup>10</sup> guidelines were adhered to and a GDPR risk assessment was carried out. No personal identifiable data was collected without permission. Anonymity was assured to all participants, who were willing for the findings to be reported in a formal report back to the sponsor and shared more widely to influence service improvements.

## 4. Introduction to Biologic and Biosimilar Medications

### Biologic Medications

A biologic<sup>11</sup> drug is one that is produced from living organisms or contains components of living organisms. These preparations are useful in the treatment of certain types of cancers, preventing infections in the case of vaccines, or modifying immune responses. Biologic drugs are used for treatment of numerous diseases and conditions, such as Crohn's disease, ulcerative colitis, rheumatoid arthritis and psoriasis to name but a few. Biologic drugs are administered by injection or infusion because they are proteins that are quickly digested and inactivated if given by mouth. Therefore, biologic drugs are supplied as powders for infusion or solutions for injection.

### Biosimilar Medications

A biosimilar is a newer version of an original biological drug, which is highly similar to another biologic medicine already licensed for use.<sup>12</sup> A biosimilar contains a version of an active substance of an already approved biologic medicine, which is referred to as the 'reference medicine' or 'originator medicine'. While the biosimilar has been shown not to have any clinically meaningful differences from the originator medicine in terms of quality and safety a biosimilar is not the same as a generic medicine, which is identical, in terms of molecular structure, to its reference drug, whereas biosimilar are not<sup>13</sup>.

## 5. Findings

The aim of the survey and focus group was to gather feedback from current users of biologic or biosimilar medications to ascertain what support or information would be

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<sup>10</sup> <https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/>

<sup>11</sup> <https://www.nhs.uk/conditions/biological-and-Biosimilar-medicines/>

<sup>12</sup> <https://www.england.nhs.uk/wp-content/uploads/2015/09/Biosimilar-guide.pdf>

valuable to them in the event that their doctor suggested switching to another medicine. In the event that people had already experienced such a switch, the research gathered their views on how this had been done, and how it might have been improved.

### Health conditions

Survey participants identified themselves as having the following conditions:

- Rheumatoid arthritis (60.54%)
- Crohn's disease (10.73%)
- Ulcerative colitis 4.60%
- Psoriatic arthritis (4.60%)
- Psoriasis (0.77%)
- Ankylosing spondylitis (0.77%)
- Other including irritable bowel, birdshot uveitis and thyroid disease (18.01%)

The survey can be found in Appendix 1 of this report.

The range of medications taken by those who completed the survey can be seen in the table below. Of the 208 respondents who were on a biologic or biosimilar medication, most (38%) had been taking them for between 1-5 years with 20% having taken them for considerably longer.

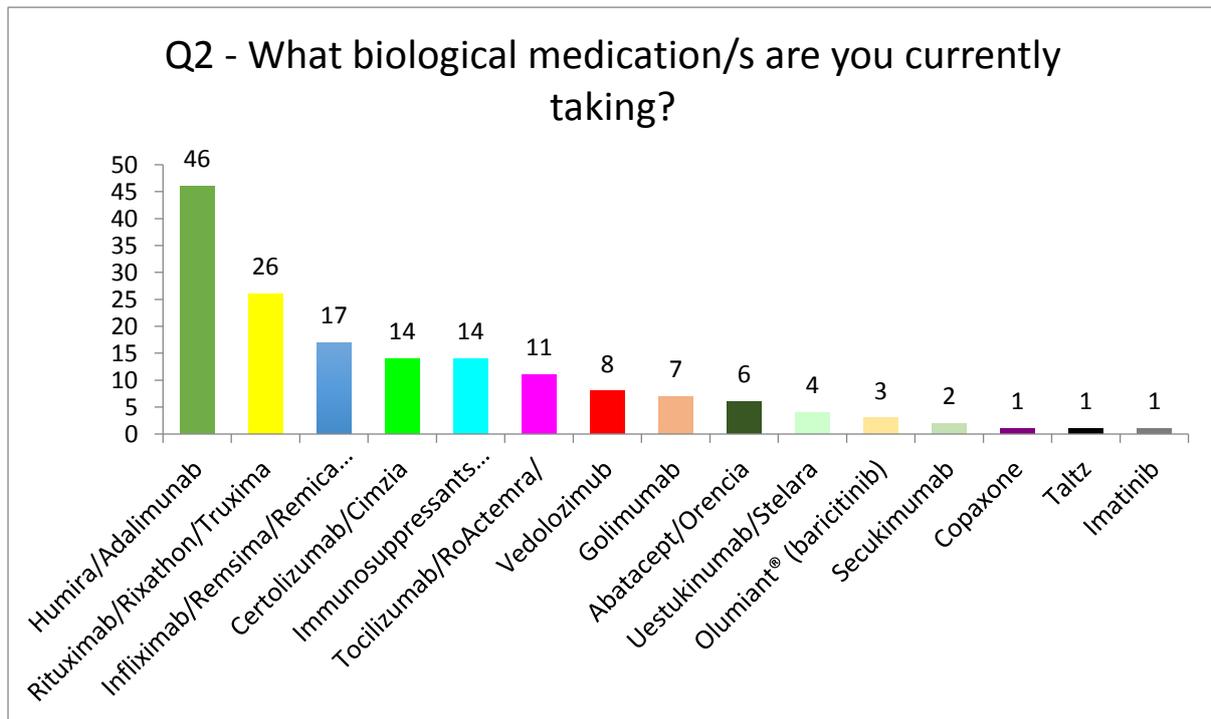
Of the 262 respondents who took part in the survey 69 people (27%) had already been changed to a biosimilar medication. This was useful as it allowed for people's experiences of the change to be reviewed. NHS England<sup>14</sup> suggest that any decision to move to a biosimilar medicine should always be made firstly on the basis of clinical judgement for individual patients and secondly on the basis of the overall value proposition offered by individual medicines, and that strong safeguards are required to ensure that patients who have responded well to existing medicine and who are then switched are closely monitored to ensure efficacy and safety. Additionally, The King's Fund<sup>15</sup> suggest that supporting patients with good information, involving them in discussions about their care and monitoring and supporting patients through periods of change promotes better mental and physical health outcomes and compliance with care.

