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Review Article

Comparative insights into biosimilar development in the UAE and India: Opportunities, challenges, and global trends

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Abstract

Biosimilars are biological medicines highly similar to approved reference biologics have transformed access to complex therapies by reducing costs and broadening treatment reach. Nearly two decades after the first biosimilar approval, global regulators are increasingly adopting harmonized, evidence-based frameworks that prioritize analytical and pharmacokinetic comparability, reducing the need for extensive clinical efficacy trials. This review examines biosimilar development in the United Arab Emirates (UAE) and India, highlighting regulatory evolution, market growth, and post-COVID policy integration. India has established itself as a global leader, with over 100 approved biosimilars and a market projected to exceed USD 4 billion by 2030, supported by mature frameworks under the Central Drugs Standard Control Organization (CDSCO) and the Department of Biotechnology (DBT). The UAE, meanwhile, is cultivating a dynamic biosimilar ecosystem through regulatory modernization led by the Ministry of Health and Prevention (MOHAP), industrial advancement initiatives, and alignment with WHO and EMA standards. Both countries are leveraging digital transformation to enhance pharmacovigilance, data transparency, and supply-chain resilience. Despite this progress, challenges remain, including regulatory complexity, limited local manufacturing, low market awareness, and unclear interchangeability policies. Yet, the post-COVID landscape presents unprecedented opportunities through AI-enabled bioprocessing, regional regulatory harmonization, and strategic investment in digital health infrastructure. Advancing equitable and sustainable biosimilar adoption in emerging and global markets will require collaborative policy reform, comprehensive stakeholder education, and continued investment in R&D and digital health capacity.

Keywords: Biosimilars, United Arab Emirates (UAE), India, Regulatory Framework, Pharmacovigilance, Digital Health, Artificial Intelligence (AI), Market Access, Global Harmonization, Post-COVID Healthcare.

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1. Introduction

Biosimilars are biological medicines designed to closely replicate their reference biologics, exhibiting no clinically meaningful differences in safety, efficacy, or quality. They provide a cost-effective alternative to expensive biologics, supporting health system sustainability and enhancing equity in patient care. The adoption of biosimilars has become a strategic priority worldwide as healthcare systems face escalating expenditure on biologics and growing demand for advanced therapies. By introducing market competition, biosimilars can reduce prices for both reference and biosimilar products, alleviating financial burdens while sustaining healthcare innovation.[1,2]

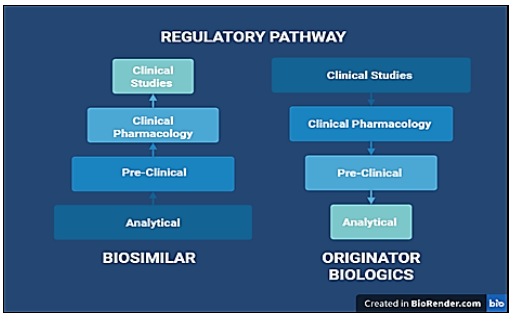

Figure 1: Comparative regulatory pathways for biosimilars and originator biologics, highlighting differences in analytical, preclinical, pharmacological, and clinical study sequencing. Adapted using BioRender.

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Biosimilar development in the UAE aligns with national strategies such as Vision 2030 and Operation 300bn, aiming to expand local pharmaceutical manufacturing and establish a regional biopharma hub.[3,4] Regulatory oversight by The Ministry of Health and Prevention (MOHAP) follows GCC biosimilar guidelines aligned with World Health Organization (WHO) and European Medicines Agency (EMA) standards, emphasizing clinical comparability, ethical marketing, and post-marketing surveillance.[5,6] Integration into reimbursement models, including Abu Dhabi's SEHA network, supports patient access, though adoption is constrained by limited domestic production, low physician and patient awareness, and restricted insurance coverage.[3,4,6] Government incentives, strategic partnerships, and digital health infrastructure foster innovation, strengthen capacity, and monitor post-marketing safety.[3,4,6]

On the other hand, India offers a complementary model with a strong domestic manufacturing base supported by initiatives such as the Biopharma Mission, Make in India, and Biotechnology Industry Research Assistance Council (BIRAC), promoting innovation, global competitiveness, and manufacturing capacity.[7,8] Regulatory oversight is provided by Central Drugs Standard Control Organization (CDSCO) and Department of Biotechnology (DBT) under the 2016 "Guidelines on Similar Biologics," which adopt a stepwise, risk-based approach focused on quality, safety, and efficacy, while Draft 2025 guidelines aim to harmonize Indian standards with WHO and EMA norms.[7,8] Biosimilars are incorporated into public and private healthcare schemes, with challenges including regulatory complexity, patent disputes, and limited clinical adoption. Policy support, R&D investment, and a strong manufacturing base enhance innovation and export potential, positioning Indian manufacturers globally.[8,9]

Despite being less costly than innovator biologics, biosimilar production remains complex, requiring advanced bioprocessing, strict quality control, and skilled expertise.[1,2,10] High investment costs, dependence on imported materials, and IP barriers limit local manufacturing in both countries.[3,4,6,7] Regulatory approaches also differ internationally: the U.S. Food and Drug Administration (FDA) require switching studies for interchangeability, whereas the EMA permits substitution without additional trials, reflecting national policy and market maturity.[1,2] Coordinated regulation, post-marketing surveillance, and education are essential to support safe use and long-term integration of biosimilars in healthcare systems.[3-9] **Figure 1** summarizes the regulatory pathway differences between biosimilars and originator biologics. Adapted from BioRender.com.

