MALAYSIAN JOURNAL OF SCIENCE
MJS
ISSN 1394 - 3065

MAHSA International Medical Sciences and Technology Conference (Mi-MED) 2024 Special issue

Malaysian Journal of Science 44 (Special Issue 1): 8-18 (December 2025) https://mjs.um.edu.my

Policy Elements Influencing the Sustainability of the Biosimilar Market in Malaysia: A Review

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Abstract:
Sustaining the market for biosimilars is key to securing the long-term benefits from biosimilar medicines. Policy can influence the achievement of those elements that contribute to the sustainability of biosimilars. Despite being the first country to implement regulatory guidelines for the approval and marketing of biosimilars, the availability and adoption of biosimilars in Malaysia remain suboptimal. This study aims to create the roadmap of policy elements that influence the sustainability of the biosimilar market in Malaysia. The study searched and reviewed articles in PubMed, Google Scholar, National Library of Medicine from 1/1/2003 to 14/04/2024. A total of 3469 results were found, with PubMed contributing 39 records (n=39), Google Scholar contributing 3074 records (n=3074), and the National Library of Medicine contributing 356 records (n=356). The biosimilars policy framework and sustainability measures were adopted from IQVIA Country Scorecards for Biosimilar Sustainability. After eliminating duplicates and applying selection criteria, 20 articles were chosen for review. The selection was justified based on relevance to the five policy domains: regulatory environment and clinical guidelines, awareness and education, incentives, pricing rules and dynamics, and purchasing mechanisms. The 20 selected papers were categorized into five main domains: regulatory environment and clinical guidelines, awareness and education, incentives, pricing rules and dynamics, and purchasing mechanisms. The analysis revealed positive developments in regulatory compliance and clinical guidelines, pricing regulations, and purchasing mechanisms. However, challenges were identified in the areas of awareness and education, pricing rules and dynamics, and incentives. Awareness and education challenges were primarily attributed to limited pharmacist training and physician skepticism regarding biosimilars. Additionally, the absence of strong financial incentives and limited patient education hindered adoption. The "single-winner tendering system" constrained market diversity, restricting competitive pricing. The literature review emphasizes the need for setting up specific prescription targets, promoting competition, and offering incentives to biosimilar manufacturers to increase market appeal. Furthermore, it is critical to enforce strict quality standards for the incorporation of tenders and align the registration requirements with global standards. Education for pharmacists and continuous training for healthcare practitioners are also essential. In Malaysia, these steps are crucial in ensuring the affordability and accessibility of biosimilars. Improving these policy components could help Malaysia create a competitive biosimilar market, increase access to affordable treatments, and eventually raise the standard of healthcare service.

Keywords: biosimilars market Malaysia, sustainability, biosimilars policy, biosimilar regulatory guidelines, literature review.

1. Introduction

Biological therapies, often known as biologics, contain therapeutic proteins and monoclonal antibodies. These are complex and big molecules that are commonly generated in manipulated organisms, such as modified bacteria. Biological therapies are a significant breakthrough in treating chronic, debilitating, as well as fatal diseases such as cancer, neurological disorders, and autoimmune diseases (Baumgart et al., 2019; Chopra & Lopes, 2017). However, they are often associated with high costs and limited patient access (Chopra & Lopes, 2017; Nahleh et al., 2022). For example, while biologics make up only 2% of all prescriptions in the US, they contribute to $120 billion, or 37%, of the entire expenditure on drugs. Additionally, since 2014, they have accounted for 93% of the overall increase in total expenditures (Lexchin, 2020; Makurvet, 2021). Similar observations have been reported in other countries (Simoens & Vulto, 2021). Biologicals made up 35% of Colombia's pharmaceutical business in 2015 (Makurvet, 2021). In Malaysia, like in other nations, the expense of innovative biologics imposes financial restrictions on the healthcare system, leading to limited patient access to these medicines (Khean, 2014; Su-Lyn, 2020). Malaysia faces the multifaceted challenge of improving public standards along with escalating health expenditures, a scenario similar to that of numerous middle- and upper-income countries (Kananatu, 2002). This forces the government to look for viable options for sustainable financing moving forward. In 2010, the estimated per capita health expenditure in PPP international US dollars reached $641, surpassing the median expenditure of $589 for upper-middle-income countries in that year (Khan et al., 2016; WHO, 2012; Yun & Yusoff, 2015). Malaysia does not allocate substantial resources to health expenditures. In 2010, the estimated total health expenditure constituted 4.4% of GDP,

