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Literature Review of International Biosimilar Medicines: Update June – September 2016

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Authors: Michael Ward, PhD BPharm(Hons)
Stephanie Reuter Lange, PhD BSc(Hons)
Kirsten Staff, PhD, MPharm, PGCertEd

School of Pharmacy & Medical Sciences
University of South Australia
CEA-19, GPO Box 2471
Adelaide, SA, 5001

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Introduction

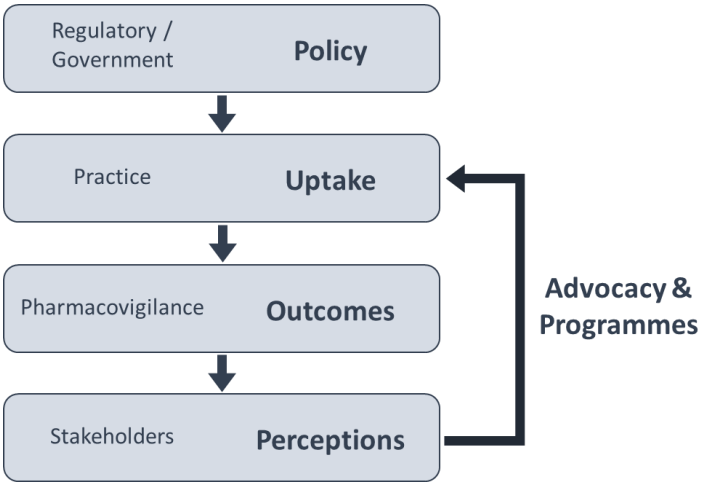
This report provides an update to the comprehensive literature search previously conducted that examined all international and Australian clinical, academic and policy journals and media articles or sources in relation to biosimilar medicines for the purpose of providing evidence which may inform policy development and the communication activities of the Australian Government's Biosimilar Awareness Initiative.

The broad objectives are to provide a review of the literature pertaining to:

- current international polices on biosimilar medicines;
- status of biosimilar use and substitution internationally;
- any current programmes aimed at increasing the uptake or confidence in biosimilars (and an evaluation of their success);
- biosimilar uptake and substitution; and
- impact of biosimilars (if any) on adverse events and health outcomes.

The five stated broad objectives for the review relate to four stages that influence biosimilar use; that is, the national and international regulatory environment that is the foundational determinant of biosimilar availability and associated switching and substitution (Policy); the subsequent uptake of biosimilars by prescribers, pharmacists and patients (Uptake); outcomes resulting from the use of biosimilars outside of the clinical development pathway (Outcomes); and finally the stakeholder perceptions that influence uptake, including the factors that modify these perceptions such as advocacy and associated programmes (Perceptions).

Figure 1: *Stages influencing biosimilar uptake and use*



In the context of this review it is critical to appreciate that the fundamental central factor to each of these areas is the potential uncertainty that exists in evidence regarding substitution, switching and extrapolation of indication, which is unique to the consideration of biosimilar medicines. This potential uncertainty originates from the highly complex nature of these medicines and the clinical development pathway of biosimilar medicines that extends from initial laboratory-based characterisation (protein structure, pharmacokinetics, etc.) through to the design and conduct of phase III clinical trials to provide evidence of similarity in clinical safety and efficacy in specific patient populations. The considerations involved in each

of these steps are significantly different to those associated with traditional small molecule drugs with which governments, regulators, prescribers, pharmacists and patients are well accustomed. In reflection of this, the following central themes have been identified:

1. Determining Access and Subsidisation: Regulatory, Government and Healthcare Provider Biosimilar Medicine Policies to Subsidisation, Switching and Substitution
2. Biosimilar Medicine Uptake: Current Practice of Prescribers, Pharmacists and Patients
3. Adverse Events and Health Outcomes of Biosimilar Medicines (Pharmacovigilance): Impact of Substitution, Switching and Extrapolation of Indication
4. Evaluating and Improving Stakeholder Biosimilar Awareness, Confidence, Attitudes and Acceptance of Biosimilar Medicines