This review examines the biosimilar landscape in the UAE and India, evaluates regulatory frameworks and implementation challenges, and situates these national models within the broader global context defined by FDA and EMA standards, identifying opportunities to overcome barriers and promote sustainable adoption in the post-pandemic era.

2. Global Biosimilars Market: Growth and Trends

As of 2025, the global biosimilar market is expanding rapidly, driven by rising demand for affordable biologics, patent expirations, and the growing prevalence of chronic diseases. Valued at over USD 28 billion in 2024, it is projected to exceed USD 120 billion by 2033, reflecting strong annual growth.[11,12] The United States is expected to achieve major savings through broader adoption and increasing FDA approvals, while Europe holding more than half of the global market maintains leadership through robust regulatory frameworks, substitution policies, and clinical acceptance. Growth remains concentrated in oncology, immunology, and diabetes, although high manufacturing costs, evolving regulations, and interchangeability concerns continue to pose challenges.[11,13,14] The major challenges and opportunities associated with biosimilars are summarized in **Figure 2.**

Within this context, the UAE's biosimilar sector remains in a developmental phase but is progressing quickly. Biosimilars accounted for 2% of biologic sales in 2022, valued at USD 96 million, and are projected to reach USD 510 million by 2030 at a CAGR of 23.2%, following the establishment of the Emirates Drug Establishment under Federal Decree-Law No. 38 of 2024.[15,16] Uptake is constrained by limited local R&D, restricted manufacturing capacity, and the absence of substitution policies, with only ten licensed producers and no active pharmaceutical ingredient (API) facilities.[16,17]

Nevertheless, biosimilars are increasingly incorporated into national formularies particularly for oncology and autoimmune diseases resulting in cost savings of up to 31.5%. Strategic measures such as mandatory health technology assessments (HTAs), prescriber accountability, and patient education, along with SEHA's integration of biosimilars into reimbursement frameworks, are improving access and affordability. Collectively, these efforts are positioning the UAE for regional leadership through regulatory innovation and targeted investment.[13-19]

In contrast, India renowned for its biologics manufacturing expertise and supportive regulatory ecosystem is emerging as a global leader in biosimilar development. Its market is projected to reach USD 2.108 billion by 2030 at a CAGR of 25.2% from 2022, while exports, currently USD 0.8 billion, are expected to grow fivefold to USD 4.2 billion by 2030 and USD 30–35 billion by 2047.[11,12] Growth is driven by the high burden of chronic diseases requiring biologic therapies, with biosimilars

improving access in oncology and autoimmune conditions. Leading Indian companies including Biocon, Intas, Dr. Reddy's, Reliance Life Sciences, Zydus Cadila, Lupin, Wockhardt, Panacea Biotec, Emcure, and Torrent reinforce India's global biosimilar leadership.[12-14].

Together, the UAE and India exemplify different but complementary trajectories: while India capitalizes on large-scale manufacturing capacity and export-driven expansion, the UAE focuses on regulatory reform, ethical governance, and health-system integration to strengthen access and establish long-term regional leadership in biosimilars.[13-19]

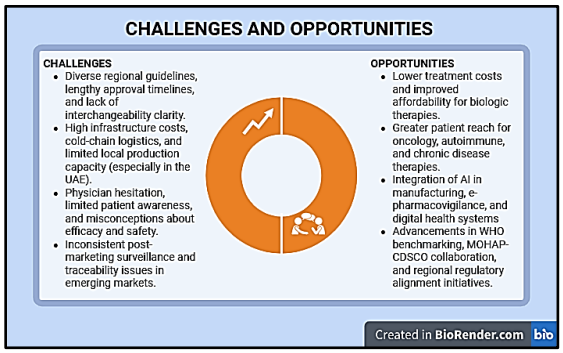

Figure 2: Key challenges and opportunities in global biosimilar adoption.

1. **Challenges:** regulatory complexity, diverse guidelines, lengthy approvals, high infrastructure costs, limited awareness, physician hesitation, inconsistent post-marketing surveillance, low local production. The major challenges and opportunities associated with biosimilars are summarized in **Figure 2.**
2. **Opportunities:** lower treatment costs, broader patient reach, AI in manufacturing and pharmacovigilance, digital health systems, WHO benchmarking, MOHAP-CDSCO collaboration, regional regulatory alignment, enhanced access for oncology, autoimmune, and chronic disease therapies (Source: BioRender). The major challenges and opportunities associated with biosimilars are summarized in **Figure 2**.

3. Global Collaboration in Biosimilar Development

Global collaboration is central to advancing biosimilar development through cross-border partnerships, harmonized regulatory standards, and multilateral forums that enhance global access and confidence in biologics.[10-12] The UAE exemplifies this cooperative approach by aligning its biosimilar strategy with international standards. MOHAP collaborates with regulators such as the U.S. FDA, EMA, and WHO to facilitate scientific data recognition, minimize duplicative testing, and accelerate biosimilar access across the UAE and the wider MENA region.[10–13,15,16] GCC partnerships with Saudi Arabia and Oman further promote regional harmonization through joint dossier reviews, rapporteur systems, and unified evaluation platforms that reduce manufacturer burden while ensuring consistent quality and safety.[13,15,16.]

