Biosimilars for the treatment of patients with psoriasis: A consensus statement from the Biosimilar Working Group of the International Psoriasis Council

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Background: As biosimilars have become available in various parts of the world, the International Psoriasis Council has reviewed aspects of their use.

Objective: To provide consensus statements from the Biosimilar Working Group about the use of biosimilars in patients with psoriasis.

Methods: A semiqualitative structured process was employed to approve the consensus statements on biosimilars using the nominal group technique. The final statements were validated by a survey of the paricipants. The approval of the consensus statements was predefined as >80% positive opinions.

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Results: A consensus was reached in 36/38 statements regarding regulatory considerations, extrapolation of indication, interchangeability, substitution at the pharmacy level, pharmacovigilance, traceability, naming, biosimilar policy, education, and cost of biosimilars. Example statements include "Switching a stable patient from a reference product to a biosimilar product is appropriate if the patient and physician agree to do so" and "Patients and patients' organisations should be involved in all decision making and policy development about the use of biosimilars."

Conclusion: The International Psoriasis Council Biosimilar Working Group provides consensus statements for the use of biosimilars in the treatment of patients with psoriasis. We suggest that these statements provide global guidance to clinicians, healthcare organizations, pharmaceutical companies, regulators, and patients regarding the development and use of biosimilars in patients with psoriasis. (JAAD Int 2020;1:224-30.)

Key words: biosimilars; interchangeability; International Psoriasis Council; psoriasis; switching; tumor necrosis factor inhibitors.

INTRODUCTION

Biologic therapies, including monoclonal antibodies and receptor fusion proteins targeting tumor necrosis factor-α or interleukins, have significantly improved the treatment outcomes for patients with psoriasis.[1-3] Although considerably more effective than traditional systemic therapies, the high cost of biologic agents has limited their use and contributed to inequalities in the care provided to patients with psoriasis in many countries.[1,4,5]

CAPSULE SUMMARY

- This study provides consensus statements from the Biosimilar Working Group about biosimilar use in patients with psoriasis, providing global guidance to clinicians, patients, and other stakeholders.
- Switching a stable patient from a reference product to a biosimilar product is appropriate if the patient and physician agree to it.

One way in which healthcare systems can maximize the value derived for patients from the money it spends on biologic medicines[6] and widen access to biologic therapies is through the use of biosimilars.[7,8] Biosimilars are drugs that are highly similar, with no clinically meaningful differences, to originator biologic medicines, as proven by high-level clinical studies.[9] The development and approval of biosimilars according to the rigorous standards of pharmaceutical quality, safety, and efficacy are still associated with significant costs.[10] However, in comparison to the developmental process for originator biologics, there is significant emphasis on the physicochemical and functional characterization of biosimilars, which is considered the foundation for the regulatory approval of biosimilars, rather than on clinical testing per se.[11,12] Clinical testing for regulatory approval must be conducted in a patient population sensitive enough for the detection of differences in efficacy or safety between the biosimilar and reference products.[13] Noninferiority or equivalence studies of a single indication, requiring sample sizes usually smaller than those for studies on the approval of new biologic agents, are acceptable and need not be repeated for every indication of the originator if extrapolation is accepted by regulatory agencies.[14] Although this accelerates the developmental process and reduces the cost of biosimilar production, the dermatology community may find it difficult to interpret data collected from biosimilar trials conducted in dissimilar disease states.[15,16] Formerly, most of the clinical testing of anti–tumor necrosis factor biosimilars approved for use in psoriasis had been performed in patients with rheumatoid arthritis. The International Psoriasis Council (IPC) called for clinical studies to be conducted in patients with psoriasis, and studies have now been conducted in patients with psoriasis.[14,17,18]

By definition, biosimilars and originators have identical primary amino acid sequences. However, there may be minor differences in glycosylation, deamination, oxidation, or 3-dimensional structures between biosimilars and originator biologics, which may affect their end-target interactions and help determine differences in efficacy and safety.[19,20] Patients and clinicians may be concerned about a potential loss of efficacy, altered immunogenicity, or unanticipated differences in adverse effects when switching to a biosimilar.[21,22]

Dermatologists worldwide are faced with the need to choose between an originator or a biosimilar

Abbreviations used:

BSWG: Biosimilar Working Group
IPC: International Psoriasis Council
NGT: nominal group technique

in biologic-naïve patients or to switch from an originator to a biosimilar in patients established on treatment.[23] However, with significant financial incentives driving the prescription of biosimilars in many health economies, biologic treatment decisions may become more physician-independent in the future.[24] Multiple biosimilar medications now exist, which may result in numerous changes in therapy for individual patients, making it almost impossible to attribute safety signals to a specific biosimilar medication.[14] Interchangeability is a major challenge for dermatologists, and traceability is imperative in order to collect accurate pharmacovigilance data on adverse events in patients with psoriasis who have been managed with biosimilar and originator biologic treatments.[24]

The IPC, a network of more than 100 experts on psoriasis dedicated to improving psoriasis care around the globe, has previously urged dermatologists to actively participate in developing policies for biosimilar prescription worldwide and has published reports on many aspects of biosimilar prescription.[11,14,16,23,24] As clinicians continue to wrestle with the opportunities and challenges that biosimilar therapeutics offer, the IPC has identified the need for clear guidance on the use of biosimilars in the treatment of psoriasis. In the current report, we describe a semiqualitative structured process employed by the IPC and the consensus statements on biosimilar prescription that have been agreed upon by IPC councilors.

