References

AL-Sabbagh, A., Olech, E., McClellan, J. E., & Kirchhoff, C. F. (2016). Development of biosimilars. *Seminars in Arthritis and Rheumatism*, *45*(5), S11–S18. https://doi.org/10.1016/j.semarthrit.2016.01.002

Alnaqbi, K. A., Bellanger, A., Brill, A., Castañeda-Hernández, G., Ana Clopés Estela, Olga Delgado Sánchez, García-Alfonso, P., Gyger, P., Heinrich, D., Germain Hezard, Kakehasi, A., Koehn, C., Olivier Mariotte, Mennini, F., Sonia Mayra Pérez-Tapia, Pistollato, M., Saada, R., Sasaki, T., Tambassis, G., … Simoens, S. (2023). An international comparative analysis and roadmap to sustainable biosimilar markets. *Frontiers in Pharmacology*, *14*. https://doi.org/10.3389/fphar.2023.1188368

Amaral, C., Rodrigues, A. R., Veiga, F., & Bell, V. (2024). Biosimilar Medicines: From Development Process to Marketing Authorization by the EMA and the FDA. *Applied Sciences*, *14*(17), 7529–7529. https://doi.org/10.3390/app14177529

Andri Wardiana, & Ratih Asmana Ningrum. (2016). The Emergence of Biosimilars in Indonesia: Guidelines, Challenges, and Prospects. *Annales Bogorienses*, *20*(2), 37–46. https://ejournal.brin.go.id/annales/article/view/6574

ASEAN pharmaceutical regulatory policy. (2022). https://asean.org/wp-content/uploads/2022/12/ASEAN-Pharmaceutical-Regulatory-Policy-Sample-Print-REV-20122022-.pdf?utm_source=chatgpt.com

Assawamakin, A., Upakdee, N., & Kongpakwattana, K. (2025). Beyond cost: A value-based framework for biosimilar procurement in emerging markets – the Thai experience. *Journal of Pharmaceutical Policy and Practice*, *18*(1). https://doi.org/10.1080/20523211.2025.2526827

Athalye, S. N., Mittra, S., & Ranpura, A. M. (2023). Biosimilars drug development: time for a paradigm shift? *Generics and Biosimilars Initiative Journal*, *12*(1), 17–22. https://doi.org/10.5639/gabij.2023.1201.005

Bas, T. G., & Oliu Castillo, C. (2016). Biosimilars in Developed and Developing East and Southeast Asian Countries: Japan, South Korea, and Malaysia—Overview, Evolution, and Regulations Assessment. *BioMed Research International*, *2016*, 1–12. https://doi.org/10.1155/2016/5910403

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. https://doi.org/10.1191/1478088706qp063oa

Castañeda-Hernández, G. (2024). Selecting the best-value biosimilar in emerging countries. *Exploration of Musculoskeletal Diseases*, 423–430. https://doi.org/10.37349/emd.2024.00067

Chaoncin Sooksriwong, Ekapong Kachai, Wanruchada Katchamart, Ponlapat Rojnuckarin, Ekaphop Sirachainan, & Tuangrat Phodha. (2025). Biosimilars in practice: Discriminant factors influencing

prescription decisions among physicians in Thailand. *PLoS ONE, 20*(7), e0327591–e0327591. https://doi.org/10.1371/journal.pone.0327591

Cordeiro, M. A., Vitorino, C., Sinogas, C., & Sousa, J. J. (2024). A Regulatory Perspective on Biosimilar Medicines. *Pharmaceutics*, *16*(3), 321–321. https://doi.org/10.3390/pharmaceutics16030321

Dutta, B., Huys, I., Vulto, A. G., & Simoens, S. (2019). Identifying Key Benefits in European Off-Patent Biologics and Biosimilar Markets: It is Not Only About Price! *BioDrugs*, *34*(2), 159–170. https://doi.org/10.1007/s40259-019-00395-w

