

The Introduction of Biosimilars – Uncharted Waters?

Report from a Stakeholder Event

Held on

Wednesday April 9th 2014

Royal College of Physicians, London



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National Rheumatoid
Arthritis Society

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Organised by:

The National Rheumatoid Arthritis Society
The National Ankylosing Spondylitis Society
The Psoriasis Association
Crohn's & Colitis UK

Executive Summary

The overwhelming contribution that biologics have made to transforming the lives of patients with serious, long-term illness was acknowledged and the UK experience with recombinant biological products may reassure participants over the use of 'similar' products. However, whilst participants have a reasonable understanding of biosimilar medicines and their impact on the UK market, greater knowledge and reassurance is needed regarding their broader use, nomenclature, the monitoring of their safety, how they will be priced, and how they will be prescribed and to whom.

There is a clear need for events involving all stakeholders. The knowledge base for biosimilar medicines amongst participants at the start of the meeting was limited. Apart from some acknowledged experts (19%), the majority either knew a little (54%) or knew only what they had read in preparation for this meeting (19%). By the end of the meeting, knowledge had increased in almost three-quarters of participants (73%) and 22% felt that their knowledge had been confirmed or endorsed.

Knowledge of biosimilar medicines should not preclude attendance at such events. Acknowledged experts cited their motivation to attend was because seeking greater awareness of the issues and concerns amongst other stakeholders was important to them. Conversely, patient organisations were keen to know more about the decisions being made by these experts and what information they can communicate to patients.

The only currently approved biosimilar medicine for rheumatoid arthritis in the UK (infliximab biosimilar) has been filed under two separate names with EMEA (Remsima and Inflectra) and will be introduced to the UK in 2015. It has demonstrated similar therapeutic efficacy and incidence of drug-related events, is well tolerated and has a comparable safety and tolerability when compared to the innovator

product, infliximab. However, there are potential safety concerns which need to be closely monitored. Whilst mechanisms are slotting into place to safeguard patient safety and maintain effectiveness of existing therapies, there is a possibility that draconian regulatory processes, the complexity and cost of development as well as pricing issues, could discourage the investment of even the most experienced of pharmaceutical companies.

Pharmacovigilance is a key concern, especially around differentiation of true biosimilar medicines that have been approved on the basis of an abbreviated development programme, from some of the intended copy biologic medicines already available in some markets that have not been approved at all.

The role of cost is also a concern. Availability of lower-priced biosimilar medicines is perceived to be changing the landscape of biologics in the pharmaceutical industry, and while this may increase pressure to prescribe the newer alternatives, eligibility criteria for treatment may remain unchanged and the hope of wider access to treatment for patients may remain unfulfilled. Concerns were raised about the cost of prescribing and the pressure to curtail drug expenditure with the use of cheaper biosimilar medicines without the necessary guidance in place regarding use of brand names.

Views regarding the impact of biosimilars are mixed. Only one in four participants believed that biosimilar medicine would drastically improve patient treatment options and only 8% thought that switching patients from a biological medicine to a biosimilar medicine would make no difference to the individual patient. Attitudes towards appraisals and approval by NICE were also mixed: 38% agreed that biosimilar medicines should be subject to the same process as biological medicines; 35% disagreed; and 27% remained unsure.

Participant views and concerns around the introduction of biosimilar medicines



Where do we go from here?

The stakeholder meeting clearly showed that more studies, more focus on pharmacovigilance and more guidance are needed to aid understanding of the impact of biosimilar medicines:

- Further meetings are needed to share progress and knowledge from a regulatory and clinical guidance perspective as well as maintain the dialogue amongst all stakeholders regarding potential issues.
- Clear, comprehensive and consistent information for use by patient organisations, starting with basics of terminology through to controls over prescribing and the monitoring of safety is necessary.
- Clear guidance for prescribers regarding nomenclature, prescribing, patient traceability and pharmacovigilance is vital.
- Mandatory inclusion in observational registries which have the capacity to accurately capture switching of therapies, monitor adverse events and compare outcomes of biosimilar medicines with biological medicines on a long-term basis is essential.

Background

Biological medicines have revolutionised the treatment of many immune-mediated inflammatory diseases (IMIDs). However, the escalating burden of chronic disease amid cost constraints means that not all patients have access to them. Biosimilar medicines have the potential to increase availability of effective treatment on a global basis, but with that opportunity comes a large degree of uncertainty, creating a vast expanse of uncharted territory for all involved. The stakeholder meeting, hosted by the National Rheumatoid Arthritis Society, took the important first step in gathering views and concerns around this important development. Presentations from representatives of industry, academic research, the British Rheumatology Society for Rheumatology Biologics Registry and regulatory bodies set out to explode some of the myths,

identify common themes and isolate areas of uncertainty that need further clarification. This report summarises the main topics covered and questions raised. It represents a first attempt to scan the landscape and identify a navigable path that will ensure that the patients with immune mediated inflammatory diseases, and indeed the wider public, are correctly informed about these new therapies.