MATERIALS AND METHODS

The study was conducted within the framework of the IPC Biosimilar Working Group (BSWG), which includes IPC councilors who are interested in biosimilars. The group conducted 1-2 meetings per year, in which the various aspects of biosimilars were discussed. The meeting attendees included members of the IPC BSWG, as well as external experts and pharma representatives. Pharma representatives participated in the meeting to present data from their respective companies. Discussions were held with the participation of the BSWG members, guests, and pharma representatives. When sensitive matters were discussed (eg, prioritization of drug use in psoriasis), the guest scholars and pharma representatives were asked to leave the meeting room and not participate in the debate. Thus, the IPC BSWG members were at liberty to express their opinions.

The consensus statements were reached using the nominal group technique (NGT).[25] NGT is a process used for solution generation, decision-making, and consensus agreement considering each participant's opinion. The NGT exercise used in this study had 3 stages: 1) Identification of essential issues on the use of biosimilars in patients with psoriasis, 2) Discussion and collapsing of the statements, and 3) Prioritizing and ranking of the statements by voting. In the identification stage, the participants were requested to submit statements about the use of biosimilars via e-mail correspondence. These statements were collected by a group facilitator, who led a consensus-reaching meeting of the IPC councilors of the BSWG. The meeting took place in February 2019. During the meeting, it was possible to submit additional statements. In the second stage of the NGT exercise, the participants discussed each idea on the list so that the meaning of the statements was made clear to everyone. Thereafter, the statements were collapsed to 38 major statements.

Twenty-three councilors of BSWG participated in the consensus voting of the statements on biosimilars, which were grouped into 10 different categories (in alphabetical order): biosimilar policy, cost of biosimilars, education, extrapolation of indication, interchangeability, naming, pharmacovigilance, regulatory considerations, substitution at the pharmacy level, and traceability. In the voting stage, the participants were asked to express their agreement on each statement using an online survey conducted using SurveyMonkey (https://www.surveymonkey.co.uk/). The degree of agreement with each statement was ranked into 5 categories: "not at all," "slightly," "moderately," "very much," and "extremely," with the latter 3 implying a positive opinion. Approval of the consensus statements was predefined as >80% positive opinions in the survey.

The study was approved for publication by the IPC. All 38 consensus statements were reviewed and voted upon by 100% of the participants in the survey.

RESULTS

The consensus approval was reached for 36 out of the 38 statements (94.7%), with 100% positive opinions ("moderately," "very much," and "extremely") in 21 (55.3%) (Table I). In approximately one-third (33.8%) of the statements, the "slightly" agreement choice was recorded. The "not at all" response was recorded in less than 1 quarter of the statements (23.7%). The categories with 100% positive opinions included cost, pharmacovigilance, and traceability. The categories with >90% positive

Table I. Statements About the Use of Biosimilars for the Treatment of Patients With Psoriasis