Farhat, F., Torres, A., Park, W., de Lima Lopes, G., Mudad, R., Ikpeazu, C., & Abi Aad, S. (2018). The concept of biosimilars: From characterization to evolution-A narrative review. *The Oncologist*, *23*(3), 346–352. https://doi.org/10.1634/theoncologist.2017-0126

Feng, K., Miranda, A. V., Obnial, J. C., Ebhodaghe, I. D., & Lucero-Prisno, D. E. (2024). Drug regulatory harmonization in the Association of Southeast Asian Nations: Is it time for an ASEAN medicines agency? A policy review. *Clinical Epidemiology and Global Health*, *28*, 101649. https://doi.org/10.1016/j.cegh.2024.101649

Green, G. M., Read, R. H., Lee, S., Tubon, T., Hunsberger, J. G., & Atala, A. (2021). Recommendations for workforce development in regenerative medicine biomanufacturing. *Stem Cells Translational Medicine*, *10*(10), 1365–1371. https://doi.org/10.1002/sctm.21-0037

Guajardo, N., & Schrebler, R. A. (2024). Upstream and Downstream Bioprocessing in Enzyme Technology. *Pharmaceutics*, *16*(1), 38. https://doi.org/10.3390/pharmaceutics16010038

Haltaufderhyde, K., Roberts, B. J., Khan, S., Terry, F., Boyle, C. M., McAllister, M., Martin, W., Rosenberg, A., & De Groot, A. S. (2023). Correction to: Immunoinformatic Risk Assessment of Host Cell Proteins During Process Development for Biologic Therapeutics. *The AAPS Journal*, *26*(1). https://doi.org/10.1208/s12248-023-00868-5

Heinemann, L., & Hompesch, M. (2014). Biosimilar Insulins. *Journal of Diabetes Science and Technology*, *8*(1), 6–13. https://doi.org/10.1177/1932296813516958

Heriyanto. (2018). Thematic Analysis sebagai Metode Menganalisa Data untuk Penelitian Kualitatif. *Anuva*, *2*(3), 317. https://doi.org/10.14710/anuva.2.3.317-324

Hirsch, I. B., Juneja, R., Beals, J. M., Antalis, C. J., & Wright, E. E. (2020). The Evolution of Insulin and How it Informs Therapy and Treatment Choices. *Endocrine Reviews*, *41*(5). https://doi.org/10.1210/endrev/bnaa015

Hoang, N. T. M., Fatokun, O., & Farrukh, M. J. (2024). Biosimilar drug lag and evolution in Malaysia: A retrospective analysis of regulatory approvals. *Journal of Applied Pharmaceutical Science*, *15*(02). https://doi.org/10.7324/japs.2025.199198

Humphreys, S. Z. (2022). Real-World Evidence of a Successful Biosimilar Adoption Program. *Future Oncology*, *18*(16), 1997–2006. https://doi.org/10.2217/fon-2021-1584

Hyrich, K. L., Watson, K. D, Silman, A. J., Symmons, D. P. M., & British Society for Rheumatology Biologics Register. (2006). Predictors of response to anti-TNF-alpha therapy among patients with rheumatoid arthritis: Results from the British Society for Rheumatology Biologics Register. *Rheumatology (Oxford, England)*, *45*(12), 1558–1565. https://doi.org/10.1093/rheumatology/kel149

Ingrasciotta, Y., Cutroneo, P. M., Marcianò, I., Giezen, T., Atzeni, F., & Trifirò, G. (2018). Safety of Biologics, Including Biosimilars: Perspectives on Current Status and Future Direction. *Drug Safety*, *41*(11), 1013–1022. https://doi.org/10.1007/s40264-018-0684-9

Iskit, A. B. (2025). Biosimilars and Interchangeability: Regulatory, Scientific, and Global Perspectives. *European Journal of Pharmaceutical Sciences*, *213*, 107224. https://doi.org/10.1016/j.ejps.2025.107224

Kabir, E. R., Moreino, S. S., & Sharif Siam, M. K. (2019). The Breakthrough of Biosimilars: A Twist in the Narrative of Biological Therapy. *Biomolecules*, *9*(9). https://doi.org/10.3390/biom9090410

