CME-accredited webinar: Biosimilar Interchangeability

Learning Resources

Key Statements:

- European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA). Joint EMA-HMA: Statement on Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU. April 2023. Available at: https://www.ema.europa.eu/en/documents/public-statement/statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf Last accessed 13 June 2023.
- European Medicines Agency (EMA). Q&A on the Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU April 2023. Available at: https://www.ema.europa.eu/en/documents/other/qa-statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf. Last accessed 13 June 2023.
- Medicines and Healthcare products Regulatory Agency (UK; MRHA). Guidance on the licensing of biosimilar products. November 2022. Available at: https://www.gov.uk/government/publications/guidance-on-the-licensing-of-biosimilar-products/guidance-on-the-licensing-of-biosimilar-products#interchangeability Last accessed 13 June 2023.

- For the list of biosimilar medicines approved via the centralised procedure via EMA, visit: https://www.ema.europa.eu/en/medicines/
- For the list of biosimilar medicines approved via the FDA, visit: https://www.fda.gov/drugs/biosimilars/biosimilar-product-information
- For the list of biosimilar medicines approved via the UK MHRA, visit: https://bnf.nice.org.uk/

Key research papers:

- Ebbers HC et al. The safety of switching between therapeutic proteins. Expert Opin Biol Ther. 2012;12(11):1473-85. https://www.tandfonline.com/doi/abs/10.1517/14712598.2012.711308?journalCode=iebt20
- Kurki P et al. Interchangeability of Biosimilars: A European Perspective. BioDrugs. 2017;31(2):83-91. https://link.springer.com/article/10.1007/s40259-017-0210-0
- Kurki P et al. Safety, Immunogenicity and Interchangeability of Biosimilar Monoclonal Antibodies and Fusion Proteins: A Regulatory Perspective. Drugs. 2021;81(16):1881-96. https://link.springer.com/article/10.1007/s40265-021-01601-2
- Barbier L et al. Regulatory Information and Guidance on Biosimilars and Their Use Across Europe: A Call for Strengthened One Voice Messaging. Front Med (Lausanne). 2022;9:820755. https://www.frontiersin.org/articles/10.3389/fmed.2022.820755/full

Key Papers used in the CME webinar :

- Barbier et al. The Efficacy, Safety, and Immunogenicity of Switching Between Reference Biopharmaceuticals and Biosimilars: A Systematic Review. Clin Pharmacol Ther. 2020;108(4):734-755. https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.1836
- Jørgensen KK et al. Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial. Lancet. 2017;389(10086):2304-2316. https://linkinghub.elsevier.com/retrieve/pii/S0140-6736(17)30068-5
- Goll GL et al. Long-term efficacy and safety of biosimilar infliximab (CT-P13) after switching from originator infliximab: open-label extension of the NOR-SWITCH trial. J Intern Med. 2019;285:653-669. https://onlinelibrary.wiley.com/doi/10.1111/joim.12880
- Glintborg B et al. To switch or not to switch: results of a nationwide guideline of mandatory switching from originator to biosimilar etanercept. One-year treatment outcomes in 2061 patients with inflammatory arthritis from the DANBIO registry. Ann Rheum Dis. 2019;78(2):192-200. https://ard.bmj.com/content/78/2/192.long
- Tweehuysen L et al. Subjective Complaints as the Main Reason for Biosimilar Discontinuation After Open-Label Transition From Reference Infliximab to Biosimilar Infliximab. Arthritis Rheumatol. 2018;70(1):60-68. https://onlinelibrary.wiley.com/doi/epdf/10.1002/art.40324
- Tweehuysen L et al. FRI0200 Higher acceptance and persistence rates after biosimilar transitioning in patients with a rheumatic disease after employing an enhanced communication strategy. Annals of the Rheum Dis. 2017;76:557. https://ard.bmj.com/content/76/Suppl_2/557.2

Helpful resources:

- US Food & Drug Administration. Interchangeable biological products. https://www.fda.gov/media/151094/downloadAvailable at: https://www.fda.gov/media/151094/download. Last accessed 13 June 2023.
- NHS England. What is a biosimilar medicine? February 2023. Available at: https://www.england.nhs.uk/publication/what-is-a-biosimilar-medicine/ Last accessed 13 June 2023.
- European Medicines Agency (EMA). Biosimilar medicines: Overview. Available at: https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview Last accessed 13 June 2023.

Helpful Information Guides for HCPs and Patients:

- US Food & Drug Administration. Biosimilars Guidances. 2021. Available at: https://www.fda.gov/vaccines-blood-biologics/general-biologics-guidances/biosimilars-guidances Last accessed 13 June 2023.
- US Food & Drug Administration. Biosimilars Basics for patients. March 2023. Available at: https://www.fda.gov/drugs/biosimilars/biosimilar-basics-patients Last accessed 13 June 2023.

- European Medicines Agency (EMA) and the European Commission. Biosimilars in the EU: Information guide for healthcare professionals. 2019. Available at: https://www.ema.europa.eu/en/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf Last accessed 13 June 2023.
- European Medicines Agency (EMA) and the European Commission. What I need to know about Biosimilar Medicines - Information for patients. Available at: https://ec.europa.eu/docsroom/documents/26643 Last accessed 13 June 2023.
- European Specialty Nurse Organisation (ESNO). A communication and information guide for nurses: Switch Management between Similar Biological Medicines. Available at: https://www.esno.org/assets/files/Biosimilars Guideline V2 EN.pdf. Last accessed 13 June 2023.

Interesting blog post:

- Barbier L et al. Biosimilar Interchangeability: Regulatory & Practical Considerations. March 2022. Available at: https://www.biosimilardevelopment.com/doc/biosimilar-interchangeability-regulatory-practical-considerations-0001 Last accessed 13 June 2023.