Introduction

Ailsa Bosworth, Founder and Chief Executive of the National Rheumatoid Arthritis Society (NRAS), began the meeting by reminding everyone of the uncertainty and caution that accompanied the introduction of anti-tissue necrosis factor (TNF) medication for rheumatoid arthritis (RA) in 2000. Since then, thousands of patients with inflammatory diseases have benefited. She highlighted how the British Society for Rheumatology (BSR) Biologics Register, established a year later has greatly contributed to increasing the understanding of how these and other products work and helped

to allay the early fears about the possibility of increased cancer risk. Now, the same hesitation surrounds the introduction of biosimilar medicines. How can something be similar but still work as effectively and safely? What is the difference between it and the original biological therapy? These are just some of the questions being asked about biosimilar medicines and ones that NRAS would like to see answered in order to ensure that all concerned are correctly informed going forward.

Presentations

Biologics and Biosimilars – ‘Spot the Difference’

Professor Peter Taylor, the Norman Collisson Professor of Musculoskeletal Sciences at the University of Oxford, began by exploding the myths regarding the lack of experience with biosimilar medicines, arguing that the journey began 40 years ago with work on mouse monoclonal antibodies (see Figure 1).

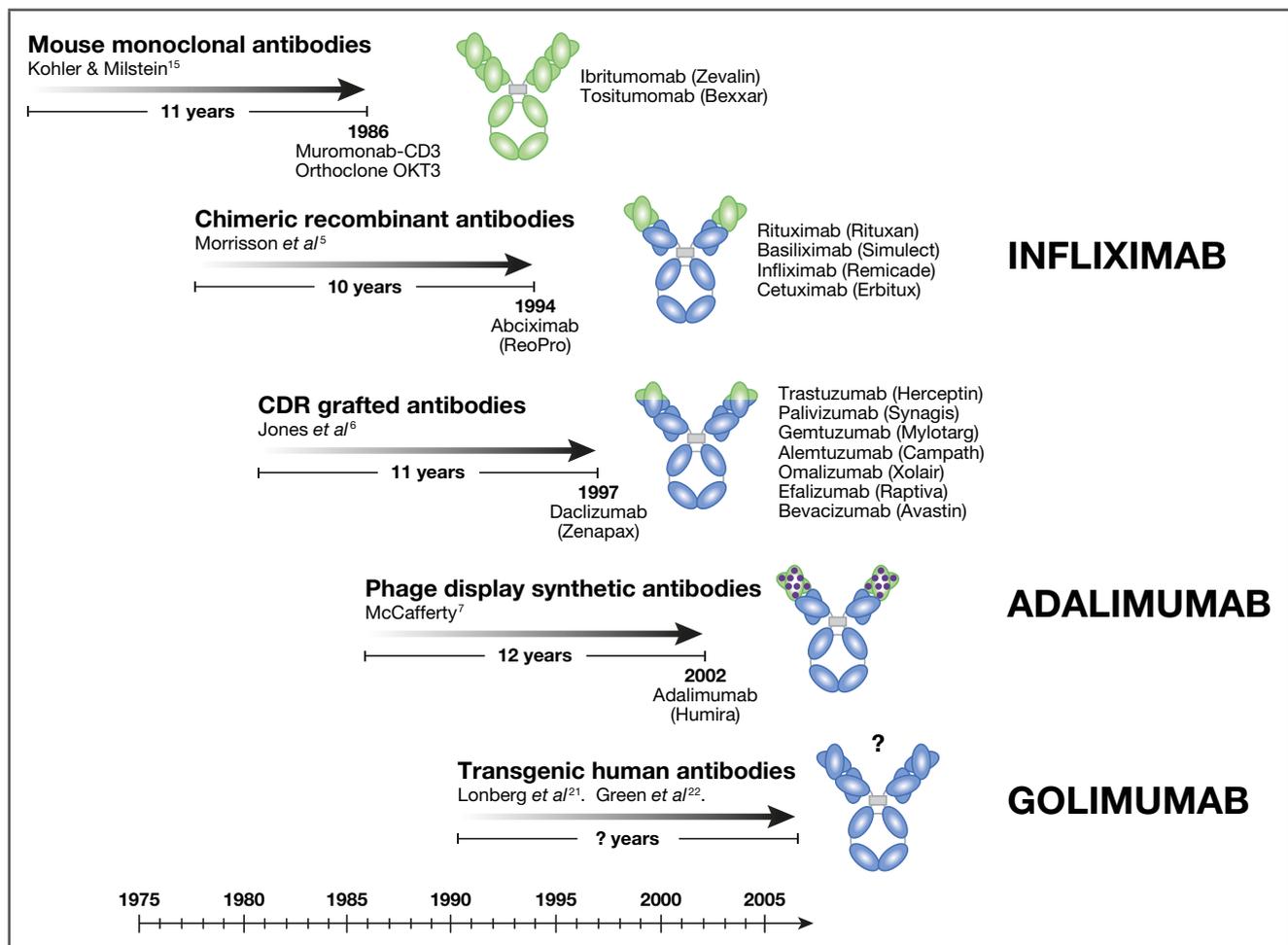


Figure 1: Evolution of monoclonal antibodies

Since then, technology has evolved to produce human antibodies and many approved biological pharmacotherapeutic options. But, batch-to-batch variation with current biologic manufacture has led to varying degrees of biosimilarity. This variability is due to the inherent complexity of the biological products, which generates massive potential for change that can affect both potency and safety of the drug, as well as the intricacies of the manufacturing process, formulation, handling and route of administration. Against this background of complexity and potential variability, physicians and patients are looking for biosimilar medicines for RA that demonstrate the same pharmacological action and antigen binding, possess equivalent effectiveness, safety and tolerability to the parent molecule, and show a durability of response. Celltrion's infliximab biosimilar (filed with two different names – Remsima and Inflectra) is the world's first biosimilar monoclonal antibody (mAb) to receive regulatory approval from an advanced and developed nation's regulatory body and clinical studies show therapeutic equivalence and similar tolerability and safety to that of infliximab.

By 2020, twelve of the top-selling biological therapies will have lost patent protection, opening up an estimated \$24 billion opportunity in EU sales and \$30 billion in US sales. However, the original optimism regarding a potential 50% market share for biosimilar medicines has waned somewhat as companies face significant technical difficulties, potential regulatory and patent issues, halted clinical trials, prohibitive development costs and the likelihood of product pricing issues.