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Received: May 11, 2025
Accepted: July 17, 2025
Published: December 12, 2025

DOI: https://doi.org/10.22452/mjs.vol44sp1.2
Malaysian Journal of Science 44 (Special Issue 1): 8-18 (December 2025)

situating it within the mid-range of high and middle-income nations in Asia, albeit beneath the international average of 6.1% GDP for upper middle-income countries (WHO, 2012; Zamzairee & Muhamad Hanafiah Juni, 2019). The annual growth rate in Total Health Expenditure (THE) has exhibited considerable variability since the year 2000, ranging from 6.4% to 20.8% (WHO, 2012). In 2004, Malaysia achieved a ranking of 59th in the UN Human Development Index, whereas its neighboring countries, Thailand and Indonesia, were positioned at 76th and 111th, respectively (EIU, 2005). According to the most recent data from the Malaysia National Health Accounts (MNHA) Health Expenditure Report, Malaysia spent RM78.2 billion, or 5.1% of GDP, on healthcare in 2021. Total Health Expenditure (THE) for Malaysia from 2011 to 2021 has steadily increased. The proportion of GDP attributed to THE varied between 3.9% and 5.1% across the same time period. The substantial growth in the value of THE in 2021 caused the proportion of THE to GDP to rise (MOH Malaysia, 2021).

In many health systems worldwide, biosimilars are considered a crucial tool for containing growing pharmaceutical spending. The entry of biosimilars into the market has been demonstrated not only to affect pharmaceutical costs but also to improve patient access to biological therapies (Advancing Biosimilar Sustainability in Europe - IQVIA, 2018). The primary goal of biopharmaceutical policy should be to establish a market that is both competitive and sustainable, consisting of off-patent reference biologics, biosimilars, and next-generation biologics. This market should ensure that biologic therapy is accessible to patients at the most affordable price possible (Simoens & Vulto, 2021). The initial regulatory framework for the commercialization of biosimilars was implemented in Europe in 2005, leading to the approval of the first European biosimilar in 2006. As of June 2023, the European Medicines Agency had granted approval to a total of 94 biosimilars (EMEA, 2023). Malaysia became one of the first countries worldwide in 2008 to adopt regulatory guidelines for the approval and marketing of biosimilar medicines. The guiding document and guidelines for the registration of biosimilars in Malaysia were completed in August 2008. The guidance document incorporates the entire set of scientific biosimilar guidelines from the European Medicines Agency (EMA), including both the product-specific guidelines and other relevant guidelines for biosimilars. Some modifications have been made to tailor the guidelines for Malaysian applications (EMEA, 2014; Kang et al., 2021). Policies impacting biosimilars have been investigated in many literature (Arianna Bertolani & Claudio Jommi, 2020; Moorkens et al., 2017; Rémuzat et al., 2017; Simoens et al., 2024; Vogler et al., 2021). It has been observed that the majority of Malaysian hospitals do not have all the biosimilars that have been licensed by the National Pharmaceutical Regulatory Agency (NPRA). This indicates the presence of possible constraints on sustainability within current policy frameworks.

There are several explanations for the necessity of comprehending how policy can enhance the sustainability of biosimilar markets. First and foremost, the problem of insufficient market trust continues to exist. Misunderstandings regarding the safety of biosimilars, which are not identical molecular entities, might lead to distrust among physicians and patients, potentially impacting their utilization (Barbier et al., 2021). Furthermore, policymakers continue to implement laws intended for common small molecules to biosimilars. It is criticized that these rules are not customised to the unique features and market dynamics of biosimilars, which leads to an unsustainable environment (Alnaqbi et al., 2023).

This study aims to establish a literature review of policy elements that influence the sustainability of biosimilars in Malaysia.

2. Methods

2.1 Conceptual Framework

This research adopted the biosimilar policy framework of the country scorecards for biosimilar sustainability (IQVIA, 2020). The IQVIA Institute for Human Data Science and Medicines for Europe has created country scorecards to evaluate the policy aspects necessary for a successful biosimilar market. The scorecards evaluate the positive influence of biosimilar medicines on the long-term viability of healthcare systems and assess the effectiveness of national policy. The sustainability scorecards include five primary policy areas. These include regulatory environment and clinical guidelines, awareness and education, incentives, pricing rules and dynamics, and purchasing mechanisms. By mapping these components for a given country and evaluating the entire impact of biosimilars on the healthcare system, the scorecards may help in evaluating the existing performance and identifying areas for enhancement.