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<sup>14</sup> NHSE Commissioning framework for biologic medicines (including Biosimilar medicines) Sept 2017

<sup>15</sup> King's Fund - How to deliver high-quality, patient-centred, cost-effective care, consensus solutions from the voluntary sector Sept 2010

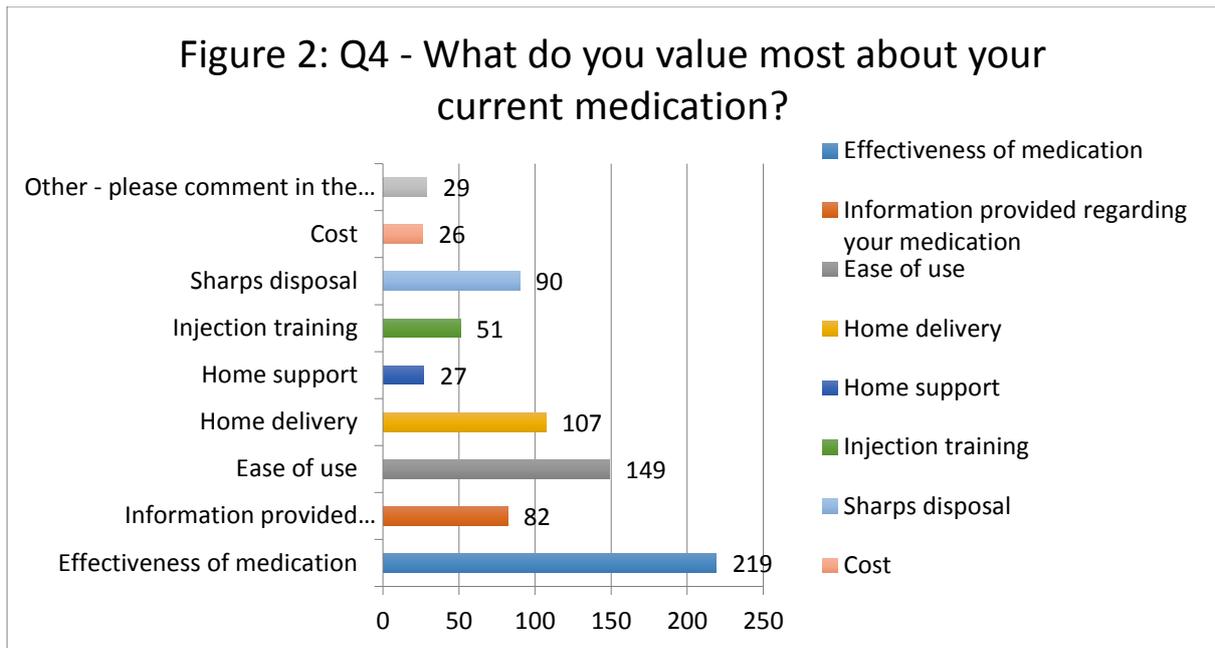
**Figure 1: What biologic medications are you currently taking? (Q2)**