	Statement	Positive opinions (n)	%
1	Evaluation of biosimilar products must meet the rigorous standards of regulatory guidance (EMA, FDA, WHO).	23	100%
2	Biosimilar assessments, including physiochemical, pharmacokinetic, and functional analytical assays, must meet rigorous standards.	23	100%
3	In comparison to the reference product, a biosimilar product should demonstrate no clinically meaningful differences in efficacy, safety, or immunogenicity.	23	100%
4	Biosimilar trials are intended to demonstrate clinical equivalence to the reference product. Use of the same endpoints (efficacy and safety) of the pivotal trials of the reference product is preferable.	23	100%
5	Biosimilar clinical trials should include both elements of crossover and parallel design.	23	100%
6	Biosimilar clinical trial designs incorporating at least 2 switches between the reference product and biosimilar are preferable.	22	96%
7	Studies designed to examine switching between multiple biosimilars can provide relevant information.	22	96%
8	Trials of biosimilars for the indication of psoriasis should be performed in patients with psoriasis.	21	91%
9	Extrapolation of indications from trials in other diseases, as determined by the regulatory agencies, is acceptable.	19	83%
10	Published clinical trial data demonstrated that a single switch from an innovator to a biosimilar is safe and effective.	22	96%
11	Prescribing biosimilars to biologic-naïve patients with psoriasis is appropriate if the patient and physician agree to do so.	22	96%
12	Switching a stable patient from a reference product to a biosimilar product is appropriate if the patient and physician agree to do so.	20	87%
13	Multiple switches between various biosimilars and reference biologics is not the preferred option but is acceptable.	15	65%
14	Treatment switches should not occur in less than an adequate period of time (usually 6 months) from initiation of the reference product, allowing full assessment of its therapeutic effect.	23	100%
15	Switching between different biosimilars should be performed with caution, until more evidence is generated supporting this practice.	17	74%
16	Clinicians should be notified and should provide approval prior to any originator or biosimilar drug substitution being made.	22	96%
17	Clinicians should be given explicit authority to override any suggested substitutions.	21	91%
18	Registries, consortia, and large, prospective databases of patients treated with biosimilars should be established.	23	100%
19	Health claims data should be used to provide pharmacovigilance when using biosimilars and reference products.	23	100%
20	Traceability should be ensured so that a specific biosimilar, and/or reference product, its producer, and its manufacturing history (eg, lot number) can be reliably identified.	23	100%
21	Each biosimilar name should be easily distinguishable from its biologic reference product and other biosimilars.	22	96%
22	Using a biosimilar brand name may be a suitable option.	20	87%
23	One biosimilar name is preferable to use in every country.	22	96%
24	Patients and patients' organizations should be involved in all decision-making and policy development about the use of biosimilars.	22	96%
25	Dermatologists and professional organizations should take an active role in the development of biosimilar prescribing policies in their respective healthcare and governmental agencies.	23	100%
26	Biosimilars should not prevent or delay access to the use of new biologic drugs.	23	100%
27	Dermatology leadership should develop guidelines for the use of biosimilars.	23	100%
28	Biosimilar resources for physicians should include summarized information on the quality of the comparability data used to demonstrate biosimilarity for approval (PK and PD profiles, clinical trial data).	23	100%
29	The impact of biosimilar education on prescribers should be measured with an emphasis on prescriber confidence and attitudes toward clinical use of biosimilars.	23	100%

Continued

Table I. Cont'd

	Statement	Positive opinions (n)	%
30	Practice guidelines for biosimilars should be developed at a local level, which will differ across countries throughout the world.	20	87%
31	Translation of biosimilar information from physicians to patients is needed for clear understanding.	23	100%
32	Dermatology leadership should develop educational programs for dermatologists about the complexity of manufacturing and use of biosimilars.	22	96%
33	Biosimilar companies are advised to communicate the quality of manufacturing to dermatologists.	23	100%
34	Cost of biosimilars should be low enough to genuinely improve patients' access to these drugs.	23	100%
35	Biosimilars are therapeutic options over their originator products if their use provides cost savings to patients and/or reduces financial burden to healthcare system.	23	100%
36	Biocopies, "intended copies", and/or "biomimic products", which are not biosimilars, should not be used.	23	100%
37	Education is needed to distinguish biosimilars from biomimics.	23	100%
38	Biomimics should not have the same name as biosimilars or originator products.	23	100%

EMA, European Medicines Agency; *PD*, pharmacodynamics; *PK*, pharmacokinetics.

opinions included cost, education, pharmacovigilance regulatory considerations, substitution at pharmacy level, and traceability.

A consensus was reached, and all the statements were agreed upon (>80% positive opinions) in the following categories: biosimilar policy, cost of biosimilars, education, extrapolation of indication, naming, pharmacovigilance, regulatory considerations, substitution at pharmacy level, and traceability. A consensus was not reached for only 2 statements, both of them in the interchangeability category. The statement "Multiple switches between various biosimilars and reference biologics is not the preferred option but is acceptable" received only 65.7% positive opinions and was, therefore, not agreed upon. A consensus on the statement "Switching between different biosimilars should be performed with caution, until more evidence is generated supporting this practice" was not reached either, with only 73.9% positive opinions (28/38 voters). These results indicate that single or multiple switching between biosimilars in patients with psoriasis is still open to argument in the councilors' opinions.

DISCUSSION

Biologic therapies have led to significant improvements in the outcomes of patients with psoriasis, with the downside of increased healthcare costs.[26] The signature promise of cost-effective biosimilars is to improve patient access to highly effective treatments earlier in the therapy cycle, decrease costs, and maintain improved health outcomes.[27] This presents an opportunity for dermatologists to deliver high-quality and high-value care.[14,26,28]

The patents of several key biologic therapies for the treatment of psoriasis have either already expired or will expire by 2020.[28] This is driving interest in biosimilar drug development by pharmaceutical manufacturers.[28] However, biosimilar use and their subsequent market uptake are contingent on physicians' confidence and willingness to prescribe biosimilars in clinical practice.[28] In this paper, the IPC provides a suite of consensus statements on the use of biosimilars for the management of psoriasis across 10 different categories: biosimilar policy, cost of biosimilars, education, extrapolation of indication, interchangeability, naming, pharmacovigilance, regulatory considerations, substitution of pharmacy level, and traceability. However, some IPC members expressed concerns regarding switching of therapies between different biosimilars and did not reach a consensus regarding multiple switches between originator biologics and biosimilars.