2.2 Paper identification

A comprehensive search strategy was implemented to identify related articles in Malaysia from 1/1/2003 to 14/4/2024. Keywords are used, including “Malaysia biosimilars policy”, “Malaysia biosimilars regulatory environment and clinical guidelines”, “Malaysia biosimilars awareness and education”, “Malaysia biosimilars incentives”, Malaysia biosimilars pricing rules and dynamics”, and “Malaysia biosimilars purchasing mechanisms”. Search engines were PubMed, Google Scholar, and the National Library of Medicine. The reference lists of specific papers and popular web search engines were manually searched to find more relevant research.

2.3 Paper selection and extraction

After identifying the publications, the duplicates were removed. Subsequently, the titles and abstracts were assessed for relevance, using the inclusion criteria. Peer-reviewed papers and publications written in English that describe five essential policy frameworks were selected. Other types were excluded. For a literature review research work, full-text articles were targeted.

2.4 Analysis

The final selected papers were categorized manually based on the content of the research.

3. Results

A total of 3469 records were overall retrieved from PubMed (n=39), Google Scholar (n=3074), National Library of Medicine (n=356), and Additional Searching (n=3) (Figure 1). Ultimately, 20

DOI: https://doi.org/10.22452/mjs.vol44sp1.2
Malaysian Journal of Science 44 (Special Issue 1): 8-18 (December 2025)