According to Professor Taylor, the way through these uncharted waters is to tread the middle path. *“On the one hand, we need to avoid drugs that are not adequately tested coming on to the market or being mandated for use just because they are cheaper. On the other hand, there is a need to avoid draconian regulatory hurdles that deny access to potentially beneficial drugs by the wider population.”*

The Industry's Perspective on Biosimilars

Matt Regan is the chair of the ABPI (Association of the British Pharmaceutical Industry) Biosimilars Taskforce and began by highlighting the enormous contribution that biological therapies have made to transforming the lives of patients with serious illness by targeting the underlying cause of disease and slowing or preventing disease progression. He went on to emphasise how an important aspect of working closely with The BioIndustry Association has been to make sure that adequate and balanced education takes place regarding evolving therapies before sharing the industries' recommendations for ensuring patient safety as biosimilar medicines enter the market (see Figure 2).

An important element of these recommendations is ensuring that prescribers understand that, unlike conventional generic medicines, biosimilar medicines that have the same international non-proprietary name (INN) cannot be presumed to be identical and should therefore be prescribed by brand name. Market research shows that confusion already exists amongst oncologists, rheumatologists and pharmacists regarding use of the brand name rather than INN. Other aspects of these recommendations focus on discouraging substitution amongst

- All biological/biosimilar medicines should be prescribed by brand name and not by International Nonproprietary Name (INN)
- Automatic substitution is not appropriate for biological medicines including biosimilars. A biological medicine including a biosimilar, must only be substituted under the direct supervision, and with the consent of, the treating physician
- Patients should be kept fully informed about their medication and should be consulted if any changes to their treatment are made
- The SmPC for a biosimilar medicine should clearly indicate the source of information contained within it, such as relevant data from its clinical development programme and clinical data derived from the originator or reference biological medicine
- Biosimilar medicines should be subject to health technology assessment processes in the UK
- Tenders which are undertaken involving biological medicines should not seek to source a single product only.
- Extrapolation of indications for biosimilar products should be evaluated by regulators on a case by case basis

Figure 2: ABPI Recommendations on Biosimilar medicines

biological and biosimilar medicines based on cost alone, the alleviation of prescriber concerns about clinical judgement and patient fears regarding choice of treatment. These recommendations demand greater research into prescribing of biologicals and biosimilars and a continuing dialogue between NICE and its stakeholders.

The ABPI makes seven recommendations which cover areas where action is needed by regulators, HTA agencies, NHS commissioners and NHS healthcare professionals who prescribe or dispense these medicines.

Matt Regan concluded by emphasising that the future is about facilitating discussion and debate with all stakeholders in order to maintain a balanced view of the evolving landscape.