**Figure 2: What do you value most about your medicines?**

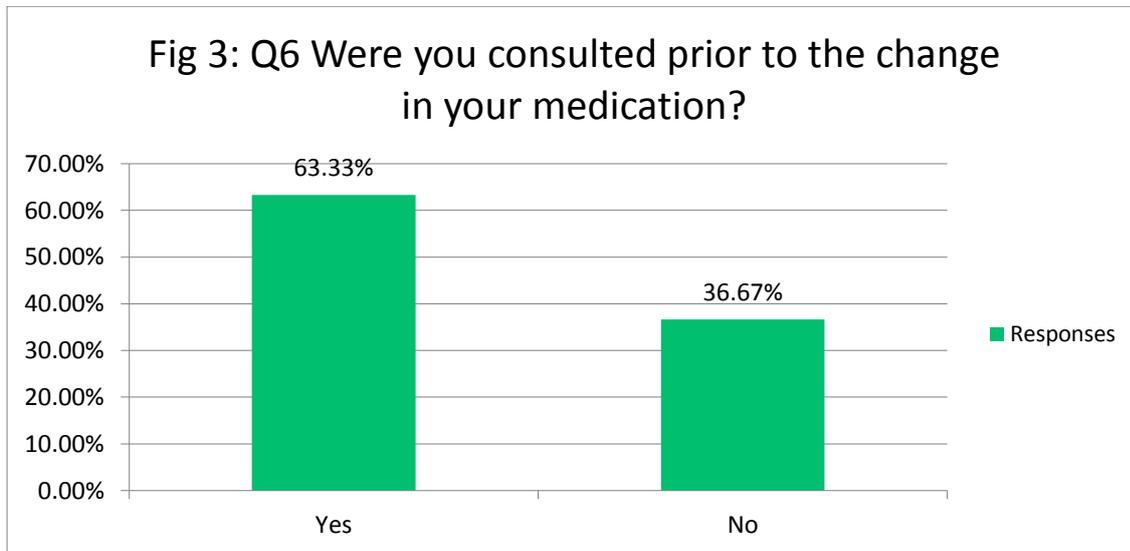
The overwhelming factor at 85% was effectiveness, followed by ease of use (58%), home delivery (41%), sharps disposal (35%) and the information provided with the medication (32%). Home support, training and cost were also mentioned.

Feedback from the focus group suggested that ease of use of an injectable device was a considerable issue for some people where normal hand strength or function was limited by their condition and that not all devices operated in the same way.



Questions six to eleven of the survey were for respondents who had already been changed to a biosimilar preparation.

**Figure 3: Were you consulted prior to the change in your medication? (Q6)**



Although 63% of respondents had been consulted in some form prior to changing their medications, 37% had not been consulted with despite the fact that this is requirement in the NHS England guidelines<sup>16</sup>.

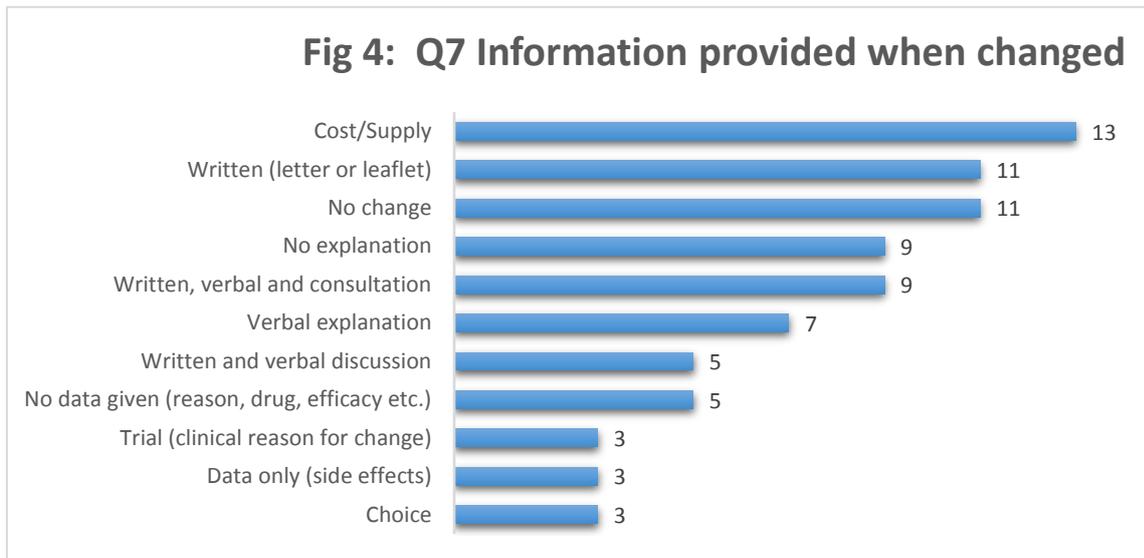
Comments below were the reasons given to patients for changing their medication.

- 11% (n= 9) reported that they had been written to and that this had been followed up by verbal information and then a consultation regarding their change.

