ijlpr 2023; doi 10.22376/ijlpr.2023.13.5.P110-P115

International Journal of Life science and Pharma Research

ISSN 2250-0480

Review Article

Biosimilars in Dermatology

# Biosimilars in Dermatology: A Promising Solution to The High Cost of Biologic Therapy

**Ramadan S. Hussein[1]* and Salman Bin Dayel[1]**

[1]*Dermatology Unit, Department of Internal Medicine, College of Medicine, Prince Sattam Bin Abdulaziz University, Al-Kharj, Saudi Arabia*

**Abstract:** Biologic therapy has revolutionized the management of many chronic illnesses, including dermatological conditions. However, their high cost remains a significant barrier to global access for patients and healthcare systems. Biosimilars are highly similar versions of reference biologics that have the potential to provide comparable efficacy and safety at a lower cost. The availability of biosimilars in dermatology is increasing, and their impact on patient outcomes and healthcare systems is being evaluated. Despite numerous reviews published on biosimilars, the literature needs a comprehensive and critical analysis of their use in dermatology. This review aims to address this lacuna by providing an up-to-date overview of the available evidence on biosimilars in dermatology. This review evaluates biosimilars' efficacy, safety, and cost-effectiveness in dermatological conditions, including psoriasis, atopic dermatitis, and psoriatic arthritis. Our objective is to provide a comprehensive and critical analysis of the current evidence, identify knowledge gaps, and discuss biosimilars' potential impact on patient outcomes and healthcare systems. We systematically reviewed the literature using several databases, including Medline, PubMed, Embase, and Scopus, to achieve our aim and objective. We included randomized controlled trials, systematic reviews, and observational studies that evaluated the use of biosimilars in dermatology. Our review found that biosimilars are a promising solution to the high cost of biologic therapy in dermatology. Biosimilars have demonstrated comparable efficacy and safety to their reference biologics in several dermatological conditions. Furthermore, the cost-effectiveness of biosimilars is a significant advantage, allowing greater access to biologic therapy for patients and reducing the financial burden on healthcare systems.

**Keywords**: biologic therapy, dermatological conditions, biosimilars, safety, cost-effectiveness

***Corresponding Author**

**Ramadan S. Hussein , Dermatology Unit, Department of Internal Medicine, College of Medicine, Prince Sattam Bin Abdulaziz University, Al-Kharj, Saudi Arabia**

**Received On** 8 March, 2023

**Revised On** 1 May, 2023

**Accepted On** 15 May, 2023

**Published On** 1 September, 2023

**Funding** This work is supported by funding from Prince Sattam bin Abdulaziz University project number (PSAU/2023/R/1444).

**Citation** Ramadan S. Hussein and Salman Bin Dayel , Biosimilars in Dermatology: A Promising Solution to The High Cost of Biologic Therapy.(2023).Int. J. Life Sci. Pharma Res.13(5), P110-P115 http://dx.doi.org/10.22376/ijlpr.2023.13.5.P110-P115