Collaborative frameworks also extend to ethics, pharmacovigilance, and manufacturing, encompassing initiatives such as the *Code of Ethical Practices*, TRIPS flexibilities, and participation in global pharmacovigilance networks.[8,10,13,14] Industrial cooperation reinforces these policies Julphar's partnership with a European R&D organization to locally produce insulin Glargine illustrates how technology transfer and joint ventures enhance national self-reliance while positioning the UAE as an emerging export hub for biosimilars in Africa, Eastern Europe, and the Middle East.[14,18]

India, meanwhile, demonstrates global leadership through vaccine diplomacy and biosimilar development. As the world's largest vaccine producer, supplying more than 60% of global demand, India strengthened international solidarity during the COVID-19 pandemic under the philosophy of "*Vasudhaiva Kutumbakam* "the world is one family" by providing vaccines, technical assistance, and capacity-building support.[5,6,12] Companies such as the Serum Institute of India, Bharat Biotech, and Biological E leveraged domestic manufacturing strength, while regulatory collaborations such as the CDSCO–FDA Memorandum of Understanding (MoU) advanced data exchange and regulatory convergence.[5,6,10,12] India's strong pharmaceutical base and skilled workforce have enabled leading biosimilar producers including Biocon, Intas, Dr. Reddy's, Reliance Life Sciences, and Zydus Cadila to expand access to affordable biologics in both domestic and international markets.[3,12]

Despite significant progress, challenges persist, including high development costs, batch-to-batch variability, patent evergreening, and divergent regulatory standards that complicate global market entry.[7,10,12] Nevertheless, India's biosimilar sector continues to grow, supported by rising domestic demand and deepening international collaborations.

Together, the UAE and India illustrate complementary pathways to global biosimilar leadership: while the UAE prioritizes regulatory innovation, regional integration, and strategic partnerships to accelerate adoption, India leverages large-scale manufacturing, export expansion, and health diplomacy to establish itself as both the *"Pharmacy of the World"* for generics and a rising global hub for biosimilars.[3,5,8,10-16,18]

4. Regulatory Oversight of Biosimilars in the UAE and India

4.1. UAE

The UAE has positioned biosimilars as a strategic component of its National Innovation Strategy, with biopharmaceuticals expected to account for over half of the pharmaceutical market. Regulatory oversight ensures rigorous comparability data and pharmacovigilance, including public reporting of adverse events to MOHAP, though coordination for timely communication of safety signals to manufacturers could be improved, as observed in Saudi Arabia.[14]

A Gulf task force of rheumatologists, health economists, and other stakeholders reviewed global trial data, particularly for autoimmune diseases such as rheumatoid and psoriatic arthritis. The task force issued consensus recommendations emphasizing regional real-world evidence, shared decision-making, and post-authorization surveillance.[15] Complementary educational initiatives address professional and patient skepticism, while policies discourage preferential prescribing of originators when equivalent biosimilars are available, supporting equitable access and rational medicine use.[16]

The UAE regulates pharmaceutical promotion and professional conduct through MOHAP's Code of Ethical Practices (2017), which covers interactions with healthcare professionals, promotional materials, sponsorship, and research activities.[15] Senior management oversight ensures compliance, with violations subject to penalties under Federal Law No. 4 of 1983.[17] Federal Law No. 8 of 2019 further classifies pharmacy as a public health profession, mandating qualified personnel and licensed pharmacists in every establishment.[18]

Pharmaceutical compounding, permitted in approximately one-third of UAE pharmacies, is regulated under Ministerial Resolution No. 228 of 2023, which defines standards for quality systems, documentation, labeling, and storage.[19] Hospital-based clinical trial collaborations are allowed under strict protocols, while specialized compounding is permitted only when no therapeutic alternatives exist, consistent with international GMP, pharmacovigilance, and quality standards.[20]

The UAE oversees generics, biosimilars, and biologics, with stricter assessment requirements for biologics due to their complexity. The lack of a unified framework in the MENA region led GaBI to host the first regional workshop in the UAE, highlighting differences in clinical data and biosimilar quality standards and emphasizing the need for harmonization.[15,16] Biosimilars are priced 30–70% below originators, with reimbursement prioritizing treatment-naïve patients on the least costly option. HTAs are generally required only for expanded indications, procurement policies discourage frequent brand switching, insurance models favor biosimilars unless clinically justified, and periodic health economic evaluations refine policies according to international best practices.[21]

National biosimilar guidelines define protocols for prescribing, dispensing, and administration, while clarifying regulatory and pharmacovigilance responsibilities. Biosimilars must be registered with MOHAP and, although similar to reference biologics, are not identical. Indication extrapolation and physician-led switching are permitted, but interchangeability requires physician approval, patient consultation, and batch-level traceability. Healthcare teams are responsible for safe use and communicating clinical rationale and cost considerations.[21]

Healthcare delivery in the UAE spans public and private sectors, with private providers delivering most care. Mandatory health insurance makes private insurers central to reimbursement, while MOHAP regulates drug pricing via international reference standards. Fragmented formularies across emirates and insurers, together with variable prescribing policies, create inequities in access to innovative therapies. Experts recommend establishing a national HTA agency, centralized formularies, harmonized coverage, reduced barriers to biologics, and protections for low-income patients to ensure inclusive and sustainable healthcare.[21]

