Living with RA

Biosimilars

What they are and what you need to know

Is there a difference between

BIOLOGICS & BIOSIMILAR

What are they and what do I need to know as a patient on biologics or as someone who may be going to start on a biologic at some point?

Many of you will recall an article we published on biosimilars in our Spring 2015 magazine. (You can find this article and more on our website about biosimilars www.nras.org.uk/biosimilars). In that article, we discussed two new biosimilar drugs, Remsima and Inflectra, which were introduced to the UK market in early 2015 as alternative options for infliximab (Remicade) Anti-TNF infusion. As relatively few people are on infliximab infusion therapy for RA by comparison to subcutaneously given biologic options, the arrival of Remsima and Inflectra didn’t have a huge impact on the treatment of RA that was particularly visible to people with RA, although in the field of autoimmune gastro diseases (such as Crohn’s and Colitis), where larger numbers of people use infliximab as the biologic of choice, there was more ‘noise’. We are now a year down the line and a larger number of people with RA as well as Crohn’s who were on infliximab have been switched to either Remsima or Inflectra without any significant difference being reported.

Since then, another new biosimilar for etanercept (Enbrel) has become available recently in the UK called Benepali which we believe will change the dynamics of the market in regard to RA as Etanercept is much more commonly used than infliximab. More biosimilars for etanercept will be coming to the UK market in the coming months.

Many more biosimilars will enter the UK market over the coming months.

Benepali has been granted marketing authorisation in the European Union (EU) for the treatment of adults with moderate to severe rheumatoid arthritis, psoriatic arthritis, non-radiographic spondyloarthritis and plaque psoriasis. Benepali is the first etanercept biosimilar referencing Enbrel to be approved in the EU, making it the first subcutaneous anti-TNF available here. Anti-TNFs are the largest component of the EU biologics market, accounting for some $10 billion of all biologics sold there.

If you are not familiar with the term ‘biosimilar’, how they compare to original biologics and how/why these are being introduced into the UK you can read more on the NRAS website www.nras.org.uk/biosimilars

By Ailsa Bosworth, MBE
CEO of NRAS
If you are currently on etanercept (Enbrel), you may find yourself in receipt of a letter advising that you are being switched to Benepali biosimilar.

Many more biosimilars will enter the UK market over the coming months and years as more original biologic drugs come off patent. So, it’s important that all people with RA, but particularly those currently on an original biologic drug, understand what is happening in regard to switching and how they personally may be affected either now, soon or at some point in the future.

What is driving the switching?

Well, quite simply money. The biosimilars may be anything between 20–40% cheaper than originator products and this represents potentially large savings to Clinical Commissioning Groups/Health Boards and NHS Trusts in regard to overall spend on biologics (bear in mind they are used in RA, Psoriatic Arthritis, Ankylosing Spondylitis, Inflammatory Bowel Disease etc.) With so many Trusts across the UK finding themselves in deficit and with increasing demand on NHS services, any ways to reduce costs are being grasped at as Finance Directors struggle to come in on budget.

What might this mean to me as an RA patient?

At some point, and particularly if you are currently on etanercept (Enbrel), you may find yourself in receipt of a letter from your Trust (or other form of communication) advising you that you are being switched to Benepali biosimilar. This happened recently to some of our members in the South West and they got in touch with us as they had concerns about what they were being told and were worried about what this might mean for them.

Are biosimilars as safe and effective as the original biologics they are replacing?

Generally this is the question which people want to have an answer to first, especially if they are doing well on their existing biologic treatment. When compared to their original biologics, all three biosimilars have demonstrated similar therapeutic efficacy and occurrence of drug-related events (side effects), they are well tolerated, and have a comparable record of safety. However, owing to the complexity of these drugs and their relative newness, NRAS still believe that ongoing safety monitoring is vital and long term safety data should be collected via the British Society for Rheumatology Biologics Registers in Manchester. We have said this all along and it is a recommendation in our revised ‘position’ paper.

Some of the specific questions raised by members who have been notified that they are being switched are:

- How long has Benepali been on the market?
- What is the safety and effectiveness record of this drug?

- Would this biosimilar be monitored by the BSR Biologics Register or a National Register set up for biosimilars or would it be left to the individual clinicians to collect data and thus could end up with no information sharing?
- This change is obviously a cost saving exercise for my Trust. However, if problems arise with the use of Benepali, would the funds be there for patients to revert onto Enbrel?
- Although biosimilars are approved by the European Medicines Agency- are they approved by NICE?
- What research findings are available to me as the patient on this drug?
- To ensure safety, will Benepali be prescribed by brand name only so there is no confusion for the patient?
- Who does the patient contact if they are unhappy with the said drug – in other words what is the complaints procedure if there is one in place?