The US Food and Drug Administration's (FDA) designation of interchangeability means that a biosimilar is expected to produce the same clinical results as the reference product when substituted at any point in therapy and to present no greater safety risk than continuous treatment using the reference product; therefore, an interchangeable product may be substituted without the intervention of the prescribing provider.[26] Draft guidance for full interchangeability, including automatic substitution, of a biologic medicine, as developed by the FDA, proposed that drug manufacturers perform at least 1 randomized clinical trial comparing patients who undergo multiple treatment switches (at least 3) with those continued on the same treatment.[29] In the past, many randomized trials have involved only

1 treatment switch.[30] However, in the phase III EGALITY trial with a biosimilar of etanercept, GP2015, randomized patients with moderate-to-severe chronic plaque psoriasis to continue on the same treatment with the originator or were made to undergo a sequence of 3 switches between the originator and the biosimilar at 6-week intervals.[31] The study assessed the effect of the treatment switches on efficacy, safety, and immunogenicity and showed that the triple switching had no effect on the safety or efficacy of the therapy.[31,32] During the study, 6 patients exhibited transient presence of low titers of non-neutralizing anti-drug antibodies (5 patients during the first 4 weeks of treatment and 1 patient at week 36).[31] During the second (triple switching) phase of the treatment, none of the patient participants exhibited the presence of anti-drug antibodies, confirming the low immunogenic potential of both the biosimilar and originator etanercept.[31] Furthermore, a 51-week, double-blinded, phase III study demonstrated the biosimilarity between GP2017 and the reference biologic adalimumab, with equivalent efficacy and similar safety and immunogenicity levels, in adult patients with active, clinically stable, moderate-to-severe plaque psoriasis.[33] Further investigation demonstrated that switching between GP2017 and the reference product up to 4 times had no detectable impact on the efficacy, safety, or immunogenicity.[33]

On the other hand, a Dutch multicenter prospective open-label study of patients with inflammatory arthropathies, including psoriatic arthritis, ankylosing spondylitis, and rheumatoid arthritis (the BIO-SWITCH study), investigated switching from the originator infliximab to the biosimilar CT-P13.[31] Overall, 24% of 197 patients discontinued the treatment with the biosimilar because of a perceived lack of effect, adverse events, or a combination of both.[34] Further analysis disclosed that 78% of the reported adverse events could be classified as subjective health complaints.[34] This might be attributed to the nocebo effect associated with the patients' negative expectations concerning the therapy, which may have led to the subjective health complaints (ie, symptoms perceptible only by the patient) and discontinuation of the therapy.[35] The nocebo effect, which can also be defined as the opposite of placebo effect, may explain why the rate of discontinuation of the therapy can be higher in open-label studies than in randomized controlled trials.[30] These data suggest that acceptance and persistence rates after switching to a biosimilar product may be influenced by the way in which switching is communicated to the patient.[34]

Our study did have some limitations. First, we only surveyed expert opinions. However, our survey reflects the debate that we, as experts, have been considering in recent years, including the general, specific, and controversial aspects of biosimilar prescription for psoriasis. Second, for the statements for which a consensus was not reached, we did not elucidate the areas of disagreement as this was beyond the scope of this study. Finally, our paper does not provide a comprehensive review of the literature and evidence regarding biosimilars as this has been provided by our previous papers on biosimilars.[11,14,23,24]

In this paper, the IPC BSWG provides consensus statements for the use of biosimilars in the treatment of patients with psoriasis. These consensus statements are intended to offer guidance to clinicians, healthcare organizations, pharmaceutical industry, regulators, and patients regarding the development and use of biosimilars for the treatment of psoriasis around the world. In conclusion, the IPC endorses evidence from clinical trials and increasing experience from daily clinical practice, which show that biosimilars are equivalent to reference products in terms of quality, efficacy, and safety profiles, including the extrapolation of the indications. However, switching clinically stable patients from originator biologics to their biosimilar alternatives still raises some concerns, although according to the available clinical trials and literature reviews, a single switch from an originator to a biosimilar is not associated with any significant risk or loss of efficacy.[36] Nevertheless, clinical evidence regarding the safety of multiple switches is limited, and the IPC strongly endorses continued patient monitoring using a registry and long-term observational studies to provide more data. The IPC also recognizes the need for careful monitoring of patient after a treatment switch and detailed recording of the therapy prescribed in the medical records.

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