Overview of the Published Biosimilar Literature

This report includes literature published 06 June 2016 to 07 September 2016

Analysis of these manuscripts identifies the following broad types of contributions:

- Education pieces
- Preclinical and clinical drug development
- Technical/methodological development
- Commentaries and individual opinion pieces
- Investigator-initiated studies and case series

Consistent with the observations of the prior review, within the time period encompassed by this update there has continued to be a significant number of papers published that were of an educational nature. As discussed previously, these manuscripts have not specifically sought to extend or expand the knowledge base in this area but instead restate what is already known or identified as uncertainties in order to inform the reader of these issues. In the context of this review, these papers do not contribute meaningfully to the specific aims; however, they play an important role in propagating the general understanding within the broader scientific and medical community. Many of these manuscripts have continued to focus on areas of current biosimilar focus, such as oncology and gastroenterology; however, within this quarterly update period there are notable examples focussing in potential future areas such as multiple sclerosis [1].

Within this quarter there have been a significant number of manuscripts published that focus upon fundamental and technological issues relating to the production and characterisation of biological agents [2-7]. Of particular note, is the number of papers published that specifically address the bioanalytical techniques that enable the physicochemical characterisation of biologic medicines. The publication of what appears to be an increasing number of manuscripts of this nature may be the result of an increasing awareness of biosimilars which has subsequently stimulated an increased appreciation of the fundamental importance of these results in the evaluation of potential biosimilar medicines. Whilst these topics are of clear importance to the development and evaluation of biosimilars, these manuscripts are highly technical which in nature and as such and do not contribute to the specific communication activities of the biosimilar initiative and therefore will not be discussed in greater detail.

Similarly, there are an increasing number of articles within the literature that specifically describe the results obtained during the commercial development of potential biosimilars. These manuscripts describe the information that regulators require for the approval of a biosimilar agent including the design and results of physicochemical characterisation, preclinical development, phase I pharmacokinetic studies and phase III safety and efficacy clinical trials. Whilst manuscripts of this nature are of clear importance to the development of biosimilars, they do not contribute to the specific aims of this review.

Given the general nature of the publications on biosimilars, it is not possible to differentiate articles of an educational nature or those pertaining specifically to biosimilar development from those that specifically seek to contribute new knowledge to the topic, and as such are pertinent to this review, through the use of specific search terms or exclusion criteria. Therefore filtering of publications relevant to this review through hand-searching was necessary.

THEME 1: Determining Access and Subsidisation: Regulatory, Government and Healthcare Provider Biosimilar Medicine Policies to Subsidisation, Switching and Substitution

There were no manuscripts published within this update period that specifically contribute new information to this theme.

THEME 2: Biosimilar Medicine Uptake: Current Practice of Prescribers, Pharmacists and Patients

A single manuscript describing the uptake of biosimilar filgrastim was published during the update period.

- Marciano *et al*, 2016: How did the Introduction of Biosimilar Filgrastim Influence the Prescribing Pattern of Granulocyte Colony-Stimulating Factors? Results from a Multicentre, Population-Based Study, from Five Italian Centres in the Years 2009-2014 [8]

  Following their manuscript describing the uptake of biosimilar erythropoiesis stimulating agents (ESAs) within a number of regions of Italy [9], the authors have sought to apply their methodology to describe the uptake of biosimilar filgrastim. This retrospective population-based drug utilisation study investigated the prescribing pattern of G-CSFs between 2009 and 2014 using the administrative databases of the Caserta, Treviso and Palermo Local Health Units (LHUs) and the Tuscany and Umbria regions. The findings of this analysis are generally consistent with those that were reported for the ESAs in which there was an overall increase in the uptake of biosimilars over the analysis period. There were also some regional differences that are likely attributed to policy differences. Campania was the first region to drive biosimilars for treatment naive patients, followed by Tuscany and Veneto (2010), Sicily (2011) and Umbria (2013).