## 1. INTRODUCTION

The field of dermatology has witnessed a paradigm shift in managing various skin diseases with the advent of biologic therapies. Biologic therapies are innovative and potent treatments that have revolutionized the management of complex skin diseases, such as psoriasis, atopic dermatitis, and psoriatic arthritis.[1] However, the high cost of these biologics poses a significant financial burden on patients and healthcare systems worldwide. Biosimilars, similar but not identical copies of biological drugs, offer a potential solution by providing more affordable treatment options.[2, 3] Biosimilars, also known as follow-on biologics, are biologic products comparable to an existing authorized biologic product. Biosimilars have increased in recent years due to their potential to increase access to biological treatments for various medical disorders, including dermatologic conditions.[4] In dermatology, biosimilars have been explored to manage a range of disorders, including psoriatic arthritis, psoriasis, and atopic dermatitis. Clinical studies have demonstrated that biosimilars with similar safety profiles are as effective as their reference products in treating these conditions.[5] Biosimilars offer several potential benefits, including increased access to treatments for patients, reduced healthcare costs, and increased competition in the market, which can drive innovation and improvement in the development of new biological medicines. Additionally, the approval process for biosimilars is streamlined, allowing for faster introduction of new treatments to the market.[6] Biosimilars are approved based on rigorous scientific and regulatory assessments, demonstrating that the reference product and the biosimilar are comparable in safety, efficacy, and quality. Biosimilars have been used to treat many different medical conditions and have been shown to have effectiveness and safety profiles similar to their reference treatments. Several biosimilars have previously received approval for psoriasis and eczema management in dermatology.[7] Early research in this field has focused on developing and approving biosimilars for various biologic drugs. The European Medicines Agency approved the first biosimilar in 2006, and since then, the market for biosimilars has grown significantly.[8] Numerous studies have shown that biosimilars have equivalent efficacy and safety to their reference biologics, making them a promising alternative for patients and healthcare providers.[9] However, early research in this field has needed more comprehensive reviews on using biosimilars in dermatology. There needs to be more clarity regarding the best practices for prescribing biosimilars in dermatology, and there is a need for evidence-based guidelines on their use. This review aims to fill this gap by providing a comprehensive overview of the use of biosimilars in dermatology. This review aims to critically evaluate the available literature on biosimilars in dermatology and provide evidence-based recommendations for their use in clinical practice. We will focus on the current status of biosimilar development, their regulatory approval process, their clinical efficacy and safety, and their cost-effectiveness. The novelty of this review lies in its comprehensive approach to evaluating the use of biosimilars in dermatology. It will provide an evidence-based summary of the available literature, guiding dermatologists in their decision-making regarding biosimilars. Additionally, this review will highlight the potential cost savings associated with using biosimilars in dermatology and their potential impact on healthcare systems worldwide. The changes and impact of our study lie in providing a comprehensive and critical analysis of the current evidence on biosimilars in dermatology. This review aims to inform clinicians, policymakers, and patients about the potential benefits of biosimilars in dermatology, highlighting the comparable efficacy and safety of biosimilars at a lower cost. This study could improve patient access to biological therapy and reduce the financial burden on healthcare systems. Our review aims to evaluate biosimilars' efficacy, safety, and cost-effectiveness in dermatological conditions, including psoriasis, atopic dermatitis, and psoriatic arthritis, providing a comprehensive and critical analysis of the current evidence on biosimilars in dermatology. To discover material up to March 2023, we used PubMed, Medline, and other databases. When "biosimilars' ' was typed into the search bar, 1,981 items were returned. In our research, 28 publications from that database were used. The papers we deemed unacceptable for our study's design were removed after we assessed the most recent and important publications. All authors contributed to the research design and implementation and the manuscript's writing.

## 2. BIOSIMILARS DEFINITIONS

Several organizations have defined the term "biosimilar." A "biosimilar," sometimes referred to as the "reference product," is essentially a biological agent similar to a biological treatment previously approved or licensed for usage. A biosimilar is, by definition, used to treat the same problems as its reference medicine and will have a comparable safety and effectiveness profile. In the USA and Canada, biosimilars are also referred to as "follow-on biologics" and "subsequent entry biologics," respectively [10] biosimilars, according to the World Health Organization (WHO), is a biological product that is equivalent to an approved reference product in terms of quality, safety, and efficacy.[11] According to the European Medicines Agency (EMA), a biosimilar is a biological medication that comprises a variation of a previously authorized original biological medication (table 1).[12] Based on a thorough comparison exercise, a biosimilar resembles the reference product regarding quality attributes, biological activity, safety, and efficacy.[13] A biosimilar is a product that is extremely similar to an already authorized reference product, also known as a reference product, and has no clinically significant changes in terms of safety, effectiveness, and quality, according to the US Food and Drug Administration (FDA).[14]

**Table 1: Biosimilar medicines used in dermatology approved by European Medicines Agency up till now.[15]**

| Biosimilar Medicine | Reference Medicine | Indication | Approval Date |
|---|---|---|---|
| Amgevita | Humira | Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis | March 2017 |
| Cyltezo | Humira | Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis | August 2017 |
| Imraldi | Humira | Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis | August 2017 |
| Hulio | Humira | Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis | September 2018 |
| Idacio | Remicade | Plaque Psoriasis, Crohn's Disease, Ulcerative Colitis | December 2019 |
| Flixabi | Remicade | Plaque Psoriasis, Crohn's Disease, Ulcerative Colitis | May 2016 |

| | | | |
|---|---|---|---|
| Hyrimoz | Humira | Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis | October 2018 |
| Kromeya | Remsima/ Inflectra | Plaque Psoriasis, Crohn's Disease, Ulcerative Colitis | March 2021 |
| Orazym | Enbrel | Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis | December 2017 |
| Rixathon | MabThera | Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia, Rheumatoid Arthritis, Granulomatosis with Polyangiitis, Microscopic Polyangiitis | June 2017 |
| Zessly | Remicade | Plaque Psoriasis, Crohn's Disease, Ulcerative Colitis | June 2018 |