4.2. India

India's biosimilar regulatory framework represents a comprehensive and evolving system that has positioned the country as a key player in the global biologics market. The regulatory oversight is led by the CDSCO, under the Drugs and Cosmetics Act, 1940, and further guided by the New Drugs and Clinical Trials Rules, 2019, as well as the Guidelines on Similar Biologics introduced in 2012 and revised in 2016.[24,25] These guidelines outline a stepwise approach to biosimilar development beginning with analytical characterization, followed by non-clinical and clinical studies to ensure that biosimilars are comparable in quality, safety, and efficacy to their reference biologics.

In 2025, the CDSCO introduced draft revised biosimilar guidelines that signify a major modernization of the regulatory framework.[25] The proposed changes focus on scientific innovation and efficiency, prioritizing advanced analytical and molecular characterization techniques over conventional animal studies. A key highlight of the draft guidelines is the provision for waiving comparative efficacy trials, provided there is strong justification based on robust analytical and PK/PD data. This reform aims to streamline the approval process, reduce development costs, and accelerate patient access to life-saving therapies without compromising safety or efficacy. Once finalized, these guidelines are expected to replace the 2016 version and bring

India's regulatory standards closer to those of the US FDA, EMA, and WHO.[25]

India's progress in biosimilars is also rooted in its strong pharmaceutical manufacturing base, skilled scientific workforce, and supportive government policies that promote biopharmaceutical innovation.[22] Since the approval of its first biosimilar a hepatitis B vaccine in 2000, India has developed one of the world's largest portfolios of approved biosimilars, making high-quality biologics more accessible both domestically and globally.[22,23] Comparison of biosimilar regulatory and promotional frameworks across the US, EU, India, and UAE are depicted in **Table 1.**

However, despite these achievements, several challenges continue to affect India's biosimilar ecosystem. The advisory nature of the current guidelines can lead to regulatory ambiguity and legal uncertainty, particularly in cases involving intellectual property rights. For instance, in the Roche v. Zydus Lifesciences (2024) case, patent disputes delayed the market entry of a biosimilar despite receiving regulatory clearance.[27] Such conflicts highlight the need for better coordination between regulatory and intellectual property frameworks.

To fully realize its potential as a global biosimilar hub, India must address these structural gaps. Strengthening the legal enforceability of biosimilar regulations, harmonizing IP and regulatory approval processes, and increasing investment in research and development (R&D) are essential steps forward. Moreover, fostering collaboration between government, academia, and industry will encourage innovation and help build advanced capabilities in biopharmaceutical manufacturing and analytical testing.[22]

Table 1: Comparison of biosimilar promotion and regulation across the US (FDA), EU (EMA), India (CDSCO), and UAE (MOHAP), highlighting differences in terminology, approval pathways, data requirements, interchangeability, and post-marketing surveillance.

Biosimilar promotion regulations				
Parameter / Aspect	**US**	**EU**	**India**	**UAE**
Regulatory Authority	FDA	EMA	CDSCO	MOHAP
Term / Definition	Follow-on biologics: highly similar to reference product	Biosimilars: equivalent to approved reference product	Similar Biologics: post-patent innovator biologics	Biosimilars: highly similar to authorized biologics
Regulatory Maturity & Laws	Highly mature; BPCIA	Extensive experience; guidance since 2005	Evolving; stepwise adoption	Biosimilar guidelines 2020
Reference Product	FDA-approved	Authorized in EU	Approved in India or recognized market	Approved by SRA/ICH countries
Data Exclusivity	12 years	11 years	Not specified	6 years (case-by-case)
Approval Pathway	351(k) Biologics License Application	Centralized EMA procedure	Biologic License Application	National MOHAP pathway
Interchangeability	Defined; rigorous evidence required	Absent; left to member states	Absent	Case-by-case
Data Requirements	Analytical similarity, animal studies	Purity, biological activity	Analytical, preclinical, clinical	Analytical, preclinical, clinical
Clinical Study Requirements	Mandatory unless waived	Reduced trials based on comparability	Stepwise: analytical, PK/PD, clinical	Stepwise: analytical, PK/PD, clinical
Extrapolation of Indications	Allowed with strong justification	Allowed based on mechanism of action	Allowed with scientific rationale	Allowed with similarity evidence
Naming / Labelling	INN + unique suffix	INN (varies per member state)	INN	INN; no suffix
Post-Marketing Surveillance	Robust REMS, pharmacovigilance	Strong PSUR and safety monitoring	PSUR and safety monitoring	PSUR required; pharmacovigilance in place

5. Safety, Interchangeability, and Regulatory Oversight

In the UAE, biosimilars must be registered with MOHAP and demonstrate that any differences from the reference product do not affect clinical performance or immunogenicity.[28] Marketing Authorization Holders (MAHs) are required to maintain a pharmacovigilance system compliant with UAE Good Vigilance Practice (GVP), including a Qualified Person for Pharmacovigilance (QPPV) and an up-to-date Pharmacovigilance System Master File (PSMF).[28,29] MAHs must submit a Risk Management Plan (RMP) addressing identified and potential safety concerns, post-marketing surveillance, and risk minimization measures.[28,29] Serious

adverse drug reactions (ADRs) must be reported within five working days, non-serious cases within nine days, with follow-up as needed. Post-marketing safety is monitored through Periodic Safety Update Reports (PSURs) or Periodic Benefit–Risk Evaluation Reports (PBRERs), with localized RMP modules applied where relevant.[28,29]