  The overall prevalence of G-CSF use increased from 0.8 per 1000 inhabitants in 2009 to 1.1 per 1000 in 2014. The main indication for use of G-CSFs was neutropenia due to chemotherapy. An increase in the proportion of biosimilar filgrastim users was observed over time increasing from 0.2% in 2009 to 66.2% in 2014. Switching between different G-CSFs was frequent (n=2591; 20.3%) during the first year of therapy. Amongst users of biosimilar filgrastim, the most frequent switch was to pegfilgrastim (296/4407; 6.7%).

THEME 3: Adverse Events and Health Outcomes of Biosimilar Medicines (Pharmacovigilance): Impact of Substitution, Switching and Extrapolation of Indication

Within this update period there has continued to be manuscripts published describing the outcomes associated with the use of biosimilar agents. As with previous publications, these reports are frequently observational in nature, of limited sample sizes and are generally uncontrolled or rely upon the use of historic controls. As such the significance of the outcomes associated with these studies is uncertain. However, they contribute to the overall perception of the outcomes associated with the use of biosimilars.

Epoetin Biosimilars

- Minutolo *et al*, 2016: Dosing Penalty of Erythropoiesis-Stimulating Agents after Switching from Originator to Biosimilar Preparations in Stable Hemodialysis Patients [10]

  This letter reports on a retrospective evaluation of erythropoiesis stimulating agents (ESA) dose requirements following switching from originator product to a biosimilar. Data from 149 consecutive adult haemodialysis patients in 11 non-profit Italian dialysis centres between 2011 and 2014 was analysed. Patients were included in the study if they had received a stable ESA originator dose, without blood transfusion, in the 6 months preceding a switch to a biosimilar. Results obtained indicate that following the switch haemoglobin (Hb) levels were unchanged, but that there was a progressive increase in biosimilar dose. At week 24 post-switch, the absolute difference from baseline of biosimilar dosage was +2,121 IU/wk (95% CI, 1,220–3,022). Of the 149 patients, an increase dose requirement occurred in 65.8%, the dose requirement was unchanged in 8.1% and decreased in 26.2%. Whilst the authors conclude that their findings "*provide evidence that switching from ESA originator to biosimilar requires higher doses of drug to maintain Hb levels*" the lack of a control group means that the findings of this study are uncertain and may be impacted by factors such as regression to the mean.

Filgrastim Biosimilars

Within this update period, two systematic reviews of biosimilar filgrastim in either febrile neutropenia [11] or stem cell mobilisation for transplantation [12] were published. These manuscripts provide an overall summary of the published literature in these areas and are consistent with that reported in the previous literature review.

An additional report of the outcomes of biosimilar filgrastim has also been published.

- Bongiovanni *et al*, 2016: Recombinant granulocyte colony-stimulating factor (rG-CSF) in the management of neutropenia induced by anthracyclines and ifosfamide in patients with soft tissue sarcomas (NEUSAR) [13]

  This report describes a retrospective analysis of 67 patients with soft tissue tumours receiving primary prophylaxis against neutropenia with either biosimilar filgrastim (Zarzio®), originator filgrastim (Granulokine®, Neupogen®) or lenograstim (Myelostim®) for a total of 260 cycles of therapy in the context of epirubicin and ifosfamide (EI) treatment. There were no statistically significant differences in the incidence of febrile neutropenia between the three groups ($p = 0.935$) or in adverse events ($p = 0.985$). Biosimilar filgrastim was associated with a cost saving of €225.25/patient over originator filgrastim.

Infliximab Biosimilars

Six manuscripts relevant to this review have been published during this update period. Importantly, a number of these reports include information on the switching of patients from originator infliximab to biosimilar in the settings of rheumatological conditions, dermatological conditions and inflammatory bowel disease. In general, these manuscripts provide positive conclusions with regards to the use of biosimilar infliximab but, as detailed below, some authors have raised concern. Consistent with the previous literature review, the majority of these studies are not adequately controlled and include small numbers which restricts the significance of their findings.

