Drivers and barriers of biosimilar uptake in APAC

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Introduction

In APAC, biosimilars represent an opportunity to generate substantial savings, with the market size expected to reach about $25–30 billion[1] by 2030

The region's regulatory environment for biosimilars is fragmented, with inconsistent access & reimbursement frameworks, unlike the centralized systems in the US and EU. Challenges such as limited pricing controls, low physician awareness, and infrastructure issues hinder adoption

Objective

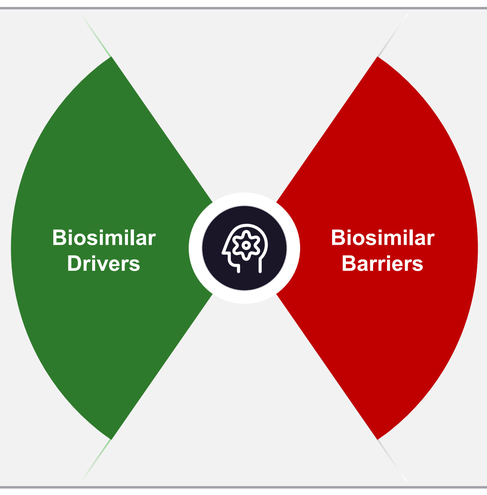
The objective of this study is to comprehensively identify and analyze the primary enablers and barriers that influence biosimilar adoption within APAC healthcare systems. By exploring drivers as well as obstacles including regulatory complexity, market access challenges, and variable provider/patient perceptions, this research aims to offer actionable insights that support wider and more effective biosimilar integration into patient care. The findings will guide stakeholders on strategies to reduce costs and improve access through optimized biosimilar uptake

Approach

A targeted literature review was conducted to examine policies, prescribing guidelines, and reimbursement requirements for biosimilars across 11 APAC countries. Major countries were compared using key variables such as regulatory clarity, market access and affordability, stakeholders' willingness to adopt biosimilars over reference products and ranked to identify major drivers and barriers influencing biosimilar adoption

Results

- High burden on health budgets - biosimilars positioned as cost-savers (e.g. SG saved ~SGD136M, 2018–22)[2]
  - Expanding public insurance coverage (KOR NHI reimbursement)
- Local manufacturing strength - Strong domestic manufacturers: IN (Biocon, Dr. Reddy's), KOR (Celltrion, Samsung)
- Streamlined regulatory frameworks for approvals and launches (IN CDSCO, KOR MFDS, TW TFDA, SG HSA)
- Growing patient demand



- Low stakeholder education – physician safety concerns regarding biosimilars due to lack of education continue to impede adoption, as evidenced in markets such as HK and VN
- Lack of streamlined initiatives/policies - formulary bottlenecks emerge from prolonged hospital procurement processes and widespread absence of automatic substitution policies
  - Regulatory friction - systematic delays in biosimilar approvals for e.g., VN's stringent SRA reference mandates
- Supply-demand misalignment - KOR's 43% share of APAC manufacturing capacity contrasted with only 29% domestic biosimilar uptake[3]

1 Regulatory clarity

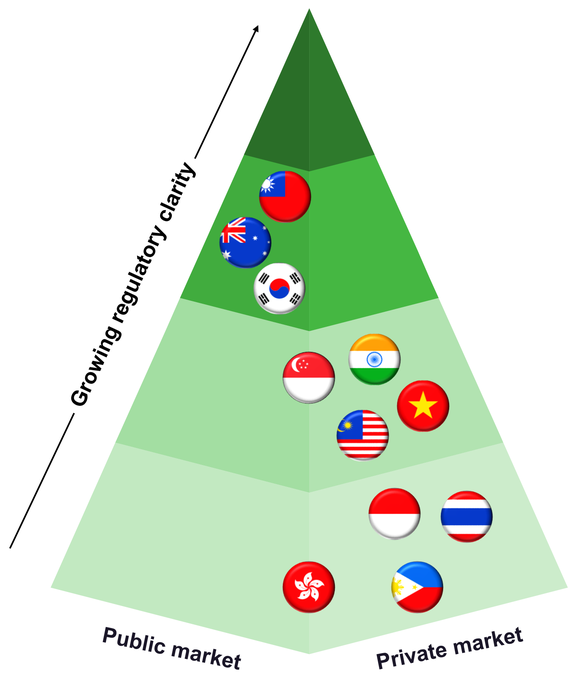


Figure 1. APAC regions regulatory clarity on biosimilar pricing and reimbursement

- In public markets, TGA (AU), MFDS (KOR), and TFDA (TW) have comprehensive frameworks aligned with international standards, with TGA permitting pharmacist substitution of 'A-flagged' biosimilars to boost uptake
- In private markets, ID (NADFC), TH (THFDA), PH (PHFDA), and HK (DH) enforce strict international-aligned oversight that can limit entry, while IN (CDSCO), MY (NPRA), VN (DAV), and SG (HSA) demonstrate stronger guideline implementation and regulatory maturity