MOHAP strictly oversees manufacturing changes that could affect biosimilar quality, requiring comparability assessments for changes in formulation, production site, or process parameters, and, where necessary, partial or full re-evaluation with stability studies.[29] Biosimilars must also meet traceability and labeling standards, including barcoding and batch-level identification, to support pharmacovigilance.[29] These measures align UAE biosimilar regulation with global best practices while addressing national public health priorities and fostering trust in biosimilar therapies.[29,39]

Promotion and advertising are governed by Federal Law No. 4 of 1983 and Ministerial Decision No. 293 of 2019, ensuring all marketing activities are scientifically accurate, evidence-based, and non-misleading.[30] Promotional materials must reflect approved labeling, including indications, dosing, contraindications, and safety information. Claims of interchangeability with reference biologics are prohibited unless explicitly authorized, and products approved solely for export cannot be promoted domestically without local marketing authorization. MOHAP requires periodic updates to materials to incorporate post-marketing surveillance findings and evolving evidence.[29,39,32]

Overall, UAE biosimilar regulation integrates rigorous pharmacovigilance, strict manufacturing oversight, traceable labeling, and ethical promotion, positioning the country as a regional leader in biosimilar governance and ensuring safe, effective, and transparent use of these therapies[33-36] The major challenges and opportunities associated with biosimilars are summarized in **Figure 2.**

5.1. India

In India, biosimilars are overseen by MAHs, with manufacturers or licensed importers responsible for maintaining product safety throughout the lifecycle.[30,28] After marketing approval, the safety profile evolves as the product reaches diverse patient populations. For biosimilars, the post-marketing phase is critical to identify safety concerns not detected in pre-authorization trials. Oversight and capacity for biosimilar safety monitoring have strengthened since dedicated guidance was introduced in 2018.[30,28]

Continuous post-marketing surveillance detects variations in consistency, immunogenicity, or adverse events. Teams monitor literature, evaluate individual case safety reports, and prepare PSURs in line with national requirements.[30,28] The Risk Management Plan provides a proactive framework to address risks from formulation differences, excipients, or delivery systems, while enabling systematic real-world data collection for signal detection and risk minimization.[30,28,29]

Under the NDCT Rules 2019, MAHs must submit PSURs every six months for the first two years and annually for the next two, report serious and unexpected reactions immediately, and conduct Phase IV safety and immunogenicity studies within two years, with possible exemptions if sufficient evidence exists.[40,28]

Monitoring neutralizing antibodies is emphasized, as they can affect pharmacokinetics, pharmacodynamics, and therapeutic efficacy. Prescribing information must remain consistent with the reference biologic, except where justified formulation or presentation differences exist, and safety information must not be omitted even if certain indications are excluded.[28,29] These measures ensure biosimilars maintain favourable benefit–risk profiles and strengthen clinical confidence.[30,45]

Interchangeability allows substitution for the reference biologic without compromising safety or efficacy. Labeling must define the biosimilar–reference relationship, including a biosimilarity statement, key characteristics, and prescriber guidance on approved indications and dosing.[30,43] Interchangeable biosimilars require distinct identifiers, such as proprietary names or manufacturer-specific suffixes, to ensure traceability.[46,31,32] Examples include Cimelri (ranibizumab-eqrn) with Lucentis and Semglee (insulin glargine-yfgn) with Lantus, allowing pharmacy-level substitution to improve access and affordability.[31,32] Cost reductions reflect regulatory efficiencies, not compromised safety or quality.[28,30]

This integrated strategy, combining rigorous post-marketing surveillance with transparent interchangeability criteria, ensures biosimilars meet the same high standards of safety, quality, and efficacy as reference biologics. By fostering a robust safety culture, clear labeling, and continued data-driven oversight, patient welfare is safeguarded while promoting broader access and affordability, reinforcing India's global leadership in biosimilar development and regulatory innovation.[30,46,47]

6. Immunogenicity and Clinical Evaluation in Biosimilar Development

Immunogenicity remains a critical consideration in the development of biosimilars, as these complex therapeutic proteins can provoke immune responses that affect safety and efficacy. Anti-drug antibodies (ADAs) may neutralize the therapeutic effect or increase drug clearance, leading to reduced pharmacological activity and potential adverse reactions such as infusion-related or autoimmune events.[48,49,50] Regulatory authorities, including the EMA and the FDA, require comprehensive immunogenicity assessment to ensure that biosimilars do not elicit higher ADA responses than their reference products, thereby confirming clinical and

immunological comparability and safeguarding patient safety.[48,49,51]

Structural attributes such as glycosylation profiles, aggregation tendencies, formulation changes, and process-related impurities can influence a biosimilar's immunogenic potential.[48,49,50] To address these risks, current regulatory practice employs a tiered testing approach beginning with ADA screening assays, followed by confirmatory specificity, titration or characterization, and neutralizing antibody (nAb) analyses to establish both the presence and clinical relevance of immune responses.[48,49,52] Sensitive, drug-tolerant assay platforms, including Gyrolab and ADCC reporter systems, are increasingly used to detect low-level immune reactivity with greater precision.[49,53]