<sup>16</sup> <https://www.england.nhs.uk/wp-content/uploads/2015/09/Biosimilar-guide.pdf>

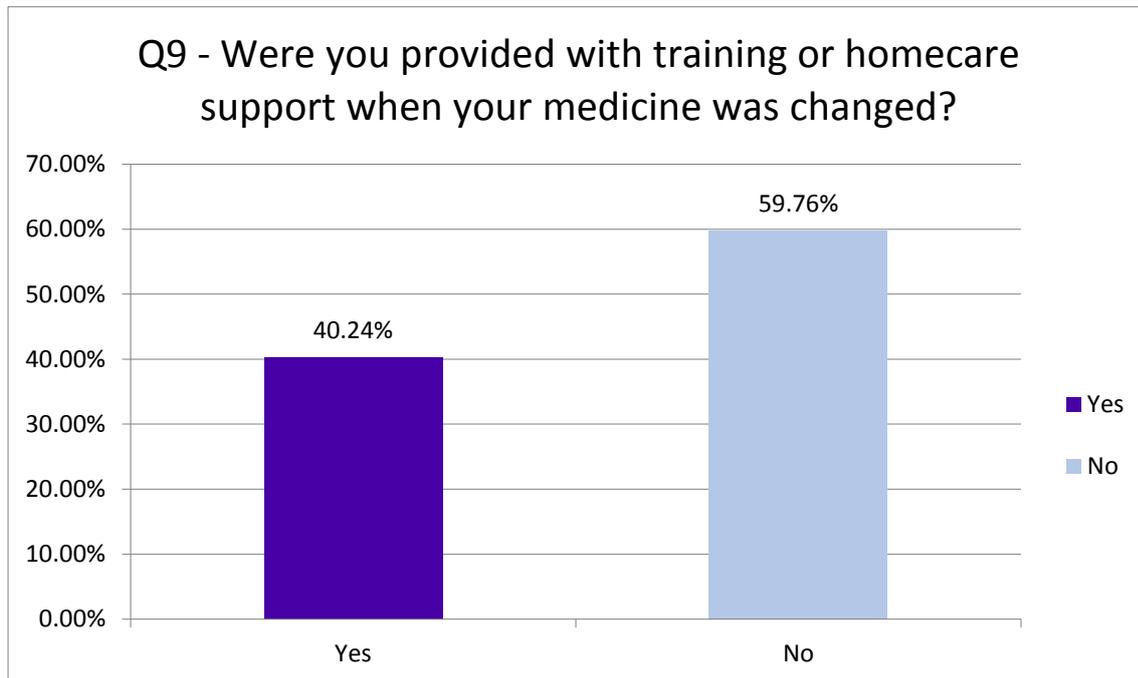
- 16% (n= 13) were told that the reason for changing their medication was to save money or because the current treatment could no longer be supplied.
- The information given to support this decision was also described as very variable and only 4% (n= 3) reported a clinical reason for the change.
- A written notification or a leaflet explaining their change in medication was given to 14% (n= 11)
- 11% (n= 9) of respondents were given no explanation at all.

**Figure 4: What was the information you were given when changing medication?**



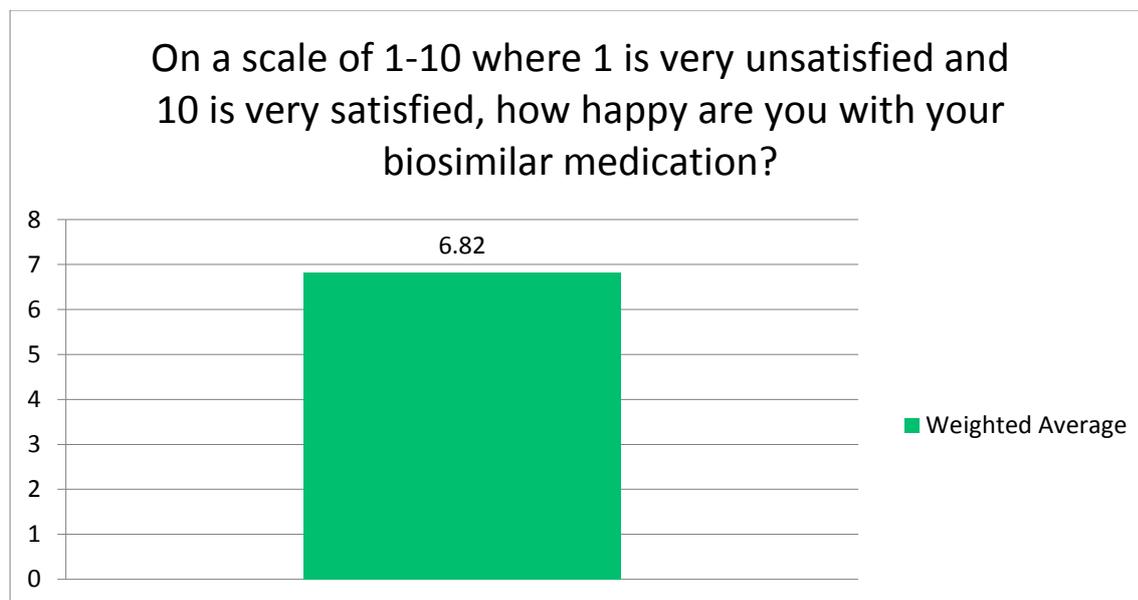
Question 9 asked what training or home care support was provided with the new medication with results shown in Figure 6. 60% (49) of respondents reported that they had been switched with no training or homecare support.