Kawalec, P., Stawowczyk, E., Tesar, T., Skoupa, J., Turcu-Stiolica, A., Dimitrova, M., Petrova, G. I., Rugaja, Z., Männik, A., Harsanyi, A., & Draganic, P. (2017). Pricing and reimbursement of biosimilars in central and eastern European countries. *Frontiers in Pharmacology*, *8*. https://doi.org/10.3389/fphar.2017.00288

Kim, Y., Kwon, H.-Y., Godman, B., Moorkens, E., Simoens, S., & Bae, S. (2020). Uptake of Biosimilar Infliximab in the UK, France, Japan, and Korea: Budget Savings or Market Expansion Across Countries? *Frontiers in Pharmacology*, *11*. https://doi.org/10.3389/fphar.2020.00970

Kuriakose, A., Chirmule, N., & Nair, P. (2016). Immunogenicity of Biotherapeutics: Causes and Association with Posttranslational Modifications. *Journal of Immunology Research*, *2016*, 1–18. https://doi.org/10.1155/2016/1298473

Kvien, T. K., Betteridge, N., Brückmann, I., Bodenmüller, W., Bryn, G., Danese, S., Gonçalves, J., Maravic, Z., Thorne, C., Wingate, L., & Cornes, P. (2025). Beyond Cost: Observations on Clinical and Patient Benefits of Biosimilars in Real-World Settings. *BioDrugs*, *39*(4), 537–553. https://doi.org/10.1007/s40259-025-00727-z

Local production & assistance. (2024). Who.Int. https://www.who.int/teams/regulation-prequalification/lpa/2?

Malaviya, A., & Mehra, N. (2018). A fascinating story of the discovery & development of biologicals for use in clinical medicine. *Indian Journal of Medical Research*, *148*(3), 263. https://doi.org/10.4103/ijmr.ijmr_1471_18

Mascarenhas-Melo, F., Diaz, M., Gonçalves, M. B. S., Vieira, P., Bell, V., Viana, S., Nunes, S., Paiva-Santos, A. C., & Veiga, F. (2024). An overview of biosimilars—Development, quality, regulatory issues, and management in healthcare. *Pharmaceuticals*, *17*(2), 235. https://doi.org/10.3390/ph17020235

McGonigle, P. (2024). How biologics have changed the drug discovery landscape. *Annual Review of Pharmacology and Toxicology*, *65:29–46* . https://doi.org/10.1146/annurev-pharmtox-061724-080811

Meher, B., Balan, S., Mohanty, R., Jena, M., & Das, S. (2019). Biosimilars in India; current status and future perspectives. *Journal of Pharmacy And Bioallied Sciences*, *11*(1), 12. https://doi.org/10.4103/jpbs.jpbs_167_18

Moorkens, E., Vulto, A. G., Huys, I., Dylst, P., Godman, B., Keuerleber, S., Claus, B., Dimitrova, M., Petrova, G., Sović-Brkičić, L., Slabý, J., Šebesta, R., Laius, O., Karr, A., Beck, M., Martikainen, J. E., Selke, G. W., Spillane, S., McCullagh, L., … Simoens, S. (2017). Policies for biosimilar uptake in Europe: An overview. *PloS One*, *12*(12), e0190147. https://doi.org/10.1371/journal.pone.0190147

Moorkens, E., Vulto, A. G., Kent, J., McClure, L., Boldero, R., Vanhove, T., Simoens, S., & Huys, I. (2020). A Look at the History of Biosimilar Adoption: Characteristics of Early and Late Adopters of Infliximab and Etanercept Biosimilars in Subregions of England, Scotland and Wales - A Mixed Methods Study. *BioDrugs*, *35*(1), 75–87. https://doi.org/10.1007/s40259-020-00456-5

MORROW, T., & Felcone, L. H. (2004). Defining the difference: What Makes Biologics Unique. *Biotechnology Healthcare*, *1*(4), 24. https://pmc.ncbi.nlm.nih.gov/articles/PMC3564302/