- Smits *et al*, 2016: Clinical outcomes following a switch from Remicade to the biosimilar CT-P13 in inflammatory bowel disease patients: a prospective observational cohort study [14]

  The authors report a single-centre prospective observational open-label study conducted within an inflammatory bowel disease centre in the Netherlands. A total of 83 patients (Crohn's Disease [CD]=57, ulcerative colitis [UC]=24, unclassified=2) were switched from originator infliximab (Remicade®) to biosimilar infliximab (CT-P13). The median duration of ongoing Remicade® treatment prior to switching to biosimilar infliximab was 25 months [range 1–168]. Within this cohort, 66% of patients were receiving concomitant immunosuppressive medication (58% thiopurines, 8% methotrexate) and 10% were receiving corticosteroids. Five patients had detectable antidrug antibodies (ADAs) at baseline. Seventy-eight patients completed follow-up and received three or more infusions of CT-P13.

  The primary endpoint of the study was the change of disease activity at week 16 (±2 weeks) after switching to CT-P13 relative to week 0 as assessed by Harvey–Bradshaw Index (CD) or the Simple Clinical Colitis Activity Index (SCCAI) (UC). Secondary endpoints included infliximab concentrations and presence of anti-drug antibodies. The median change in disease activity for both CD and UC patients was 0 (CD range: −23 to +7, UC range: −3 to +6). Additional medication during follow-up was initiated in four patients due to increased disease activity. Two patients developed new detectable ADA levels during follow-up.

  The absence of a control group from this study limits the interpretation of the findings presented however the authors conclude that "*switching from Remicade® to CT-P13 in a real-life cohort of IBD patients did not have significant impact on short-term clinical outcomes*".

- Keil *et al*, 2016: Clinical monitoring: Infliximab biosimilar CT-P13 in the treatment of Crohn's disease and ulcerative colitis [15]

  This prospective observational study monitored responses to induction treatment with biosimilar infliximab in 52 patients diagnosed with IBD (CD=30, UC=22) in centres across the Czech Republic. Treatment response was assessed with the Crohn's Disease Activity Index (CDAI) or the Mayo Scoring System (MSS) in patients with CD or UC, respectively, at baseline and after 14 weeks. Concomitant therapy included 5-aminosalicylates (n=40), low-dose systemic corticosteroids (n=14), azathioprine (n=29) or other therapy (n=4). At 14 weeks, all patients with Crohn's disease achieved either a remission (15/30) or partial response (15/30), and in those with ulcerative colitis, remission was achieved in 9/22 and a partial response in 12/22. Two patients, both with ulcerative colitis, discontinued treatment prior to Week 14; one experienced an allergic reaction and the other ceased due to a lack of response and the development of pneumonia. Additional adverse events of phlebothrombosis (n=1) and herpes labialis (n=1) were reported. ADA

development was not assessed. The authors conclude that, whilst this is a small open label observational study, the results indicate "*positive clinical outcomes following administration of CT-P13 to IBD patients*" but that "*in the absence of a comparative study, some concerns remain about the equality of CT-P13 and infliximab RMP in the indication of IBD*".

- Schulze *et al*, 2016: CT-P13 (Inflectra™, Remsima™) monitoring in patients with inflammatory bowel disease [16]

  The stated aim of this study was to investigate the "*feasibility of CT-P13 serum level monitoring by implementing a routinely used ELISA for trough serum levels of Remicade™*". However, ultimately this study compares the concentrations of infliximab attained in patients with inflammatory bowel disease treated with CT-P13 (n=33) versus a historic control group treated with originator infliximab (n=86) over a period of 38 weeks. This study relied upon the use of the Remicade™-validated ELISA (IDKmonitor® infliximab drug level ELISA Immunodiagnostic, Bensheim, Germany). Whilst the study purports to investigate the feasibility, it does not present any *in vitro* data validating the assay for use with biosimilar infliximab which is the first step in investigating the feasibility of such an approach.