**Figure 5: Were you provided with training or homecare support? (Q9)**



When asked if respondents were happy with the biosimilar they were currently using there was a fairly even spread across the Likert Scale from dissatisfied (Score 1) to very satisfied (Score 10). Figure 6 shows a weighted average of 6.8 out of 10.

**Figure 6: How satisfied were you with your biosimilar medication?**



Questions ten and eleven asked respondents if they had any concerns or if they were pleased with particular aspects of their new biosimilar medication. Once again responses were mixed.

Some respondents reported variously that:

- *The new medication was more difficult to administer*
- *I had discomfort or a rash when injecting*
- *My new medication wasn't as effective as I had hoped*
- *I would have liked more information*
- *Support wasn't available even when I had side effects and poor health.*

However, on a positive note some people reported that:

- *The injection device was easier to use*
- *Using an injection device rather than a pen was better*
- *I hadn't noticed any difference since changing*
- *I am feeling well*
- *The new medication had a very positive impact on my daily life.*

The remainder of the survey was for all respondents and questions 12-14 asked respondents to consider, if they were to be changed to a biosimilar, what concerns they would have and what would be helpful in terms of support and information.

## What information would be helpful? (Q12)

226 respondents answered question 12 regarding what information would be helpful if they were required to change their medication to a biosimilar. The answers were all free text with results themed as follows ranked in order of priority.

- *Reassurance that changing to a biosimilar will not result in any alteration to current levels of health and that if it did they could change back (a large plurality – 101 out of 226 – wanted this reassurance)<sup>17</sup>.*
- *What is the difference between biosimilar was and biological medications?*

People wanted information which answered this question, including what studies had taken place and what side effects there might be. People wanted leaflets of information that clearly told them what to expect, what their choices were and where they could go for help.

- *Discussion and a follow up consultation with my consultant or specialist team.*
- *Cost of medication-* only 10 people cited cost as a required piece of information.

Respondents who indicated they would like further support specified that this should take the form of regular monitoring from doctors, nurses and specialist teams, with regular check-ups to ensure their medication was working and to deal with any issues.

Several people mentioned the services they currently have for home delivery, the devices they use and disposal of used products which they wanted to remain the same.

There were concerns regarding change, especially where people had a tough journey to get to their present levels of health or if they experienced side effects particularly if they lived alone with no one to monitor or offer support if needed.

Question 14 asked what concerns people would have if required to change to a biosimilar?

The following represent the top three themes from qualitative comments:

- *Effectiveness*
- *Side effects*
- *Worries, being scared or concerned about safety, risk and reactions to medication.*

Of the 231 who responded 45% were concerned that the replacement drug would be less effective or cause side effects. Although 11 respondents stated that they had no concerns, the majority of respondents were apprehensive about the safety and risk aspect of any new treatment and also very concerned that a replacement drug would not work as well and they would become ill again and that worried them deeply.

Conditions requiring treatment with biologic or biosimilar medications are complex and potentially life changing, so support from organisations beyond the NHS, such as disease-specific charities, can be highly useful in assisting people to manage their health and gain the maximum benefits from their medicines. To explore this further, question

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15 of the survey asked what groups or charities people belonged to in support of their condition. The largest following was for the National Rheumatoid Arthritis Society (NRAS) and all results are in the list with numbers of respondents in brackets.

- NRAS (81)
- Arthritis Care (15)
- Crohn's & Colitis UK ( 25)
- Improving Thyroid Treatment (5)
- Health Unlocked (3)
- Facebook groups (6)
- Birdshot Uveitis Society (3).

#### Focus Group Findings

The following questions were used to establish a structure to the group's discussions.

#### Q1 - Ascertaining the level of knowledge in the room

Participants were asked what they considered to be a biosimilar medication<sup>18</sup>. There was a high level of knowledge in the room regarding what a biosimilar was but also much anxiety regarding the outcome of switching to a biosimilar treatment. Of the seven participants, four were on biologic preparations. One had been switched to a biosimilar but due to issues had been changed back to their original medication. The remaining two had been changed to a biosimilar. In terms of administration route, two were on intravenous infusions given monthly/six-monthly in a hospital setting and the remainder were on sub-cutaneous injections self-administered at home on various regimes.

#### Q2 - Had anyone been changed to a biosimilar?

This question was given additional prompts during the focus group with questions such as:

- What was your experience?"
- What was the process?
- What went well?
- What didn't go so well?
- Were you made aware of your rights?

Generally participants reported a very poor experience citing the following as reasons for discontent.

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<sup>18</sup> Reference as footnote 10 and definition used as on page 5

- *Lack of information.*
- *Lack of choice.*
- *Choice of biosimilar made because they had stock from a previous patient, then had issues getting stock and had to be changed again.*
- *Procedure for the choice of drug not in line with EU regulations.*
- *Not monitored at the time of change and left in a room with no means to call for assistance. Told to get out of bed with IV and seek help.*
- *Current supplier is only in EU – how will this be affected by Brexit going forward?*

Q3 - If your medicine was changed to a biosimilar

a) What would you want to know?