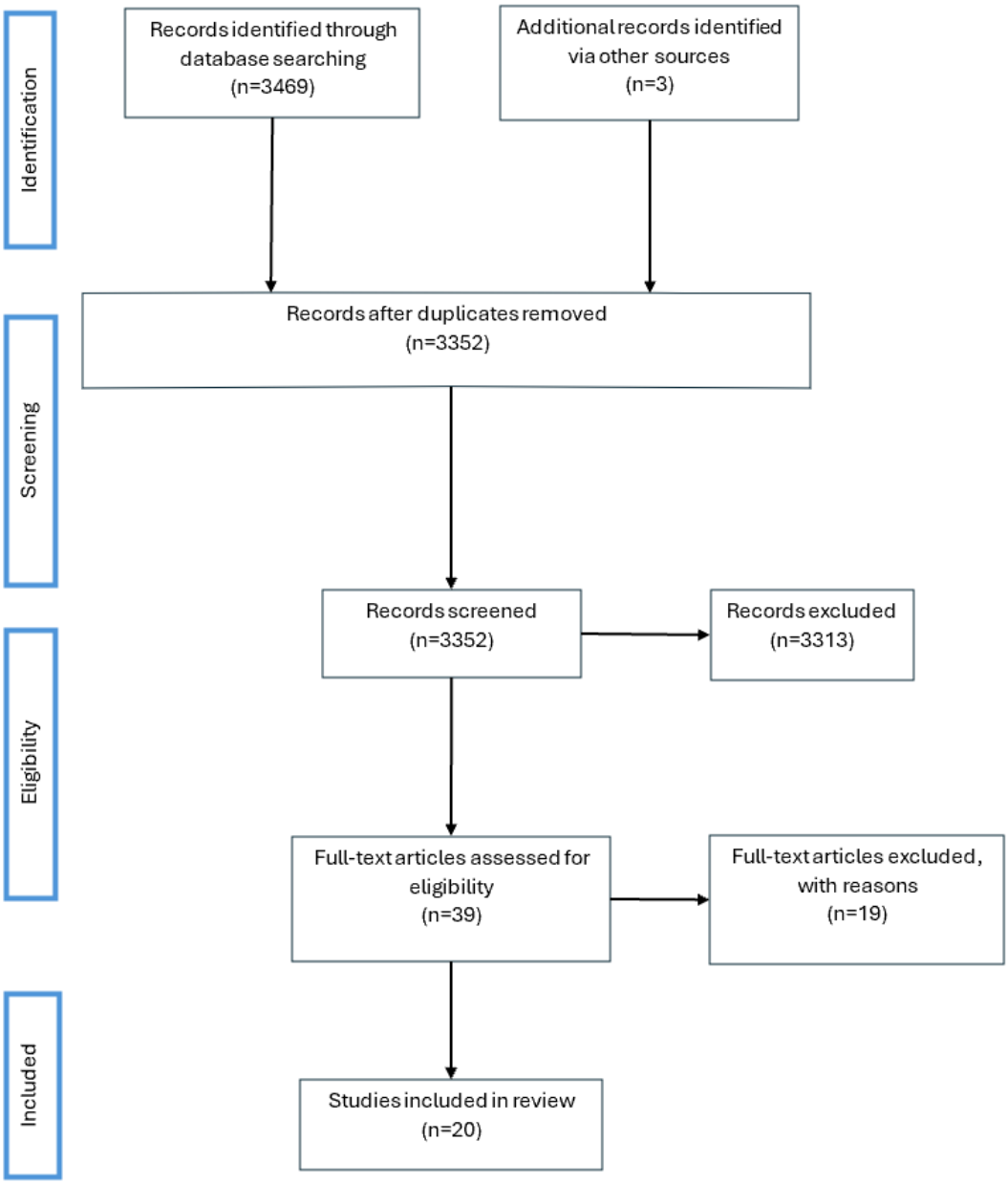

Figure 1. Review process flowchart

articles were chosen, passing all screening procedures, and thematically analysed. The emerged policies and practices were classified under five key policy-related domains (Table 1).

The review process began with an extensive search across multiple databases, identifying 3,469 records through database searches and 3 additional records from other sources. After removing duplicates, 3,352 unique records remained for screening. The initial screening process excluded 3,313 records based on relevance and predefined eligibility criteria. Subsequently, 39 full-text articles were assessed for eligibility. Of these, 19 were excluded due to various reasons, such as lack of direct relevance to biosimilar policies or insufficient data on sustainability factors. Ultimately, 20 studies were selected for the final review. This approach ensured that only the most relevant and high-quality sources were included in the review.

3.1 Category 1: Regulatory environment & clinical guidelines

Researchers identified the regulatory environment and clinical guidelines practices of physicians: time from EMA approval to first biosimilars sales, treatment guidelines for biosimilar use.

3.2 Category 2: Awareness and education

Regarding awareness and education, comprehensive training /education for pharmacists and physicians is noted.

3.3 Category 3: Incentives

This category consists of incentives to promote biosimilar use, and prescription quotas or financial incentives for providers that do not restrict physician choice.

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Table 1. Policy domain and findings

Policy domains	Findings
Regulatory environment & clinical guidelines	Malaysia's biosimilar guidelines were established in 2008, following the principles of the European Medicines Agency. The registration requirements for biotherapeutics (BTPs) and biosimilar products align with international regulatory practices, but there is some unique labeling, package insert requirements, and registration conditions specific to the Malaysian regulatory context. The World Health Organization (WHO) guidelines have played a significant role in establishing regulatory frameworks for biosimilars globally. Biosimilars marketing approval is a complicated process. (Abas, 2011; Bas & Oliu Castillo, 2016; Kang et al., 2020, 2021; Khoo et al., 2017a; Mohd Sani et al., 2020; Wadhwa et al., 2022)
Awareness and education	Pharmacists' knowledge about biosimilars varies by study. Many pharmacists lack of biosimilars training. Physicians' awareness of prescribing biosimilars is noted. (Chong et al., 2022; Mohd Sani et al., 2022a, 2023a, 2024a; Shakeel et al., 2020b)
Incentives	Encouraging biosimilars prescribing, strict quality standards, and procurement pooling for larger volumes are suggested. Local producer incentives and price competition help biosimilars enter earlier. (Godman et al., 2021, 2021; Godman et al., 2021a; Hamzah et al., 2020; Maniadakis et al., 2018a)
Pricing rules and dynamic	Competition between biosimilars and the originators was extreme, and low competition hampered price reduction. The overall procurement price trend was stable until 2014. (Godman et al., 2021a; Hamzah et al., 2020; Kang et al., 2021; Maniadakis et al., 2018a) Cost and strong pharmacovigilance influence biosimilar prescribing. Due to affordability and local production, Malaysia uses biosimilars extensively. (Chong et al., 2022; Godman et al., 2021; Godman et al., 2021a; Hamzah et al., 2020)
Purchasing mechanism	Tendering can reduce costs if supported by strong legal and organizational frameworks and stakeholder management. Government, regional procurement agencies, and international organization's competitive bidding or tendering can affect buyer prices. (Hamzah et al., 2020; Khoo et al., 2017a; Maniadakis et al., 2018a)

3.4 Category 4: Pricing rules and dynamic

Two primary themes were identified regarding pricing rules and dynamics: dynamic price competition between biosimilars and the originators, and factors influencing cost-effectiveness.