  Whilst the focus of this manuscript was upon the comparison of drug concentrations between biosimilar and originator groups, the study was subject to some design limitations. In particular there were imbalances between the two treatment groups. For example, CD was more frequent (87.9%) than UC (12.1%) in the biosimilar group but less common in the originator group (68.9%). Concomitant therapy differed between groups where one-third of biosimilar patients (of these AZA=61.5% and glucocorticoids=38.5%) received concomitant therapy as compared with half of originator patients (of these AZA=40.4%, oral glucocorticoids=53.8%, MTX=5.7%). Prior exposure to adalimumab was more common in the originator group; 40% of both groups were reported as having had prior IBD therapy, of which 94.9% in the originator group had received adalimumab as compared with 64.3% in the biosimilar group.

  The conclusion that this manuscript demonstrates the "feasibility" of using a specific commercial assay kit for the monitoring of biosimilar infliximab is limited by the absence of data presented to validate the assay with biosimilar drug product. However, it is unlikely that the use of biosimilar infliximab would impact upon the assay performance. As such, this manuscript demonstrates that use of biosimilar infliximab results in drug concentrations consistent with those associated with the use of the originator product as would be anticipated. Additionally, there were no differences in ADA concentrations between those treated with biosimilar or originator despite greater use of immunosuppressant medications within the originator group.

- Gentileschi *et al*, 2016: Switch from Infliximab to Infliximab biosimilar: Efficacy and safety in a cohort of patients with different rheumatic diseases [17]

  This letter by authors from the Rheumatolgy Unit at the University of Siena (Siena, Italy) briefly describes a cohort of 23 patients with an assortment of different rheumatic diseases (11/23 psoriatic arthritis, 8/23 ankylosing spondylitis, 2/23 rheumatoid arthritis, 2/23 Crohn's disease and associated axial spondyloarthritis, and 1/23 Behçet's disease) who were switched from originator infliximab to biosimilar infliximab as a result of "*local regulatory issues*". Patients had previously received originator infliximab for a mean time (SD) of 71.65 (44.4) months. At the time of the switch, all of the patients were considered by the clinician to be in complete disease remission whilst receiving originator infliximab at a dose of 5 mg/kg

every 8 weeks. It is reported that following the switch to biosimilar infliximab disease relapse occurred in 7 out of 23 patients (30.43%) after a mean time of 1.71 months (range 1–2) from switching and that 7 of the remaining 16 patients required "*close observation and monitoring*" of disease control. Of the patients who relapsed, the mean prior infliximab treatment duration was 62.28 (SD= 49.95) months. Patients who relapsed following the switch to biosimilar infliximab were switched back to originator infliximab (5 mg/kg every 8 weeks), in association with a tapering dose of oral corticosteroids. The authors report that this resulted in a "*remarkable clinical improvement*" in four patients, "*at least partial*" response in one patient and no response in two patients. However, as indicated by the authors, the ability to draw firm conclusions from this study is limted by "*the small number of patients, the absence of a control group, and the short-term follow-up*".

- Dapavo *et al*, 2016: The infliximab biosimilar in the treatment of moderate to severe plaque psoriasis [18]

  This manuscript reports on the outcomes associated with the use of biosimilar infliximab in patients with psoriasis who were both treatment naïve or switching from originator infliximab. Response was assessed using the Psoriasis Area and Severity Index (PASI) and visual analogue scale (VAS) for arthritic pain scores at baseline and at each visit. Within the cohort of 30 switching patients, the median duration of originator infliximab was 237 weeks (range 14–576 weeks). Following switching, the median follow-up ws 23 weeks (range 13–33 weeks), with a median number of cycles of 4 (range 2–7). There were no statistically significant differences in PASI or VAS arthritic pain scores between baseline and end of follow-up. The only adverse event reported in this cohort was a single patient that developed herpes zoster which resolved with standard care. Within the five infliximab naïve patients, the mean PASI score at the commencement of the treatment was 27.3, and at week 10 four patients achieved a 75% improvement in PASI score. No data on the development of ADAs is provided for either the switching or treatment naïve cohorts.

  The authors conclude that "*Patients with psoriasis taking infliximab originator treatment can switch to the infliximab biosimilar without experiencing a significant change in clinical response or additional adverse events*" and that biosimilar infliximab could "*reduce the growing pressure on health care budgets*".