“It is important to build on the established success of the European regulatory pathway in bringing biosimilar medicines to the market and focus on successfully bringing these therapies into practice in a way that preserves prescriber and patient choice and ensures effective traceability for all biological medicines”.

The Perspective of the Regulator

Dr William Richardson, Medical Adviser and Pharmacovigilance Advisory Board Member

at NDA Regulatory Science Ltd, began by reminding everyone of the UK’s existing experience with biological medicines – beginning many years ago with Edward Jenner and his work on the smallpox vaccine – and now extending across a number of therapeutic areas with biologics. A common thread for all these medicines is that regulation has focused on central authorisation by the European Commission based on data submitted to the Medicines Control Agency demonstrating quality, efficacy and safety. The regulatory requirements of biosimilar medicines will be similar to these innovator products, but there will be some important differences.

“A biosimilar medicine is not required to be identical to the reference product – only similar in all-important respects. The fact that there will be no requirement for the same biological system to be used in manufacture and that clinical trials in all indications for the reference product may not be necessary to obtain marketing authorisation for those same indications, will impact on dossier requirements and change the development timelines,” advised Dr Richardson.

Although the time taken to develop the cell-line and manufacturing process to achieve similarity will be longer, the pre-clinical and clinical

development programmes should be shorter (as shown in Figure 3). However, the review of biosimilar medicines will not be accelerated.

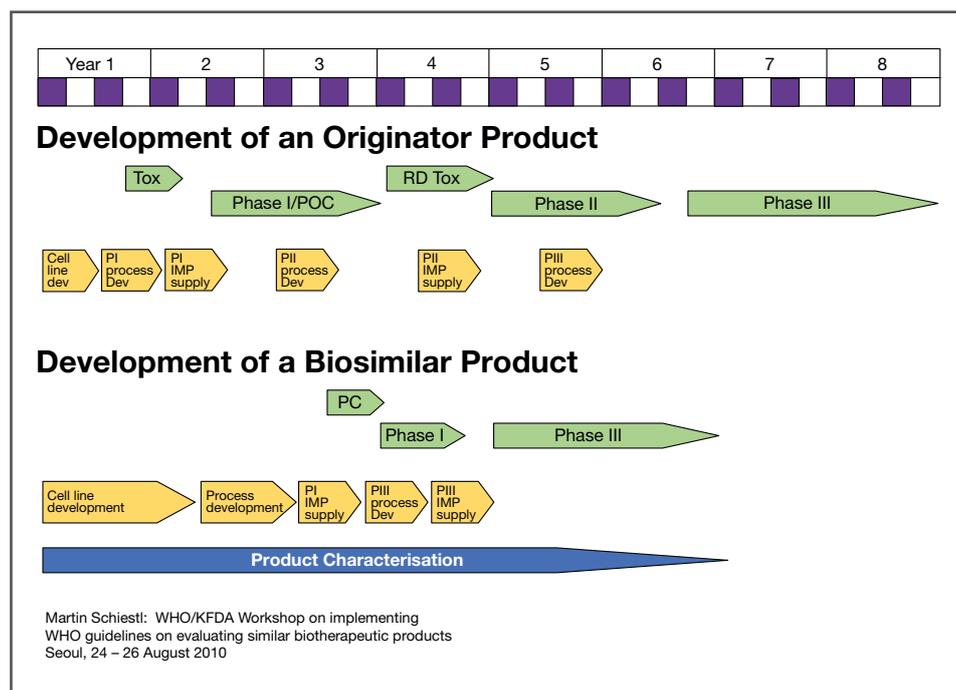


Figure 3: Development timelines for biosimilar medicines compared to originator biological products

According to Dr Richardson, territory for regulators is not the uncharted depths that it may appear to others, emphasising that 16 biosimilar medicines have received marketing authorisation in the EU to date based on five biological products – somatropin, epoetin alfa, filgastim, infliximab and follitropin-alfa. He acknowledged, however, that UK experience is limited and biosimilar infliximab, which has been approved for all the same indications as the reference product based on data from two clinical trials in RA and ankylosing spondylitis, is only being introduced to the UK in 2015. These studies confirmed the experimental findings of similarity between biosimilar infliximab and the reference product, with non-clinically detectable differences in efficacy and a similar adverse drug reactions profile (in terms of nature and incidence) and immunogenicity profile. The only safety signal was a higher number of serious infections including active tuberculosis (TB) in the biosimilar infliximab arm compared with the originator product arm (6 and 1 respectively in a clinical programme involving 871 patients). This numerical imbalance has raised a number of uncertainties prompting further follow-up – namely long-term safety and immunogenicity, interchangeability with originator product, efficacy and safety in extrapolated indications and potential differences in very rare adverse reactions such as lymphomas. Dr Richardson concluded by outlining components of the risk management plan in place for biosimilar infliximab:

“There are studies planned to examine these uncertainties. In addition, there is an educational programme for prescribers and an important focus on treatment record keeping in terms of use of brand names and batch numbers to ensure traceability at all times.”