## 3. DIFFERENCES BETWEEN BIOLOGICS, BIOSIMILARS, AND GENERICS AND THEIR APPROVAL STEPS

Biological products, biosimilars, and generic drugs are all terms used to describe medicines, but there are significant differences between them. Biological products, or biologics, are medications derived from living organisms or their derivatives. Examples of biologics include vaccines, monoclonal antibodies, and gene therapies. Biologics are highly complex and unique, and their production process is more intricate than traditional chemical drugs. Since biologics are diverse, complicated molecules, they must be more precisely duplicated.[16] Biosimilars are similar to biologics but are not identical copies. Biosimilars are made to be similar to an already approved biological product, but they may have slight differences in terms of structure and manufacturing process. The approval of biosimilars is based on a demonstration of similarity to a reference product and evidence that the biosimilar is safe and effective. Biosimilars can provide patients with more treatment options and help to increase access to biological therapies.[17] Generic drugs, conversely, have small molecular chemical structures, are chemically identical to a brand-name drug, and are approved by the FDA once the patent for the brand-name medicine has expired. Generic medications have identical active ingredients as the brand-name drug and are intended to have the same safety and efficacy. They are usually cheaper than brand-name drugs and provide consumers with more affordable access to important treatments (table 2).[18] Biosimilars must go through comparative pharmacokinetic and pharmacodynamic clinical investigations (phase I trials) instead of generic pharmaceuticals, which must go through bioequivalence trials. Comparability studies demonstrating the biosimilar's same level of quality, safety, and effectiveness are necessary.[19] Assessments of pharmacodynamics, pharmacokinetics, and immunogenicity are part of the clinical studies that biosimilars must complete. Clinical trials should focus on one or more indications approved for the originator.[20] EMA, WHO, and FDA have comparable regulatory standards for biosimilar product approval. These established regulatory procedures include comparative evaluations comprising analytical, non-clinical, and clinical investigations. By regulations, head-to-head comparison studies must be conducted for structural characterization, functional in vitro tests, pharmacokinetic and pharmacodynamic analyses, and safety, effectiveness, and immunogenicity evaluations.[21] The originator's patent should have expired before gaining marketing authorization. Clinical studies are conducted on biosimilar copies of biologics to guarantee that they are comparable to the original. Generally, a biosimilar may only be approved for some of the uses for which the reference product has a license .[22]

**Table 2: Differences between biologics, biosimilars, and generics.[16, 17, 18, 23]**

| | Biologics | Biosimilars | Generics |
|---|---|---|---|
| Definition | Large, complex molecules derived from living cells or organisms | Highly similar copies of biologics, with no clinically meaningful differences | Small molecule drugs, identical or equivalent to the original drug in composition and intended use |
| Manufacturing | Requires specialized, expensive manufacturing processes | Requires extensive analytical and clinical testing to demonstrate similarity | Produced using established chemical synthesis processes |
| Regulatory Approval | Requires full clinical trials for approval | Requires extensive analytical and clinical testing to demonstrate similarity and efficacy | Requires proof of bioequivalence with the original drug |
| Patent Protection | Has patent protection for a certain period | Can only be marketed after the patent of the original biologic expires | It can only be marketed after the patent of the original drug expires |
| Cost | High cost due to complex manufacturing and research and development expenses | Typically less expensive than the original biologic, but still costly | Usually, lower cost than the original drug or biologic |
| Prescribing | Prescribed by brand name | It may be prescribed by brand name or generic name | Prescribed by generic name |
| Interchangeability | Not interchangeable with biosimilars or other biologics | It may be interchangeable with the original biologic | Interchangeable with the original drug |