- Tanaka *et al*, 2016: Safety and efficacy of CT-P13 in Japanese patients with rheumatoid arthritis in an extension phase or after switching from infliximab [19]

  This manuscript reports the results of an open-label, multicentre, extension study in 72 patients with rheumatoid arthritis that had previously completed a 54 week phase I/II study. The primary endpoint was the safety of biosimilar infliximab (CT-P13) with methotrexate during long-term treatment with CT-P13 (maintenance group, n=38), and after switching from originator to biosimilar infliximab (switch group, n=33). At baseline of the extension study (prior to switching), the number of ADA-positive patients in the switch group (the group previously treated with originator infliximab) was 16 (48.5%), which was higher than that in the maintenance group (the group previously treated with after biosimilar infliximab) (12 patients; 31.6%).

  The duration [mean ± standard deviation (SD)] between the initial and final treatments in the extension study was 80.5 ± 19.7 weeks in the maintenance group as compared with 69.0 ± 29.5 weeks in the switch group. Within the biosimilar maintenance group, study participation was discontinued in 6/38 patients (adverse events=4, lack of efficacy=1, consent withdrawal=1) as compared with 10/33 patients

discontinuing in the switch group (adverse events =8, lack of efficacy=1, lack of efficacy and consent withdrawal=1, other reason=1). During the extension study, all patients that experienced an infusion-related reaction were positive for ADA at extension study baseline.

The authors conclude that biosimilar infliximab was "*well tolerated in patients who maintained the treatment after 54 weeks and in patients who switched to CT-P13 after 54 weeks of IFX treatment*".

THEME 4: Evaluating and Improving Stakeholder Biosimilar Awareness, Confidence, Attitudes and Acceptance of Biosimilar Medicines

Prescribers

❖ Pasina *et al*, 2016: A survey among hospital specialists and pharmacists about biosimilars [20]

This Letter-to-the-Editor briefly reports on an educational intervention and survey to evaluate hospital specialists' attitudes to prescribing biosimilars and their opinion regarding the quality, efficacy and safety of biosimilars. The educational interventions were promoted by the Lombardy Region Health Department, and supported by grants from the Region Health Directorate of the Lombardy Region (Progetto FARMAGOOD-Biosimilari). Limited details are provided on the structure of the educational intervention. The description provided indicates that the educational intervention consisted of four independent clinical pharmacology and pharmacoeconomics researchers who discussed the scientific principles that allow the licensing of biosimilars, the potential economic benefits and the evidence supporting the risk–benefit ratio of biosimilars currently approved by the EMA and that this was followed by four specialists in rheumatology, gastroenterology, nephrology and paediatricians who reported their opinions and experience with biosimilars and reference products.

A total of 446 specialists voluntarily participated in the educational interventions, of whom 214 specialists, including nephrologists (27%), gastroenterologists (31%), paediatricians (26%) and haematologists/oncologists (31%), completed a survey. Details of the survey content are not provided. The authors report that "*knowledge of the scientific principles for licensing biosimilars was considered poor by most of the specialists (about 74%)*" and that "*Prejudices related to the supposed lesser efficacy of biosimilars (especially in the indications obtained by extrapolation) and concern for the higher risk of adverse drug reactions (ADRs — especially immunogenic) were the main reasons for specialists to doubt biosimilars"*. Of the 47 specialists that consented to the evaluation of their educational intervention, 21 reported a favourable opinion and good experience with biosimilars whilst 26 (55%) concluded that biosimilars had reduced efficacy or increased risk of adverse events than the originator product. The authors suggest that nephrologists and paediatricians more frequently reported favourable opinions, but the basis for this statement is not provided.