The Perspective of the BSR Biologics Register

In the absence of Kimme Hyrich, Professor Peter Taylor presented a brief overview of the British Society for Rheumatology Biologics Register, including what it has taught us about biological use in RA and what the challenges will be in capturing real-world biosimilar medicine exposure and outcome data.

The Registry began as an observational, prospective cohort study in 2001. The primary aim was to monitor the long-term effects of biologic therapies in patients with RA treated during routine clinical practice. Its initial focus was the original anti-TNF therapies but it has now expanded to include rituximab, certolizumab and tocilizumab and involves over 250 NHS hospitals.

At baseline, the Register collated clinical data on disease characteristics, disease activity, comorbidities and previous and current therapy. It also collected patient data on demographics, occupation, smoking and quality of life and national datasets provided cancer incidence outcomes. Continuous data gathered at national level shows that, in the period between 2001 and 2008, the number of patients with a good response to anti-TNF has increased, which probably reflects the fact that the drugs are now used earlier and more effectively. One of the most important functions of the Registry is to detect any safety signals with anti-TNF. However, data shows that there is a slightly reduced risk of cancer with anti-TNF and that untreated RA is associated with a slightly elevated risk of lymphoma.

The introduction of biosimilar medicines throws up a number of challenges, not least that patients may be exposed to biosimilar medicines at a number of points along the treatment pathway. For example, they could receive a biosimilar medicine directly following failure of DMARD treatment, or it may be following failure of the parent drug or the failure of another biological agent. It will be important to capture all exposures to the biosimilar medicine irrespective of where they are in the pathway.

A number of additional challenges were also identified:

- The expected number of treated patients is currently unknown: it may remain small, but with an increasing choice of therapy, or may expand if the biosimilar medicine becomes the preferred treatment option.
- Identification of patients requires that treatment details need to be captured based on trade names not generic names, and batch numbers on packaging should be used to identify the drug. Specific attention needs to be paid to home-delivered infusion therapy, as packaging is not always available.
- The infrequency of capture of disease activity scores in an observational register can make the differentiation between primary and secondary treatment 'failure' difficult. The exact date of 'switch' must be available and it may therefore be appropriate to capture data more frequently.
- Identifying the appropriate mechanism for comparing outcomes will be important. These will differ depending on whether patients are starting a biosimilar medicine de novo or switching from the parent drug.

Professor Taylor concluded by saying that Registers are a valuable source of 'real-world' outcome data and that they may be even more important for biosimilar medicines given the limited number of patients exposed at the time of marketing approval. However, there will be some challenges in collecting and interpreting data; therefore, support will be needed from physicians, nurses, patients, trusts, drug companies and the NHS.

Panel Discussion

Immediately following the presentations, there was a chance for delegates to ask questions of the speakers. Key observations and concerns were as follows:

There was praise for the ABPI's recommendations in safeguarding choice and traceability of the biosimilar medicines but concerns regarding pharmacovigilance (PV) were expressed. Matt

Regan emphasised that this was being addressed by the ABPI but acknowledged that the organisation needed to make this activity more explicit in the position paper to avoid further confusion. This update has now been done and an updated ABPI position paper is now available including the enhanced PV requirements.

Although not directly relevant to the use of biosimilar medicines in RA, the first biosimilar insulin is expected in 2015 and serves as a good example of the challenge regarding future rollout of these agents to primary care. Dr Bill Richardson agreed that this use of biosimilar medicines in primary care was reasonable grounds for concern and that should prompt the introduction of the requirement they should not be prescribed outside specialist care.

There were concerns about giving carte blanche to use a drug in all the indications for which the biological product was approved when it raised a TB safety signal in RA. Dr Richardson emphasised that it was highly likely that the TB signal came about by chance but given the strength of the signal and the data available, the Committee for Medicinal Products for Human Use (CHMP) obligated the company to investigate the signal further. Extrapolating the use of a biosimilar medicine to other indications was based on the fact that there was no reasonable grounds not to do so.

The durability of response with biosimilar infliximab was questioned. Dr Richardson highlighted that given that immunogenicity is a problem with infliximab, it is reasonable to suspect problems may occur with the biosimilar medicine and so it will need to be studied over a longer period.