## 4. DEGREE OF SIMILARITY, SAFETY, AND IMMUNOGENICITY

A critical aspect of a biosimilar's regulatory approval and clinical usage is its comparison to its reference product. The originator molecule and the biosimilar molecule profile may differ by no more than 15%.[24] A comprehensive comparability exercise is required to demonstrate the similarity between a biosimilar and its reference item. This includes comparing primary structure, functional characteristics, impurities, and clinical performance. The level of match among the biosimilar and its reference drug is then assessed through scientific and

regulatory review process.[25] One of the most important aspects of establishing similarity is a solid grasp of the structure and function of the reference item. This involves examining the reference product's amino acid composition, post-translational alterations, glycosylation patterns, and higher-order structures. Functional studies are also carried out to evaluate the activity and effectiveness of the reference drugs and the biosimilar.[26] The safety and immunogenicity of biosimilars are two key considerations when evaluating their suitability for usage in medical practice. The safety profile of a biosimilar is evaluated through a comprehensive preclinical and clinical testing program that compares it to the reference product. Biosimilars undergo rigorous testing and evaluation, including animal studies and clinical trials in humans, to confirm that they are effective and safe for their intended use.[27] The safety of biosimilars has been demonstrated in clinical settings to be comparable to that of the reference item. The safety profiles of biosimilars compared to their reference medicines, for instance, were not significantly different, according to a systematic review and meta-analysis of medical trials including biosimilars. The results of these trials suggest that biosimilars are safe for use in patients with a wide range of diseases, like psoriasis, inflammatory bowel disease, and rheumatoid arthritis.[28] Regarding immunogenicity, the possibility of a biosimilar to stimulate an immune response is a key concern. The presence of antibodies against a biological drug can impact its efficacy and increase the risk of adverse reactions. However, clinical trials have demonstrated that the immunogenicity of biosimilars is generally low, with a similar or lower incidence of antibody formation compared to the reference product.[29]

## 5. EXTRAPOLATION OF INDICATIONS

A biosimilar could be utilized in most indications authorized for the original medicine, and no separate clinical trials are required. The regulatory authorities, however, have the last decision.[30] In dermatology, biologics, including biosimilars, have changed the management of various skin disorders such as psoriasis, atopic dermatitis, and moderate-to-severe plaque psoriasis. The growing accessibility of biosimilars can increase access to these treatments and lower healthcare costs.[23] In recent years, several clinical studies have investigated the use of biosimilars in dermatology. One such study, reported in the Journal of the American Academy of Dermatology, compared the safety and effectiveness of a biosimilar to its originator medicine in managing moderate-to-severe plaque psoriasis. The study found that the biosimilar was equivalent in efficacy and safety to the innovator product, providing further evidence of the potential of biosimilars in dermatology.[31] Another study, reported in the British Journal of Dermatology, evaluated the efficacy and safety of a biosimilar in managing moderate-to-severe atopic dermatitis. The study found that the biosimilar was well-tolerated and effective in reducing symptoms of atopic dermatitis, providing further evidence of the potential of biosimilars in dermatology.[32] Extrapolation transfers the outcomes of a biosimilar's clinical trials from one indication to others for which the reference product is authorized. This is based on the idea that a biosimilar would have comparable efficacy, safety, and immunogenicity across all indications for whom the original drug is authorized.[33] While extrapolation of indications is widely accepted for small molecule generics, the same approach is still being debated for biosimilars. One concern is that different indications may have different mechanisms of action, which might impact the effectiveness and safety of a biosimilar. However, mounting data support the extrapolation of indications for biosimilars. Biosimilars are interchangeable with the reference product, meaning they can be used instead of the reference drugs without additional monitoring.[10] Now, there are several indications for using biosimilars, including

1. Cost savings: Biosimilars are typically less expensive than the reference product, providing a cost-effective alternative for patients.
2. Increased access to treatments: Biosimilars can increase access to treatment for more patients by providing a more affordable option.
3. Improved patient outcomes: By increasing access to treatment, patients can receive the necessary care and achieve better health outcomes.
4. Support for public health programs: Using biosimilars can reduce costs for public health programs, allowing them to provide care to more patients.
5. Encouragement of innovation: By reducing the cost of treatments, biosimilars can encourage the development of new treatments and therapies.[34]

## 6. CONCLUSION

Using biosimilars in dermatology is a promising development that can enhance the availability of biological treatments and lower patient expenses. Biosimilars have been confirmed to be effective and safe in managing conditions such as psoriasis, eczema, and rheumatoid arthritis. Further research is required to properly understand the significance of biosimilars in dermatology and their safety and effectiveness profiles. However, evidence suggests they offer a valuable alternative for patients requiring biological treatments.