We can help to clarify some of the information requested in the above questions. Our article has already addressed the first 3 bullet points. Clearly what happens if the patient experiences side effects following switching, which they hadn’t experienced on the original drug, would be determined by the particular rheumatology team and their biologics pathway, and the first step for the patient would be to contact their rheumatology nurse specialist for advice.

NICE have made it clear that they will not be carrying out Single Technology Appraisals of individual biosimilars as they come onto the market following EMA approval. Their position can be seen here (www.nice.org.uk/news/article/evaluating-biosimilar-medicines). They have made it clear that a decision regarding the choice of biosimilar or originator biologic for an individual patient rests with the responsible clinician in consultation with the patient. The specific clinical trial data relating to clinical trials of a particular biosimilar can be found by entering an appropriate search request into Google or other search engines.

All stakeholders, including the Association of British Pharmaceutical Industry (ABPI) and the British Society for Rheumatology (BSR) have made it clear that all biosimilar medicines MUST be prescribed by their brand name to ensure that prescribing pharmacists, clinicians and patients alike can be assured that they are getting the correct drug. This is one of the recommendations in our ‘position’ paper too.

NRAS revise their ‘Position Paper’ on biosimilars

Since developing our original position paper back in the summer of 2014, we have revised some of our views in the light of the experience of the actual
introduction of biosimilars and the fact that the safety and effectiveness data being reported from across Europe and the rest of the world is pretty much the same as for the original biologic products. Furthermore, the designation of a biologic drug as a "biosimilar" by a regulatory authority demands that extremely rigorous quality controls are met with respect to characterisation of the biosimilar in relation to the originator drug. This can give us a great deal of confidence as patients. These quality controls for the biosimilars are much more stringent than were required for originators back in the early days of biologic DMARDs. We also have to adapt to the reality of what is actually going on in the NHS and the need to make savings where this is possible, feasible and the responsible thing to do, provided that quality and safety of care are prioritised and rheumatology benefits from some of the funds saved.

What specifically has NRAS revised?

In particular we have revised our recommendation "that no-one who is stable on an original biologic product should be switched purely on grounds of cost alone." We have changed our view on this because the safety and efficacy data is comparable to the original products and we would want to see the savings generated by using cheaper biosimilars reinvested to improve patient care and outcomes for people with RA and other forms of inflammatory arthritis. The NRAS revised position paper can be read on our website www.nras.org.uk/biosimilars

We have three very clear recommendations to make and we would like to work with other stakeholders to create a best practice 'national' switching policy which ensures that patients are properly advised and informed about switching in a way which prioritises proper care planning, shared decision making and does not leave patients anxious and with a string of questions like those listed. Unless we take such an approach there is a danger that these issues will be addressed differently in different trusts and parts of the country, leaving patients confused about what should be happening to them.

We think the following issues need to be addressed at a national level:

- Patients must be properly informed through robust shared decision making mechanisms about being switched – a template letter from the Trust sent to all patients simply telling an individual they are being switched, with inadequate information is not satisfactory or appropriate. The whole team needs to adopt a shared approach to this issue.
- The manufacturers must agree to long term safety data collection through the BSR Biologics Registers
- Gain share from the savings must benefit the rheumatology service and patient outcomes in an equitable way (i.e. any savings from switching patients should not all go to the Commissioners/Health Board or Hospital Trust for use in a completely different therapeutic area or simply to reduce deficits)

We hope that this article will go some way to help explain what is happening in relation to the adoption of biosimilar medicines for the treatment of RA in the UK as more of these drugs become available. It seems likely that some Trusts will be quicker to adopt switching than others and that there will be differences between the way in which these drugs start to be prescribed as mentioned above, which is why we would like to see best practice established quickly to prevent people being alarmed at suddenly being advised of a change in their medication which comes 'out of the blue'.

For more information, please visit our website: www.nras.org.uk/biosimilars

Biosimilars, the biologics register and you.

As patents begin to expire on some biologic therapies you may be taking for your rheumatoid arthritis, new drugs will come to the market based on the existing drug. Your local trust may elect to change your medication to the new biosimilar drug, all of which are fully approved by the European Medicines Agency.

The biologics register is extremely keen to recruit patients who are taking biosimilar medication. If you are receiving the Inflectra or Remsima biosimilars of infliximab or the Benepe biosimilar of etanercept you can contact your rheumatology specialist nurse and ask to be recruited to the biologics register. Alternatively, if you are already on the biologics register you can contact us directly by telephone on 0161 275 7390 or 0161 275 1652 or by email at neil.wall@manchester.ac.uk.

Your contribution to the register is important in helping with treatment for rheumatoid arthritis and helping to ensure the long term effects and safety of biologic treatment.

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