Niazi, S. K. (2025). Affordable mRNA novel proteins, recombinant protein conversions, and biosimilars—Advice to developers and regulatory agencies. *Biomedicines*, *13*(1), 97. https://doi.org/10.3390/biomedicines13010097

Palinkas, L., Horwitz, S., Green, C., Wisdom, J., Duan, N., & Hoagwood, K. (2015). Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. *Administration and Policy in Mental Health and Mental Health Services Research*, *42*(5), 533–544. https://doi.org/10.1007/s10488-013-0528-y

Patil, N., Ranjan, A., Gaurav, Mukherjee, D., Panda, B. K., Diksha, Komal, Narang, R. K., & Singh, A. (2025). Navigating Biosimilar Regulatory Pathways in Emerging Markets: Insights from BRICS Nations. *Applied Drug Research, Clinical Trials and Regulatory Affairs*, *10*. https://doi.org/10.2174/0126673371316219240929170401

Paul, P., Kapur, R., Mittra, S., Shah, N., K Rao, G., E Erick, M., Umesh, S., & N Athalye, S. (2024). Increasing adoption of quality-assured biosimilars to address access challenges in low- and

middleincome countries. *Generics and Biosimilars Initiative Journal*, *13*(-), 1–15. https://doi.org/10.1016/j.ejps.2025.107224

Rahalkar, H. (2021). Evaluation of the Regulatory Requirements for Development and Approval of Biosimilar Medicines in the BRICS-TM Countries: Improving Patients" Access. *Herts.Ac.Uk*. https://doi.org/https://uhra.herts.ac.uk/id/eprint/16863/1/16075765%20RAHALKAR%20Hasumati%20final%20PhD%20submission.pdf

Rahalkar, H., Sheppard, A., Santos, G. M. L., Dasgupta, C., Perez-Tapia, S. M., Lopez-Morales, C. A., & Salek, S. (2021). Current regulatory requirements for biosimilars in six member countries of BRICS-TM: Challenges and opportunities. *Frontiers in Medicine*, *8*. https://doi.org/10.3389/fmed.2021.726660

Rizwan, A., Dubey, K., Malhotra, V., & Bhatnagar, S. (2026). Biosimilars: Bridging the Gap in Biologics, Access, and Affordability. *Journal of Pharmaceutical and BioTech Industry*, *3*(1), 2. https://doi.org/10.3390/jpbi3010002

Roche. (2023). *Roche | Roche's Annual Report 2023*. Roche.Com. https://www.roche.com/investors/annualreport24

Rémuzat, C., Dorey, J., Cristeau, O., Ionescu, D., Radière, G., & Toumi, M. (2017). Key drivers for market penetration of biosimilars in Europe. *Journal of Market Access &Amp; Health Policy*, *5*(1), 1272308. https://doi.org/10.1080/20016689.2016.1272308

Sampathkumar, K., & Kerwin, B. A. (2024). Roadmap for Drug Product Development and Manufacturing of Biologics. *Journal of Pharmaceutical Sciences*, *113*(2), 314–331. https://doi.org/10.1016/j.xphs.2023.11.004

Scott Morton, F. M., Stern, A. D., & Stern, S. (2018). The impact of the entry of biosimilars: Evidence from Europe. *Review of Industrial Organization*, *53*(1), 173–210. https://doi.org/10.1007/s11151-018-9630-3

Sekhon, B., & Saluja, V. (2011). Biosimilars: an overview. *Biosimilars*, *Volume 1*, 1–11. https://doi.org/10.2147/bs.s16120

Shanmugarajan, D. (2024). An overview of biosimilars. *International Journal of Basic & Clinical Pharmacology*, *14*(1), 117–123. https://doi.org/10.18203/2319-2003.ijbcp20243846

Sheridan, M., Massich, M., & Nazanin Ashourian. (2024). Biosimilars. *Journal of Infusion Nursing*, *47*(1), 19–29. https://doi.org/10.1097/nan.0000000000000528

Shin, G., Han, H., Choi, G., Lee, D., & Bae, S. (2025). Demand- versus supply-side policies in market penetration of biosimilars: Which is more effective? *BioDrugs*, *39*. https://doi.org/10.1007/s40259-025-00721-5

Similar biological medicinal products - scientific guideline | European Medicines Agency (EMA). (2005, October 30). European Medicines Agency (EMA). https://www.ema.europa.eu/en/similar-biological-medicinal-products-scientific-guideline?