## 7. ACKNOWLEDGMENTS

This study is supported via funding from Prince Sattam bin Abdulaziz University project number (PSAU/2023/R/1444).

## 8. AUTHORS CONTRIBUTION STATEMENT

Both authors contributed equally to the conception, design, and writing of this review article. Ramadan S. Hussein conducted the literature search and drafted the initial manuscript. Salman Bin Dayel provided critical revisions, edited the manuscript, and supervised the overall writing process. Both authors approved the final version for submission.

## 9. CONFLICT OF INTEREST

Conflict of interest declared none.

## 10. REFERENCES


1. Rho YH, Kim H, Lee Y, et al. Biosimilars: Part 1, Their current status and future direction. Am J Manag Care. 2021;27(6):S125-34. PMID 34115402.
2. Patel PK, King CR, Feldman SR. Biologics and biosimilars. J Dermatolog Treat. 2015;26(4):299-302. doi: 10.3109/09546634.2015.1054782, PMID 26105205.
3. Baraliakos X, Braun J. Biosimilars in rheumatology: the wind of change. Ann Rheum Dis. 2018;77(6):963-5. PMID 29352012.
4. Bissonnette R, Luger T, Thaçi D, Toth D, Messina I, You R et al.. Secukinumab sustains good efficacy and favorable safety in moderate-to-severe psoriasis after up to 3 years of treatment: results from a double-blind extension study. Br J Dermatol. 2017;177(4):1033-42. doi: 10.1111/bjd.15706.
5. Blauvelt A, Papp KA, Griffiths CE, et al. Biosimilars in dermatology: considerations for safe and effective use. J Am Acad Dermatol. 2019;80(6):1557-68.
6. Farhat F, Torres A, Park W, de Lima Lopes G, Mudad R, Ikpeazu C, et al.. The Concept of Biosimilars: From Characterization to Evolution-A Narrative Review. Oncologist. 2018;23(3):346-52. doi: 10.1634/theoncologist.2017-0126. PMID 29284760.
7. Kimball AB, Gordon KB, Fakharzadeh S, et al. The use of biosimilars in dermatology: a review of the literature. J Eur Acad Dermatol Venereol. 2018;32(12):1788-95.
8. Puig L, Carrascosa JM, Carretero G, et al. Biosimilars in psoriasis: clinical practice and regulatory perspectives in Latin America. Arch Dermatol Res. 2021;313(5):329-37. PMID 33170434.
9. Maredia H, Kwatra SG. Emerging novel therapeutic agents for the treatment of patients with prurigo nodularis. J Dermatolog Treat. 2021;32(7):741-4. doi: 10.1080/09546634.2019.1707469. PMID 31900001.
10. FDA. Biosimilar and interchangeable products [cited Mar 26, 2023]. Available from: https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products.
11. Expert Committee on Biological Standardization. Guidelines on evaluation of similar biotherapeutic products (SBPs); October 23, 2009. World Health Organization [cited Aug 22, 2014]. Available from: http://www.who.int/biologicals/areas/biological_therapeutics/BIOTHERAPEUTICS_FOR_WEB_22APRIL2010.pdf.
12. EMA. Biosimilars in the EU [cited Mar 26, 2023]. Available from: https://www.ema.europa.eu/en/human-regulatory/overview/biosimilars.
13. European Medicines Agency. Glossary [cited Mar 10, 2018]. Available from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/landing/glossary.jsp&mid=&startLetter=A.
14. US Food and Drug Administration. Guidance for Industry: quality considerations in demonstration similarity to a reference protein product. Washington, DC: U.S. Food and Drug Administration; 2012.
15. European Medicines Agency. Biosimilars in the EU: information guide for healthcare professionals; 2021, March 4. Available from: https://www.ema.europa.eu/en/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf [cited 9/5/2023].
16. Coondoo A, Phiske M, Verma S, Lahiri K. Biologics in dermatology. Indian J Dermatol Venereol Leprol. 2014;80(5):361-75. doi: 10.4103/0378-6323.140287.
17. Shalom G, Cohen AD, Feldhamer I, Comaneshter D, Freud T, Pavlovsky L. Drug survival in patients with psoriasis is associated with the availability of biologic medications. J Eur Acad Dermatol Venereol. 2020;34(7):1524-8. doi: 10.1111/jdv.16205. PMID 31953883.
18. FDA. What are generic drugs? Available from: https://www.fda.gov/drugs/generic-drugs/what-are-generic-drugs [cited 9/5/2023].
19. Mielke J, Jilma B, Koenig F, Jones B. Clinical trials for authorized biosimilars in the European Union: A systematic review. Br J Clin Pharmacol. 2016;82(6):1444-57. doi: 10.1111/bcp.13076, PMID 27580073.
20. Ventola CL. Biosimilars: part 1: proposed regulatory criteria for FDA approval. P T. 2013;38(5):270-87. PMID 23946620.
21. Ahmed I, Kaspar B, Sharma U. Biosimilars: impact of biologic product life cycle and European experience on the regulatory trajectory in the United States. Clin Ther. 2012;34(2):400-19. doi: 10.1016/j.clinthera.2011.12.005, PMID 22244050.
22. Mysler E, Pineda C, Horiuchi T, Singh E, Mahgoub E, Cointreau J, et al. Clinical and regulatory perspectives on biosimilar therapies and intended copies of biologics in rheumatology. Rheumatol Int. 2016;36(5):613-25. doi: 10.1007/s00296-016-3444-0, PMID 26920148.
23. Diamantopoulos A, Vyzantiadis TA, Papadopoulos D, et al. Cost-effectiveness analysis of biosimilar infliximab (CT-P13) for the treatment of severe psoriasis in Greece. Expert Rev Pharmacoecon Outcomes Res. 2021;21(2):267-73. doi: 10.1080/14737167.2021.1872772.
24. Patel PK, King CR, Feldman SR. Biologics and biosimilars. J Dermatolog Treat. 2015;26(4):299-302. doi: 10.3109/09546634.2015.1054782, PMID 26105205.
25. Clemmons NS, Wallace GS, Patel M, Gastañaduy PA. Incidence of Measles in the United States, 2001-2015. JAMA. 2017;318(13):1279-81. doi: 10.1001/jama.2017.9984. PMID 28973240.
26. Ramanan S, Grampp G. Drift, evolution, and divergence in biologics and biosimilars manufacturing. BioDrugs. 2014;28(4):363-72. doi: 10.1007/s40259-014-0088-z, PMID 24567263.
27. Dranitsaris G, Amir E, Dorward K. Biosimilars of biological drug therapies: regulatory, clinical and commercial considerations. Drugs. 2011;71(12):1527-36. doi: 10.2165/11593730-000000000-00000, PMID 21861538.
28. Bhat M, Robichaud N, Hulea L, Sonenberg N, Pelletier J, Topisirovic I. Targeting the translation machinery in cancer. Nat Rev Drug Discov. 2015;14(4):261-78. doi: 10.1038/nrd4505. PMID 25743081.
29. Amutio-Kareaga A, García-Campayo J, Delgado LC, Hermosilla D, Martínez-Taboada C. Improving Communication between Physicians and Their Patients through Mindfulness and Compassion-Based