There was a query as to whether there would be a limit to the number of companies able to manufacture biosimilar medicines and the rationale for companies like Samsung leaping into the market was questioned. Matt Regan highlighted that, due to the costs associated with development, it would mainly be the bigger companies that invest. The involvement of large companies outside mainstream pharmaceuticals is not new as companies like 3M and BASF originally invested in this area many years ago. All it required for these organisations to get involved was the assembly of a team of experts, of which there were many available, to enter the market.

Participants were keen to know whether, if there was a decrease in the cost of treatment with the introduction of biosimilar medicines, the eligibility criteria would change and make treatment more accessible. Matt Regan was not convinced that there would be a change in eligibility criteria as the price difference would not be dramatic enough for the threshold to change. However, he did highlight that the medicines bill has been capped in the NHS for the first time and the pharmaceutical industry has underwritten the overspend to take affordability off the table. He emphasised that what was needed now was a change in the mechanism that prevents patients from achieving early access to treatment.

Participant Response

Keypad response devices were used throughout the meeting to identify the audience composition and views on a number of issues relating to biosimilar medicines. The audience comprised a mix of pharmaceutical company representatives (31%), patient organisation representatives (24%), healthcare professionals (8%), pharmacists (8%), patients (4%) and academic researchers (2%). Approximately one quarter (24%) classified themselves outside these categories.

When asked about their knowledge of biosimilar medicines at the start of the meeting, the majority were either experts in the field of biosimilars (19%) or had a little knowledge of biosimilars (54%). 21% knew only what they had read in preparation for this meeting and 6% confessed to knowing nothing about them at all.

During the course of the meeting, participants were asked a series of questions regarding their understanding of biosimilar medicines and the impact the products will have on patients. The results are summarised in the table below.

Question	Agree	Disagree	Not sure
Biosimilars will drastically improve patient options for treatment	24%	27%	49%
Biosimilars will replace originator biologic therapies over time	31%	43%	26%
Biosimilars are the same as biologics just cheaper	16%	74%	10%
Biosimilars available in the UK will only be manufactured in the UK	0%	96%	4%
Biosimilars are the same as generic drugs	0%	100%	0%
Switching patients from a biologic to a biosimilar will make no difference to the individual patient	7%	60%	33%
Pharmaceutical companies are worried they will lose their hold on the market share of the biologic	81%	11%	8%
Biosimilars must be appraised and approved by NICE in the same way as biologic therapies	38%	35%	27%

At the end of the meeting, participants were asked about their knowledge of the type of pharmacovigilance system in place in the UK to track and monitor adverse effects for all biological medicines, including biosimilar medicines. Just over a third (38%) said that they did know, whilst 18% only knew this information for biological medicines. 18% of participants did not know about pharmacovigilance.

When asked about the impact of the evening's event, knowledge had increased in almost three-quarters of participants (73%) and 22% felt that their knowledge has been confirmed or endorsed. Only a small proportion of attendees (4%) felt that they had more questions about biosimilar medicines than when they arrived.

Meeting Evaluation and Feedback

Individual comments on the value of the meeting were captured on the event evaluation forms and indicated that all the individual presentations were seen as useful by participants as shown in the chart below.

The high level of met expectations (50% of attendees had all their expectations met and 33% had three-quarters of their expectations met), and the high value of usefulness was attributed to both the speaker presentations and the panel discussion. Also, the unanimous interest (100%) in attending further events highlighted the need for greater sharing of information and discussion around biosimilar medicines.