2 Market access and affordability

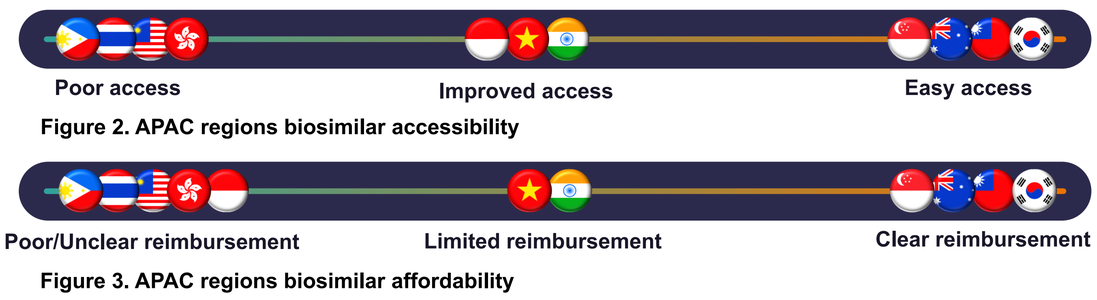


Figure 2. APAC regions biosimilar accessibility

Figure 3. APAC regions biosimilar affordability

- KOR enforces mandatory price cuts and incentivizes local biosimilars, while AU benchmarks the lowest molecule price and requires originators to reduce prices by ≥25%
- TW sets biosimilar entry at 85% of originators with later adjustments, and SG reimbursement drives prices 80–90% below reference products
- ID's UHC covers basic biologics but limits high-cost biosimilars, while VN relies on hospital tenders and IN offers 30–40% discounts in mostly private-pay markets
- Rest of the markets like MY (30–50% lower) and HK (50–80% lower) see reduced prices but limited reimbursement restricts uptake. TH includes select biosimilars in universal schemes, whereas PH's PhilHealth offers near-universal coverage but lists only a few biosimilars

3 Stakeholder perception

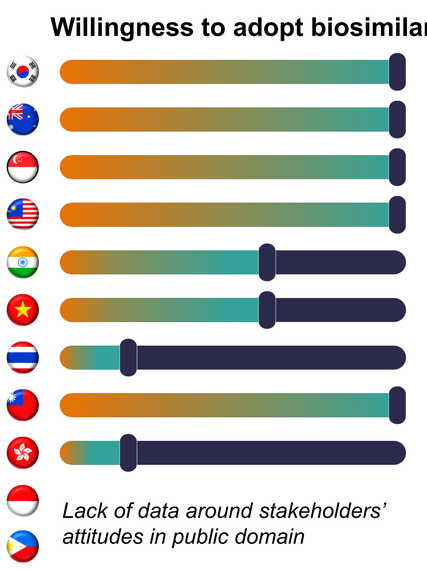


Figure 4. Stakeholders' willingness to adopt biosimilar vs. reference product

- Stakeholders in countries like KOR, AU, SG, MY, TW actively adopt biosimilars, driven by policy and budget priorities
- Despite rising willingness, substandard quality of biosimilars hinder stakeholder trust despite growing adoption in VN
- In IN, lower costs drive physician uptake, but limited patient awareness and affordability restrict market expansion
- In HK, limited awareness and lower biosimilar use sustain safety and efficacy concerns; in TH, physicians endorse biosimilars as first-line, expanding patient access and supporting equivalence with reference products

4 Impact on biosimilar adoption

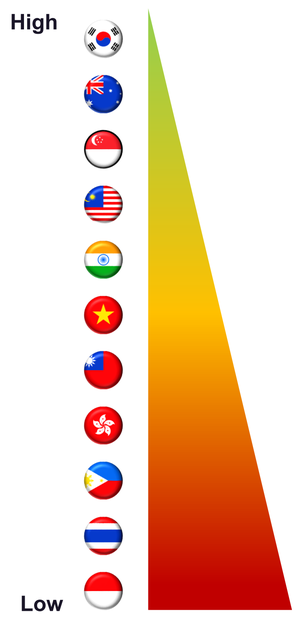


Figure 5. Biosimilar adoption in APAC regions

- Biosimilars dominate cancer drug markets in KOR (>60% in 2020) and SG (>95% with >80% price cuts)
  - Uptake is rising in AU through government–industry support, while MY adoption grows steadily, with generics and biosimilars making up 75% of prescriptions
- IN and VN show sharp growth, with IN's adoption jumping from 18% in 2014 to 88% in 2020, though regulatory and access gaps persist.
- TW, PH, HK, and ID have lower uptake due to policy, pricing, and reimbursement barriers, but regulators are pushing adoption: PH (Medicines Policy 2022–2030), TH (Thailand 4.0 for research and collaboration), TW (targeting 30% by 2027 with NHIA support), and ID (policy-driven encouragement

Conclusion

The APAC region is at a pivotal stage in biosimilar adoption, with the potential to reshape healthcare delivery and generate major cost savings by 2030:

- **Monitoring regulatory and access evolution -** Addressing the differences in approval pathways and access policies supports more predictable and timely access to biosimilars
- **Enhancing the value proposition -** Biosimilars can create additional value through innovative delivery routes, patient engagement initiatives, and adherence support. Long-term real-world evidence further strengthens trust and confidence among HCPs and patients
- **Access and affordability considerations -** Participation in public procurement systems and national listing processes can expand reach and improve availability of biosimilars. Balancing affordability with sustainable pricing strategies is key to ensuring broader patient access and healthcare system stability

References: 1. APAC Biosimilars Market Size, Share, Trends & Growth Forecast Report. *Market Data Forecast 2025-2033*; 2. She Hui Tan, et al. Impact of Value-Driven Healthcare Strategies for Biosimilar Adoption: The Singapore Story. *PharmacoEconomics – Open* 2024; 3. S. Panda, et al. Indian Biosimilars and Vaccines at Crossroads–Replicating the Success of Pharmagenerics. *Vaccines* 2023. Additional detailed sources in supplementary material

Limitations: Results based on review articles and secondary desk research available on public domains. Countries were selected based on the availability of the information to rank key variables

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