Additional prompt questions during the focus groups included:

- Reasons for the change
- what rights would you have?
- Details regarding the new medicine
- Support needs.

Feedback was mainly linked to concern regarding adverse reactions and the impact on health.

- *Can I change back?*
- *What would I do if it goes wrong? How would I get immediate help? Would I call 999 or seek emergency help? Would I ring my current condition helpline? Would I be able to see someone quickly?*
- *If I need to have medication by IV I would want to be surrounded by nurses and doctors. It is fearful to be left alone in case of adverse reaction*
- *I would want my family included and involved*
- *How similar would the biosimilar be? I would want detailed information, a data sheet of the new drug and details of all possible side effects*
- *Can I refuse to change?*
- *Can I agree to change with a promise that I can go back if I don't get on with the biosimilar?*
- *Will I receive the same level of home support that I receive now and will first dose be monitored, as it was when I initially started on current biologic?*
- *Would I receive assurance that there will be no change to my condition clinically as a result of the change?*
- *I would want clarity on the reason I am being asked to change*
- *What will the carrier of the biosimilar be as I had irritation before the biologic carrier was changed*
- *What are the risks and benefits?*

- *Total reassurance that the change won't affect me clinically*
- *Would need specialist advice on travel requirements – letter for plane, details re storage requirements during travel, how to get help/advice while away*
- *Would my current regime of treatment be changed?*
- *What time of day is best to take medication?*
- *How does medication need to be stored during transit and at patients home?*

b) Who will inform me and how will this be done<sup>19</sup>

Prompts during the focus group included:

- How will the process of change be arranged?
- Who will tell me?
- Will it be face to face so I can ask questions?
- What information will be given?
- Do I have a choice?

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<sup>19</sup> Appendix 2 – Summary of NHS Consent

### Patients' comments

*I would like consistency of clinician so the team around me stays the same, including my GP*

*Helpful to have advance notice by letter (possibly 2 months before) followed by a face to face consultation with specialist and then monitoring regarding the change-over*

*Chronic or long-term conditions require a different approach than acute. I would want to be told by my rheumatologist or specialist physician*

*I would like to know what choice I have and any alternatives*

*I would need reassurance **from someone I trust** that there would be no impact on my current quality of life*

*I would want the initial dose to be monitored with a link person known to me to provide support*

*Want to feel they I am being treated as an individual rather than part of a blanket change-over*

*I would need to feel safe and held in mind*

*If there was more than one option of biosimilar would want detailed information on each so I could make an informed choice*

*It would be helpful to have additional input and back-up from specialist groups such as NRAS, psoriasis etc. to support me and for staff with limited knowledge of biologic and biosimilar medication*

c) When is it likely to be?

Prompts included:

- How much time will I get to decide?
- When will the process begin?
- Why is this happening now?
- What considerations should there be?
  - *Can I choose when the exchange takes place?*
  - *The time of year is important as I don't want to change medications around significant times such as Christmas.*
  - *Also I would like staff to take account of individual circumstances such as birthdays, special events etc.*

- *Would need to avoid holiday periods as there are less staff available on bank holidays and weekends to monitor and provide support*
- *Also seasons have an impact on health – symptoms of illness are worse when it is cold and wet or hot and humid; Infection susceptibility higher in Winter; symptoms such as headaches and ear pressure are worse in Summer*
- *Helpful to consider changing people in cohorts with a dedicated team to learn from findings to apply to next cohort and so on.*

The group collaboratively felt that the following considerations regarding the timing of any notification would be reasonable or acceptable:

- *Letter approximately eight weeks prior to a 1:1 consultation*
- *To have the option to co-decide on a bespoke timeline for the individual*
- *The process of change will be very overwhelming so it would be better if it was done in stages with the full support of specialist organisations.*

d) What support would you expect to receive?

Prompts included:

- What is required for those on intravenous hospital biologics and those self-injecting via a pen or injection device at home?
- Newly diagnosed and existing patients?
- What would be needed in terms of written support and would a face to face consultation be needed?
- Person to person/written support?
  - *Should be consultant led with GP oversight*
  - *Participants differed in their views regarding the involvement and ability of their GP. It was generally felt to be helpful if the GP was fully informed as they were their local and immediate source of clinical support*
  - *Both the patient and GP should receive copies of all letters and test results*
  - *Information should be easy to understand with no jargon*
  - *Important that there should be an equal relationship between the patient and clinician*
  - *All participants felt that it was important for safety and continuity of care that there was a process for a multi-disciplinary review of their care at least annually to include the patients GP and all the consultants and teams for each of their conditions. This should produce an annual care plan, which could be reviewed annually as well as monitored at each appointment and updated.*
  - *Treated with KINDNESS – participants felt that this was essential as their conditions resulted in both physical and emotional trauma*
  - *For those on IV infusion*
  - *Number to ring from home after treatment if experience any problems*

- *Monitored closely for first dose*
- *Individual approach for each*
- *How would I know that things are not right or if I have cause to be concerned?*

For those on injections at home

- *What to expect*
- *When should I be worried*
- *24hr Helpline with rapid response option if required.*

e) What aftercare and training would you expect?