Clinical trials are designed to evaluate the effects of ADAs on pharmacokinetics, efficacy, and safety, while post-marketing surveillance, including pharmacovigilance programs and Post-Authorization Safety Studies (PASS), continues to monitor delayed or long-term immune-mediated outcomes.[50,52,51] For biosimilars with well-characterized and inherently low immunogenic potential such as certain insulin or filgrastim products regulators may permit reduced clinical study requirements if robust analytical and in vitro comparability data are available.[48,50] Effective immunogenicity management thus relies on coordinated efforts among regulators, manufacturers, and clinicians, integrating comparability studies, risk-based monitoring, and clear prescribing guidance to ensure sustained therapeutic safety and performance.[48,50,54]

7. AI and Digital Transformation in Biosimilar Monitoring

The UAE's digital health ecosystem underpins advanced post-marketing surveillance for biosimilars, integrating real-time data, AI-driven decision-making, and evidence-based oversight. MOHAP's AI-powered Digital Health Monitoring Centre centralizes health information, facilitates early warning systems, and informs policy using national and global health data.[55] Complementing this, the EHS 2023–2026 roadmap promotes telemedicine, predictive analytics, and smart hospital initiatives such as Care AI and the Digital Twin, enhancing operational efficiency, sustainability, and regulatory oversight.[56,57]

The COVID-19 pandemic accelerated the adoption of AI and mobile applications for vaccination management, virtual consultations, and risk prediction, improving patient safety, resource allocation, and healthcare access.[56,57] Biosimilar monitoring benefits from platforms including MOHAP's Riayati, DHA telehealth, and EHR-linked pharmacovigilance systems, enabling centralized reporting, real-world data analysis, and proactive risk management while ensuring privacy compliance.[55-57] For biosimilar insulin, continuous glucose monitors, insulin pumps, and mobile applications facilitate real-time adherence tracking and post-marketing safety evaluation.[58,59]

Regulatory oversight for AI and digital health is robust. Abu Dhabi's Department of Health established the region's first healthcare AI policy in 2018, emphasizing patient safety, data privacy, transparency, and ethical accountability, while Dubai's Ethical AI Guidelines (2021) provide a self-assessment toolkit and promote expert oversight for AI-driven decision-support systems,[55,59] Software as a Medical Device (SaMD), including AI applications, is regulated by MOHAP and the Drug Control Department in alignment with EU MDR and U.S. FDA guidance, with devices classified according to risk and subject to periodic registration.[55,59]

Centralized health data management through EMRs integrated with the NABIDH platform supports secure data exchange, real-time analytics, and interoperability.[56,57] Legal safeguards are enforced via Federal Law No. 2 of 2019, Federal Decree-Law No. 45 of 2021 classifying health information as sensitive personal data, and Federal Decree-Law No. 34 of 2021 on cybersecurity, which penalizes unauthorized access and promotion of unlicensed medical products.[56]

In biosimilar research and development, AI and machine learning streamline production, enhance precision, and reduce development timelines through in silico modelling and analysis of complex biological data.[60,- 62] IoT-enabled real-time monitoring ensures batch consistency and minimizes deviations, while predictive simulations and AI-assisted biomarker identification support efficient, targeted clinical trials with smaller cohorts.[58,60,62] Big data analytics guide decision-making from molecular design to commercialization, reducing biosimilar production costs compared with originator biologics. AI also strengthens pharmacovigilance by integrating patient-reported outcomes, detecting rare or long-term adverse events, and supporting compliance with regulatory "totality of evidence" requirements.[58,60]

Through this integrated approach, the UAE leverages digital health, AI, and advanced data systems to ensure biosimilar safety, traceability, and affordability, establishing itself as a regional leader in digital healthcare and technology-enabled pharmacovigilance.[55-62]

7.1. India

India is rapidly advancing healthcare through digital technologies and AI, enhancing access, efficiency, and patient-centered care while supporting biosimilar development and post-marketing surveillance. The CDSCO SUGAM portal facilitates online submissions, real-time tracking, and digital approvals for pharmaceuticals, medical devices, and biosimilars, following guidelines emphasizing stepwise development, in vitro studies, and reduced animal testing. Preclinical applications are submitted through the

Review Committee on Genetic Manipulation (RCGM) portal, clinical trial applications via SUGAM under the DCGI, and marketing authorization applications are filed in eCTD format through CDSCO systems.[56,62]

Broader initiatives such as Make in India strengthen efficient management of large-scale health data, supporting regulatory oversight and innovation.[62] Despite these advancements, challenges remain, including limited standardization, concerns around data privacy and governance, ethical issues like informed consent, and socioeconomic barriers affecting vulnerable populations.[56,62]

AI plays a pivotal role across the biosimilar lifecycle. Platforms such as DeepChem, GraphConv, ChemBERTa, and GENTRL employ deep learning, graph-based models, and reinforcement learning to predict molecular properties and generate novel compounds.[60,62] In precision medicine, tools like Tempus analyse genomic data to guide personalized treatments.[63,64] AI also evaluates critical quality attributes of biosimilars compared with reference products using graph neural networks, ensuring safety and consistency.[60,62]