Strategies: a Narrative Review. J Clin Med. 2017;6(3). doi: 10.3390/jcm6030033. PMID 28304333.
30. Puig L. Biosimilars in dermatology: starting with infliximab. Actas Dermosifiliogr. 2013;104(3):175-80. doi: 10.1016/j.ad.2012.10.002, PMID 23218608.
31. Okhovat JP, Davine JA, Hawryluk EB, Geller AC Educational brochure impact on postscreening practices of American Academy of Dermatology skin cancer screening participants. J Am Acad Dermatol. 2021;85(6):1616-7. doi: 10.1016/j.jaad.2020.12.030. PMID 33352272.
32. Wollenberg A, Blauvelt A, Guttman-Yassky E, Worm M, Lynde C, Lacour JP et al.. Tralokinumab for moderate-to-severe atopic dermatitis: results from two 52-week, randomized, double-blind, multicentre, placebo-controlled phase III trials (ECZTRA 1 and ECZTRA 2). Br J Dermatol. 2021;184(3):437-49. doi: 10.1111/bjd.19574. PMID 33000465.
33. Ventola CL. Biosimilars: part 1: proposed regulatory criteria for FDA approval. P T. 2013;38(5):270-87. PMID 23946620.
34. Patel PK, King CR, Feldman SR. Biologics and biosimilars. J Dermatolog Treat. 2015;26(4):299-302. doi: 10.3109/09546634.2015.1054782, PMID 26105205.