Prompts included:

- What do you receive now?
- What would be helpful?
- What is lacking in current arrangements or what works well?
  - The provision of detailed information following initial doses such as: don't drive; don't plan anything for following day etc.
  - For the nurse to administer first dose
  - An information pack to be provided for new medication
  - Perhaps an online resource, video or chat link for asking questions or obtaining more information.
  - A follow up appointment provided to see how patient is doing and to discuss any issues.

### **Patient Quotes**

*It has been a long journey to get to good*

*Feels like going back into the wilderness*

*Being well and able to do normal things with my family and go to work is priceless*

*The drug gives you back your life.*

*The illness robs you of control over your life. You then get control back with biologic. Now feels like losing control again.*

*It is very lonely and isolating having these types of conditions and having to self-administer at home*

*Having to change from tablets to giving oneself an injection is already a huge psychological shift. Now having to change again is very hard*

*Being made to feel guilty about being on an expensive drug adds to the burden already placed upon them by their illness*

*No two people are the same because of the way the drug responds to each individual. The damage the illness has already done and how it started. Other co-morbidities play a huge part and how long it took them to stabilise their condition. All this means their reactions to the new drug cannot be truly estimated.*

*The lack of information, poor information and limited reassurance concerning biosimilar causes high levels of anxiety especially as finding the right drug in the first place takes time. Patients have already been through a considerable amount to get on the correct medication for their condition.*

## 6. Conclusion

The findings from the survey and focus groups raise clear concerns about patients' experiences of being switched onto biosimilar medicines from their existing biologics. Shared decision-making appears not to be a reality for many patients, and many people also find they do not have the support they should receive to understand any changes, or to monitor and manage side effects or other adverse consequences.

Many people described their journey to their current levels of health as being tortuous with a high level of anxiety about being changed to a biosimilar medication. Concerns were expressed about impact on health and whether this would have serious repercussions in their ability to work and to lead a normal life.

Patients requiring biologic medications are often in complex situations which are unique to them and therefore it was felt there is no 'one size fits all' solution. There was very little information accompanying the change to a biosimilar medication and therefore the possible adverse consequences were unknown by many of the participants.

The lack of choice about being changed to a biosimilar was frequently mentioned. Patients are not clear about whether, if a new preparation does not suit them, they would be able to change back to their previous medication. It would be helpful to have a leaflet and information pack to support any change and explain what should happen if this situation arises in order to allay any fears. People also wanted reassurance that any existing support systems will remain if they change medication and that any new devices will be easy to use.

Patients said they would like to receive written information followed by discussion and monitoring by their consultant or specialist teams and that any change should happen collaboratively.

It was noticeable that despite the enormous amount of knowledge held by patients there was still a lot of uncertainty about the impact of changing to a biosimilar. The following questions raised by patients were the most imperative:

- What could the impact be on my condition if required to change medication?
- Would there be known and unknown side effects?
- Could I become ill again?
- Would I be able to get help?
- What contingency plans or business continuity plans are in place if a batch of medication was faulty or if there was a lapse in supply?
- What would the impact of Brexit be?

From the concerns raised and the suggestions about need for better information, shared decision making and collaborative working between patients and clinicians it

would seem helpful to co-produce a set of tools to assist patients in the journey they describe. The aim would be to better inform and empower patients to take control of their situation and be more equal partners in their treatment plan and choice of medication.

## 7. Appendices

### Appendix 1: Copy of Biologic to Biosimilar Survey

#### Introduction

The Patients Association is the only independent support organisation for all users of UK health and social care services. Our mission is to harness the patient voice, to improve services and support people to engage fully in their own care.

Each year we facilitate and manage a number of national and local projects, reports and training events in order to gain patient feedback on all aspects of patient experience.

As you are no doubt aware the NHS is currently looking to the future to see how it can best deliver services that are safe and of high quality that take account of new advances in medicine but also take account of budgetary restraints. Part of this process will be to review costs of treatment and compare with alternatives that may provide the same effect at a lesser cost. However, it is important that any changes to any treatment are discussed with patients and the benefits and disadvantages clearly considered.

Medications are one of the areas where changes may be made to provide the same level of treatment but at a reduced cost. For instance when you go to the chemist for over the counter medication you will have a variety of options with a variety of costs for the same treatment. NHS England has outlined some Good Practice Principles to ensure that any changes in patient medication will be communicated and managed correctly. The Patients Association want reassurance that these good practice guidelines are being adhered to and patients are well informed and fully involved in shared decision making about the best treatment for their specific condition.

You have been invited to take part in this survey because you require a biologic medication for treatment of a specific medical condition. Your participation will enable the Patients Association to better understand the needs of patients on these types of medications and the issues surrounding changes to medication, involvement in shared decision-making and any educational needs.