Snider, D. M., Pandit, S., Coffin, M. L., Ebrahimi, S. B., & Samanta, D. (2022). DNA-Mediated Control of Protein Function in Semi-Synthetic Systems. *ChemBioChem*. https://doi.org/10.1002/cbic.202200464

Supat Thongpooswan, Das, A., Patil, P., Latymer, M., Llamado, L., & Wee, J. (2024). Physicians' and patients' perception of biosimilars and factors affecting biosimilar prescribing in selected Asian countries: A survey study. *Expert Opinion on Biological Therapy*, *24*(10), 1–12. https://doi.org/10.1080/14712598.2024.2400523

Szkodny, A. C., & Lee, K. H. (2022). Biopharmaceutical Manufacturing: Historical Perspectives and Future Directions. *Annual Review of Chemical and Biomolecular Engineering*, *13*(1). https://doi.org/10.1146/annurev-chembioeng-092220-125832

ten Ham, R. M. T., Hoekman, J., Hövels, A. M., Broekmans, A. W., Leufkens, H. G. M., & Klungel, O. H. (2018). Challenges in advanced therapy medicinal product development: A survey among companies in Europe. *Molecular Therapy - Methods & Clinical Development*, *11*, 121–130. https://doi.org/10.1016/j.omtm.2018.10.003

Thompson, C., Sanchez, J., Smith, M., Costello, J., Madabushi, A., Schuh-Nuhfer, N., Miranda, R., Gaines, B., Kennedy, K., Tangrea, M., & Rivers, D. (2018). Improving undergraduate Life Science Education for the biosciences workforce: Overcoming the disconnect between educators and industry. *CBE—Life Sciences Education*, *17*(3), es12. https://doi.org/10.1187/cbe.18-03-0047

Tinsley, S. M., Grande, C., Olson, K., Plato, L., & Jacobs, I. (2018). Potential of Biosimilars to Increase Access to Biologics: Considerations for Advanced Practice Providers in Oncology. *Journal of the Advanced Practitioner in Oncology*, *9*(7), 699. https://pmc.ncbi.nlm.nih.gov/articles/PMC6570521/

Uppal, A., Chakrabarti, R., Chirmule, N., Rathore, A., & Atouf, F. (2021). Biopharmaceutical industry capability building in India: Report from a symposium. *Journal of Pharmaceutical Innovation*, *17*(4), 1555–1562. https://doi.org/10.1007/s12247-021-09596-9

Vulto, A. G., & Jaquez, O. A. (2017). The process defines the product: what really matters in biosimilar design and production? *Rheumatology*, *56*(suppl_4), iv14–iv29. https://doi.org/10.1093/rheumatology/kex278

Vulto, A. G., Vanderpuye-Orgle, J., van der Graaff, M., Simoens, S. R. A., Dagna, L., Macaulay, R., Majeed, B., Lemay, J., Hippenmeyer, J., & Gonzalez-McQuire, S. (2020). Sustainability of

biosimilars in Europe: A Delphi Panel Consensus with systematic literature review. *Pharmaceuticals*, *13*(11), 400. https://doi.org/10.3390/ph13110400

WHO Technical Report Series, No. 977. (2022, April 22). *Guidelines on evaluation of biosimilars*. Www.Who.Int. https://www.who.int/publications/m/item/guidelines-on-evaluation-of-biosimilars

World bank open data. (2017). World Bank Open Data. https://data.worldbank.org/country/indonesia?