In manufacturing, AI enhances cell line development, process control, and real-time monitoring, improving batch consistency and reducing variability.[60,62] During clinical trials, AI supports patient selection, predicts immunogenicity risks, identifies key endpoints, and analyses omics data, particularly advancing personalized therapies in oncology.[63,64] For regulatory submissions, AI consolidates analytical, preclinical, and clinical data into comprehensive "totality of evidence" packages and anticipates regulatory queries using predictive models based on historical approvals.[60,62]

Post-approval pharmacovigilance benefits from AI, enabling rapid analysis of real-world data from patient registries and early detection of adverse events. Machine learning identifies patterns of biosimilar-adverse effects, while unsupervised models monitor deviations relative to reference products. Compliance with privacy regulations, including General Data Protection Regulation (GDPR) and India's data protection framework, ensures transparency and interpretability of AI models, strengthening regulatory confidence and enabling collaboration with international agencies such as the FDA and EMA.[59,60,63-65]

8. International Reference Pricing for Pharmaceuticals

Pharmaceutical pricing in the MENA region is influenced by varying levels of universal health coverage (UHC) and reliance on External Reference Pricing (ERP). The UAE and Saudi Arabia achieve over 80% UHC, whereas Egypt and Morocco cover only around 30%, leaving many patients to bear significant out-of-pocket costs.[69,70] ERP is commonly used alongside origin-country prices, GCC member state prices, and HTA references. In practice, ERP focuses on cost-minimization rather than value-based pricing, which can create administrative burdens and delay product launches.[69,71] For patented drugs, prices are typically set at the lowest value among the origin-country ex-factory price, proposed import price, or the median CIF from reference countries, with adjustments based on therapeutic importance and comparison with similar registered drugs.[70,71]

Generic pricing follows a capped model below the innovator, with market competition driving further reductions. In the UAE, imported generics are initially priced at the lowest benchmark value, with additional discounts applied for later entrants. Locally manufactured generics are set below innovator prices, while partially local generics follow imported-product rules. These measures aim to balance affordability with the promotion of local pharmaceutical production.[69,70]

The UAE healthcare system is administered by federal and local authorities, including MOHAP, the Dubai Health Authority (DHA), and the Department of Health (DOH) Abu Dhabi. While public institutions provide care, the private sector delivers approximately 70% of outpatient services and over 40% of inpatient services. Total healthcare spending is around USD 1,200 per capita.[71] Mandatory health insurance has shifted the funding landscape, with private spending now covering about half of total expenditure. Over 60 insurers serve a population of 9.3 million, resulting in fragmented reimbursement and emirate-specific formularies. Access to innovative therapies depends on insurance tier, with government schemes supporting nationals and low-income expatriates. MOHAP oversees drug approval, authorization, and pricing, while DHA and DOH manage regional access and reimbursement. The absence of a unified reimbursement code and inconsistencies among payers hinder timely market access, highlighting the need for a national HTA agency to streamline pricing and ensure equitable access to medicines.[71] The major challenges and opportunities associated with biosimilars are summarized in **Figure 2**.

8.1. India

India's biosimilar sector is regulated under the Drugs (Prices Control) Order (DPCO) and overseen by the National Pharmaceutical Pricing Authority (NPPA), which sets ceiling prices for essential and life-saving drugs, including biologics.[70,71] Biosimilar prices generally follow a price-link policy, applying a fixed discount of 15–30% relative to the reference product.[72]

The NPPA, under the Department of Pharmaceuticals, ensures affordable access, monitors compliance and availability, advises on policy, and establishes ceiling prices for scheduled formulations. India's pharmaceutical industry, the third largest globally by volume, is a major supplier of generics, vaccines, and anti-retroviral drugs, valued at USD 50 billion and projected to reach USD 130 billion by 2030.

Regulatory oversight supports public health and economic well-being, particularly for vulnerable populations.[70,71]

Public platforms such as Pharma Sahi Dam and Pharma Jan Samadhan, supported by IPDMS 2.0, provide price information and grievance redressal. Manufacturers must price scheduled formulations at or below NPPA ceilings; non-compliance incurs repayment, interest, and penalties. Ceiling prices are revised annually, with reductions after patent expiry. Regulation applies to controlled or scheduled drugs, while patented drugs enjoy a five-year exemption, and market-based pricing applies elsewhere. The NPPA also monitors drugs on the National List of Essential Medicines, including paracetamol, insulin, and antibiotics.[72,73]

Pricing and reimbursement policies aim to balance affordability, accessibility, and sustainability while incentivizing R&D and innovation. Coverage is provided through public schemes, private insurers, public undertakings, and self-funded programs, although out-of-pocket spending exceeds 45% of total healthcare costs, with roughly 70% of the population under some form of health insurance.[70,72,74] Key payer schemes include:

1. **Government-subsidized health insurance:** Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (PMJAY, 2018) provides full coverage for secondary and tertiary hospitalization, including prescribed medicines, to over 12 crore vulnerable families (~40% of the population).[70]

2. **Social health insurance:** Employer–employee funded programs such as the Central Government Health Scheme (CGHS) and Employee State Insurance (ESI) Scheme cover outpatient, inpatient, and medicine costs for government employees and organized sector workers, with similar state-level schemes for local populations.[70]

3. **Private voluntary health insurance:** Regulated by the Insurance Regulatory and Development Authority of India (IRDAI), private insurers offer individual and group policies that reimburse healthcare costs, including medicines, according to policy terms.[70,74]

Drug pricing and reimbursement in India are shaped by regulatory, economic, and policy considerations, balancing patient access, healthcare sustainability, and incentives for innovation. Challenges include reduced profitability, uncertainty in price revisions, inconsistent DPCO application, and limited authority for NPPA to enforce penalties, potentially impeding innovation.[72,73] Affordability of non-DPCO drugs, variations in reimbursement formularies, and complex approval processes may also delay access.