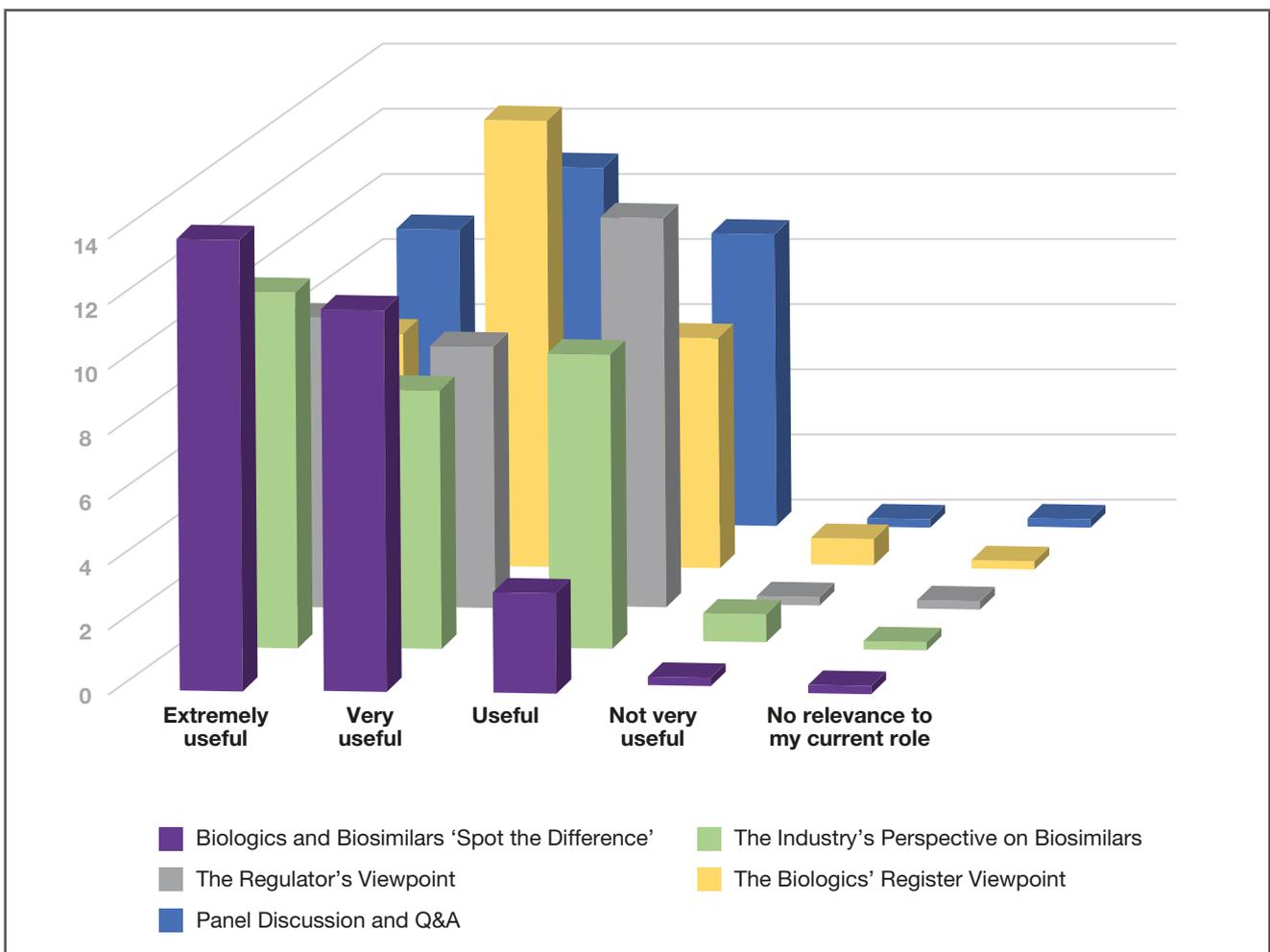
When participants were asked their view on the biggest impact of biosimilar medicines, many cited this as a reduction in treatment cost and wider access to innovative therapies but the risk of confusion remains:

"Potentially broader access for patients = wider use = potentially better controlled disease"

"Potentially wider choice of treatment for patients without breaking the NHS bank"

"Cost reduction of originators"

"I hope it would drive down the cost of biologic/ biosimilar drugs and make them available to more patients and make patients eligible to



treatment much earlier in their disease. As a pharmacist, I fear confusion and conflict.”

“Challenge the NHS to ensure managed entry processes, ensure adequate pharmacovigilance and product traceability”

However, this benefit is counter-balanced by a fear of a higher level of risk as well as confusion and conflict:

“I am not sure, but perhaps cheaper options albeit possibly carrying a higher level of unknown risk”

“That HCPs are not aware that there is a risk of automatic substitution if prescribed by INN and pharmacovigilance cannot be adequately monitored”

“Knowledge of GPs around biosimilars leading to poor prescribing to the detriment of patients”

“Risk and confusion over multiple products”

“Increased side effects, decreased efficacy”

These concerns are demonstrated by a hypothetical example provided by a pharmacist attending the meeting (see Figure 4). The example below illustrates why it is so necessary to give all stakeholders the ability to air their concerns and for the stakeholders who participated in this event to be able to continue the discussion as these drugs enter the UK market.

Figure 4: Real-life prescribing issues for community pharmacists - how to ensure that patients are prescribed and supplied with the same product each time and what the consequences will be of them receiving different ones.

In community pharmacy, the whole process starts with the prescription being handed in to the dispensary. Each patient has their own Patient Medication Record (PMR) on our computer system. We pull up the patient’s details, and then enter on to the system the item prescribed. This will be entered as it appears on the prescription because the label then produced must match the drug name as it appears on the prescription.

For example, if the doctor has prescribed ‘Enbrel’, we will select ‘Enbrel’ on our system and the label printed will read ‘Enbrel’. The computer will then give us a number of options to choose from (25mg or 50mg, syringes or pre-filled pens). We then make the appropriate selection and continue the process until a label is printed and a record of the supply is made on the patient’s PMR.