Participation in this survey is entirely voluntary and all responses are strictly confidential. There is no requirement for you to provide any personal information unless you are interested in being involved in a focus group taking place in Birmingham in the next few months. Participation in the focus group is also entirely voluntary but would require you to be resident in or close to Birmingham or able to travel there easily.

**Please submit your responses by Friday 31<sup>st</sup> August 2018.** The information you provide in this survey will only be used in accordance with the permissions you give us below. You can view our privacy policy on our website: <https://www.patients-association.org.uk/privacy-policy>. "

If you have any questions at all regarding the survey please do not hesitate to contact the Patients Association helpline on 020 8423 8999

1. What condition(s) has your doctor recommended that you take a Biologic medication for?
  - a. Rheumatoid Arthritis
  - b. Psoriasis
  - c. Crohn's Disease
  - d. Ankylosing Spondylitis
  - e. Ulcerative Colitis
  - f. Psoriatic arthritis
  - g. Other - please specify in box below
2. How long have you been on this medication?
3. What do you value most about your current medication?

Please tick all that apply

  - a. Effectiveness of medication
  - b. Information provided regarding your medication
  - c. Ease of use
  - d. Home delivery
  - e. Home support
  - f. Injection training
  - g. Sharps disposal
  - h. Cost
  - i. Other - please comment in the box below
4. Have you recently **been changed to a biosimilar**<sup>20</sup> medication?
  - a. Yes – **if yes** please answer questions 5 - 11 below
  - b. No – **if no** please go to question 12 and ignore questions 5-11
5. Were you consulted prior to the change in your medication?
  - a. Yes
  - b. No

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<sup>20</sup> A biosimilar is a biologic medicine highly similar to another already approved biologic medicine

biosimilars are approved according to the same standards of pharmaceutical quality, safety and efficacy that apply to all biologic medicines



## Appendix 2: NHS Commissioning Support Group Toolkit

Minimum Standards for Patient Involvement in Decision Making:

- Introduction to biosimilars – definition
- Development, licensing/ approval process and comparability
- Basic details of the drug and planned switching programme, any potential changes to homecare provider or services, where relevant
- Clinical monitoring that will be provided.
- Supportive statements from the speciality and regulatory bodies and relevant patient groups.
- Savings will support the treatment of an increasing number of patients and the uptake of new and innovative medicines within the NHS.
- FAQs giving details of the new medicine and any changes to homecare supplier, if applicable.
- Include contact details or a patient helpline number direct to clinicians for patients to ask further questions.
- Details of any patient engagement events

### Key points for Patient Engagement

Patient engagement can be approached through a variety of means:

- Biosimilar information sessions with consultants, specialist nurses, pharmacists and administrative staff.
- Trust Patient Forum: Engage with the Trust's patient forum or Patient Advice and Liaison Service (PALS). Consider a meeting led by a senior clinician, consultant nurse specialist or senior pharmacist in consultation with Patient Forum or PALS.
- Engaging with patient groups, such as the local branches of the National Rheumatoid Arthritis Society, to ensure consistent and positive messages are being passed to patients, and ensure they are prepared for any patient queries.
- Patient group helplines and websites for each of the **four main disease areas**<sup>21</sup> are able to offer information, advice and support to patients and carers and this information should be provided to patients.
- Face to face sessions: sessions with patients should be held where required to inform or address concerns. Listen to the patient for areas of concern, knowledge gaps and address any queries in the meeting; checking for suitability of information and the impact of responses on patient confidence.
  - Utilise the Medicines Value Programme Template Patient Letter and FAQs.

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<sup>21</sup> Crohn's & Colitis UK; National Ankylosing Spondylitis Society; National Rheumatoid Arthritis Society; Psoriasis Association

- Medicine information helplines should be used to facilitate patient education and engagement, and address any patient concerns re the switch

Summary of reference sources regarding NHS Principles on patient involvement and consent

1 - NHS Constitution

2 - NHS Scotland. The Charter of Patient rights and responsibilities. 2012

3 - NHS Wales Guide to Consent for Examination or Treatment. July 2017

4 - Consent – What you have a right to expect. DOH 2003

5 - Consent: patients and doctors making decisions together. GMC 2008

6 - Principles of Consent. RCN 2017

- Seeking consent is part of joint decision making (3,5)
- Patients will be involved and consulted on all decisions about their care and treatment – also called ‘shared’ or ‘joint’ decision making (1,2,5)
- Patients have the right to ask for more information (4)
- Patients have the right to accept or refuse treatment offered (1,4,5,6)
- Decisions should take be based on the patient’s values and preferences and the health professional’s clinical know how (3,5)
- Giving and obtaining consent is usually a process, rather than a one-off event (3)
- Patients must be kept informed about the progress of their treatment, and are able to make decisions at all stages, not just in the initial stage (5,6)
- Patients must be made aware of any material risks involved in a recommended treatment, and of any reasonable alternative or variant (3)