Rising population and lifestyle-related diseases increase pharmaceutical demand, straining supply chains and raising production costs. Budget constraints in government-funded insurance schemes, limited rural infrastructure, intellectual property rights, international pricing trends, supply chain disruptions, and fluctuations in input costs and inflation further influence drug prices and manufacturer cost recovery. Together with market dynamics, these factors shape public and private sector responses to reimbursement policies and the scope of price controls.[70-74]

9. Post-COVID impact on Biosimilar Development

The COVID-19 pandemic temporarily disrupted biosimilar development in both the UAE and India, affecting supply chains, clinical trials, and healthcare operations. In India, biosimilar manufacturing faced raw material shortages, reliance on China for key active pharmaceutical ingredients, and limited staffing at trial sites due to quarantine measures, while hospital-based services were partially constrained [75-78] In the UAE, regulatory processes and healthcare operations experienced short-term delays, but government incentives, streamlined approvals, and public–private collaborations enabled a rapid recovery.[79-81]

Despite these disruptions, both countries leveraged the pandemic as a catalyst for digital transformation and AI integration in biosimilar development and monitoring. In the UAE, initiatives under Vision 2021 and Operation 300bn employed predictive analytics, blockchain, and IoT-enabled monitoring to enhance supply chain transparency, pharmacovigilance, and biosimilar surveillance.[82-84] Digital platforms, including MOHAP's AI-powered monitoring centers, EHR-linked pharmacovigilance, and telemedicine systems, facilitated real-time reporting, early detection of adverse events, and evidence-based policy while maintaining patient privacy.[85]

Similarly, India accelerated digital health adoption, with the Ayushman Bharat Digital Mission (ABDM), CoWIN, and Aarogya Setu enabling real-time tracking, patient-provider connectivity, and inclusive health record management.[76,77] AI-supported platforms optimized biosimilar manufacturing, monitored treatment adherence, predicted patient outcomes, refined clinical trial designs, and consolidated regulatory submissions, ensuring continued supply and robust post-marketing surveillance[78,79] Sector-wide programs such as Make in India, the Biopharma Mission, and BIRAC maintained uninterrupted biosimilar availability for both domestic and international markets, even during periods of disruption.[77]

The pandemic also highlighted the importance of resilient regulatory and reimbursement frameworks. In the UAE, integration of biosimilars into insurance schemes and national formularies ensured cost-effective utilization while preserving safety, traceability, and clinical oversight.[79,75] In India, regulatory guidance enabled continuous monitoring of adverse drug reactions, real-world evidence collection, and compliance with pharmacovigilance requirements, despite operational constraints.[78,76]

Overall, COVID-19 exposed vulnerabilities in biosimilar supply chains and clinical trial operations but simultaneously accelerated policy innovation, digital health adoption, and AI-driven oversight. These developments strengthened post-marketing surveillance, optimized production and clinical evaluation, and ensured equitable patient access. Both the UAE and India now exemplify resilient, technology-enabled biosimilar ecosystems, demonstrating the capacity to maintain safe, affordable, and accessible biologic therapies under pandemic conditions.[75-85]

10. Conclusion

The global biosimilar landscape is rapidly advancing as nations strive to balance innovation, affordability, and regulatory rigor. India and the UAE exemplify this evolution, India through its robust pharmaceutical manufacturing base and progressively evolving regulatory framework, and the UAE through strategic investments, forward-looking healthcare reforms, and a strong commitment to quality and ethics. Both countries demonstrate growing alignment with global standards, emphasizing modernization, ethical efficiency, reduced reliance on animal testing, and strengthened risk management systems. Despite these strides, challenges persist, including regulatory complexity, legal and policy gaps, manufacturing intricacies, brand loyalty, and limited stakeholder awareness. Addressing these barriers through enhanced regulatory transparency, greater international harmonization, and closer collaboration among regulators, industry, and healthcare providers will be essential to unlocking the full therapeutic and economic potential of biosimilars. Overall, this review highlights that coordinated innovation, ethical oversight, and strategic policy alignment can position India and the UAE as regional leaders in biosimilar development. By advancing harmonized frameworks and fostering stakeholder confidence, both nations are well poised to transform biosimilars into a cornerstone of accessible, high-quality, and sustainable healthcare in the post-pandemic era.

11. Declarations

Ethics approval and consent to participate. Not applicable.

12. Authors' Contributions

B.K.A and J.R conceptualised, wrote, and reviewed the manuscript.

13. Data Availability

No datasets were generated or analysed during the current study.

14. Source of Funding

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15. Competing Interests

The authors declare no competing interests.

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