If the doctor prescribes ‘etanercept’, the label printed must also read ‘etanercept’ so this would be selected on our system together with the correct strength and device. At the moment, there is only one brand of etanercept available so the patient would receive Enbrel brand however, the prescription is written.

After a dispensing label and record have been produced, the computer system gives the option of ordering whichever product was selected. As there is only one brand, Enbrel would be ordered.

However, if four other etanercepts became available, say 'Anbrel', 'Inbrel', 'Onbrel' and 'Unbrel', the pharmacist would not necessarily know which brand the doctor intends the patient to have if he writes 'etanercept' on the next prescription.

Each pharmacy may have a different computer system and cascade of brands to choose from depending on which wholesaler they use. One pharmacy system might have their cascade with products in alphabetical order so the 'Anbrel' would be chosen by default unless altered manually. Another might have a cascade in cost order so the cheapest brand would be selected by default. Different wholesalers might favour different brands depending on discounts they have negotiated with drug companies.

It could be that by writing 'etanercept' the doctor intends that the cheapest option is selected, therefore keeping his drug spend lower. He might assume that the patient will always receive same brand of medication and/or not necessarily be aware of the number of alternatives available. The cheapest drug one month might not be the cheapest the next month so the patient could potentially receive a different brand each month! The only way of ensuring that the patient always receives the same biologic is to prescribe by brand name.

At the end of each month, pharmacies post all the prescriptions dispensed to the Prescription Pricing Authority. The prescriptions are mostly read by a scanning machine if computer printed. The pharmacy is reimbursed (approximately 2 months later) for the cost of the drugs prescribed/dispensed and that all-important dispensing fee of 90p. Using the costs below, if the doctor had prescribed 'Enbrel' we would be reimbursed £715.00 +90p.

Enbrel (£715); and for illustrative purposes: Anbrel (£815); Inbrel (£615); Onbrel (£515) and Unbrel (£415).

If the prescription reads 'etanercept' we would be reimbursed £415 + 90p in this scenario. So there is potential for making a loss. Therefore, there is huge pressure on us to supply the cheapest brand listed.

Before posting, the prescriptions are sorted into bundles, one for each prescriber. The PPA then compiles data for prescribing costs of each doctor so there is huge pressure in them to prescribe the most economical brands.

If, when the patient comes to collect their medication, they realise the wrong brand has been prescribed or ordered, the pharmacy would be stuck with a very expensive non-returnable fridge-line and then have to swallow the cost (and time) of contacting the prescriber and getting the prescription amended. (Usually the cost of a couple of phone calls as hospital doctors are notoriously difficult to identify and track down, plus a stamped envelope to the prescriber plus a stamped addressed envelope back to the pharmacy, followed by several phone calls chasing this up.) How to make a thumping loss in one fell swoop!

The other concern is that the Biologics Register might not be accurate as, although the doctor might assume that a patient might have been dispensed one particular brand of medication every time and have relayed this to the compilers of the Register, the patient may well have received a variety of brands. Then, any adverse effects or even benefits of treatment recorded could be attributed to the wrong product.

Currently we have to ring the manufacturer to order 'Humira' and 'Cimzia'. It's possible that we'd have to phone drug companies direct to obtain supplies of biosimilar medicines. Each company has its own system. Pharmacies may need to open accounts with a number of different drugs companies.

Until recently, we had to photocopy prescriptions for 'Enbrel', anonymise it then fax the copy with an order form to the supplier to prove we actually had a prescription before they would release it to us! All eating into our 90p profit.

Further information

ABPI position on biosimilar medicines. Accessed at:

<http://www.abpi.org.uk/our-work/library/Documents/ABPI%20position%20on%20biosimilar%20medicines.pdf>

EuropaBio. Guide to biological medicines. Available at:

http://www.europabio.org/sites/default/files/report/guide_to_biological_medicines_a_focus_on_biosimilar_medicines.pdf

European Medicines Agency. Questions and answers on biosimilar medicines. Available at:

http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2009/12/WC500020062.pdf

MHRA Drug Safety Update. Available at:

<http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON084739>

WHO. 55th Consultation on International Non-Proprietary Names for Pharmaceutical Substances Geneva, 16-18 October 2012. Executive Summary. Available at:

http://www.who.int/medicines/services/inn/55th_Executive_Summary.pdf

IAPO International Alliance of Patient Organisations – briefing papers available at:

<http://www.patientsorganizations.org/showarticle.pl?id=1763>

European Generic Medicines Association – Biosimilars Handbook Second edition 2011 available at:

<http://www.egagenerics.com/index.php/biosimilar-medicines/introduction>

European Commission – Consensus Information Paper 2013

http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/biosimilars_report_en.pdf

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Wednesday 9th April 2014
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