Patients, Caregivers and Public

❖ Peyrin-Biroulet *et al*, 2016: Patient Perspectives on Biosimilars: A Survey by the European Federation of Crohn's and Ulcerative Colitis Associations [21]

The aim of this online survey of members of the European Federation of Crohn's and Ulcerative Colitis Association (EFCCA) conducted between November 2014 and October 2015 was to examine the perspectives that patients with inflammatory bowel disease (Crohn's disease [CD]=62%, ulcerative colitis [UC]=38%) have towards biosimilars. Of the 1059 respondents, 52.9% of patients with Crohn's disease and 32.3% of patients with ulcerative colitis were currently receiving treatment with an anti-TNF agent. Approximately 14% or respondents had discontinued an anti-TNF agent due to either a lack of efficacy or adverse effects.

The survey comprised 15 multiple choice questions and was supported by an "*unrestricted grant from Abbvie*". The use of multiple choice questions limits respondent's capacity to the options that are presented to them. Overall, the tone of the questions presented and the options available to respondents were generally focussed on potential limitations or concerns relating to biosimilars with very limited scope to address potential benefits. On this basis there are limitations with regards to this studies capacity to truly reflect the patient perspective on biosimilars.

The authors report that the most common biosimilar-related concerns amongst the respondents were safety (46.5%) and efficacy (38.6%). Respondents were permitted to provide multiple responses and so some are likely to have expressed concern regarding both safety and efficacy. Approximately one quarter of respondents indicated that they had no specific concerns about biosimilars. Almost half of respondents indicated that they would like to know whether they were receiving the biosimilar or the reference drug. Respondents expressed a clear desire to be provided with information, with 42.8% indicating that patients should systematically be given information about biosimilars and 25.1% thought that patient associations should be informed and able to give their opinion on biosimilar-related matters.

When focussing on issues of particular significance to IBD such as extrapolation of indications, in response to the question "*The biosimilar of REMICADE (infliximab) has been successfully developed and used for the treatment of rheumatologic diseases. On June 27, 2013, the biosimilar of REMICADE (infliximab) received positive opinion from the European Medicines Agency (EMA) for the treatment of inflammatory bowel disease by extrapolating data from rheumatoid arthritis*", 30.3% of respondents would prefer clinical trials in IBD and 24.3% would prefer to wait for more IBD-specific data before accepting a biosimilar. However, 27.2% of the respondents would trust their treating physician to make the decision with regards to extrapolation of indication, but only 0.8% would trust their pharmacist. The rationale for the authors to include the pharmacist as an option within this specific question is unclear.

Similar results were obtained regarding interchangeability where 30.0% would accept the exchange if their treating physician approved it. Only 1.0% of the respondents might accept the exchange if the drug was delivered by their usual pharmacist. When asked "*If the pharmacist hands out the biosimilar, changing the initial prescription without the consent of the prescribing physician*" 62.4% indicated that they would try to obtain the reference drug.

Of the 15 questions in the survey, only one question was related to the potential benefits of biosimilars. When asked "*The biosimilar will be less expensive than the reference drug, you think that*", 31.3% of the

respondents indicated that they believed that more patients would be treated with biologics due to their lower price.

Despite the potential limitations of this study in exploring patient perspectives on biosimilars, the authors ultimately conclude that "*patients want to be informed and involved"* and that *"They highlight the need to involve patients in decision-making when starting a biosimilar*".

Pharmacists

- Tomaszewski, 2016: Biosimilar Naming Conventions: Pharmacist Perceptions and Impact on Confidence in Dispensing Biologics [22]

  This web-based survey of 781 members of the Academy of Managed Care Pharmacy and the Hematology/Oncology Pharmacy Association was conducted between May and June of 2015 to determine pharmacist perceptions of biosimilar naming conventions and their impact on confidence to dispense biosimilars and to measure the burden that is created by laws and regulations requiring pharmacists to complete post-dispense notifications. Respondents reported preferring a biosimilar naming convention that use a non-proprietary base with a designated suffix (48.1%), compared with the use of a non-proprietary base alone (26.3%) or a non-proprietary base plus a prefix (14.2%). However, when specifically asked about substitution, respondents were most comfortable when the products shared the same non-proprietary name (62.9%). 64.9% of participants reported a perception of increased burden when required to provide a post-dispense notification to prescribers when dispensing a biosimilar.

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