3.5 Category 5: Purchasing mechanism

A primary theme that was identified in the purchasing mechanism is the tender/bidding rules.

4. Discussion

This study aimed to present a comprehensive analysis of the policy areas of biosimilars in Malaysia. Thus, the sustainability of biosimilars is estimated. Several interventions were implemented and embraced to promote the utilization of biosimilars, which were deliberated within five overarching domains.

4.1 Regulatory environment & clinical guidelines

In 2008, Malaysia adopted the guidelines of the European Medicines Agency for biosimilar regulations and issued its own guideline (Bas & Castillo, 2016; Sani et al., 2020). While there is a consensus on the fundamental principles regarding the importance of quality assessment in evaluating biosimilars, there is a lack of published discussions providing specific details on this matter (Abas, 2011; Sani et al., 2020). The National Pharmaceutical Regulatory Agency (NPRA) has approved a total of 24 biosimilar products and has documented 499 adverse event (AE) reports. Additionally, NPRA has approved ten Phase III clinical trials in Malaysia, of which four trials are currently in progress (Sani et al., 2020). The registration requirements for novel BTPs and biosimilar products adhere to international regulatory standards. Specific labeling and package insert requirements, as well as registration conditions, are distinct from the regulatory framework in Malaysia (Khoo et al., 2017b). The guidelines established by the World Health Organization (WHO) have played a significant role in establishing the regulatory framework for biosimilars in various countries and promoting regulatory alignment on a global scale (Kang et al., 2020; Wadhwa et al., 2022). Biosimilars pose greater complexities compared to traditional generics, and obtaining marketing approval for them is significantly more intricate (Bas & Castillo, 2016).

4.2 Awareness and education

The variation in awareness among healthcare professionals (ranging from 47% to 86%) suggests that differences in professional training, institutional exposure, and availability of biosimilar-related workshops contribute to the discrepancy.

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Table 2. Positive policy elements, Policy challenges, and Potential policy solutions

Positive Policy Elements
1. High alignment with international best practices, including regulatory frameworks adapted from the European Medicines Agency (EMA) and the World Health Organization 2. Training programs for physicians and pharmacists enhance awareness and professional 3. Reference pricing mechanisms promote competitive pricing and affordability of biosimilars. 4. Government and private hospital procurement contracts ensure market stability and accessibility.
Policy Challenges
1. Lack of localized treatment guidelines and delays in biosimilar market entry due to complex approval processes. 2. Limited patient education initiatives and insufficient outreach efforts. 3. Absence of strong financial incentives for hospitals, prescribers, and patients to encourage biosimilar adoption. 4. Lack of mandatory price reductions for originator biologics, limiting market competitiveness. 5. Single winner tendering systems reduce market diversity and hinder price competition.
Potential Policy Solutions
1. Develop localized biosimilar treatment guidelines to streamline market entry and complement international policies. 2. Launch targeted educational campaigns for both healthcare professionals and patients, using digital platforms and outreach programs. 3. Introduce financial incentives, including reimbursement schemes and prescription targets, to encourage biosimilar uptake. 4. Implement mandatory price reduction policies for originator biologics to promote affordability and competition. 5. Revise tendering systems to support multi-winner models, ensuring fair competition and sustainable procurement practices.

Between 22% and 74% of pharmacists have received training on biosimilars and have obtained information about biosimilars from scientific publications, pharmaceutical companies, and continuing education (Mohd Sani et al., 2022b). Over 80% (n=305) of the participants exhibit a high level of understanding regarding the definition, features, effectiveness and safety, cost considerations, compatibility, and application of BSMs. The majority of papers expressed opposition to the automatic substitution by pharmacists due to the limited evidence supporting this practice (Shakeel et al., 2020a; Mohd Sani et al., 2024b). In other studies, about pharmacists' educational activities, it can be seen that a significant majority (62.8%, n=573) of respondents did not receive adequate training in biosimilars. However, a large proportion (80.6%, n=736) recognized the crucial role that pharmacists play in promoting the prescription of biosimilars (Mohd Sani et al., 2023b).

In other studies, the majority of oncologists (72%, n=26) expressed agreement or strong agreement that switching will not have a substantial impact on the effectiveness of the treatment. However, a smaller percentage agreed or strongly agreed that it will not result in the development of additional negative effects (56%) or harmful immune reactions (64%). The average knowledge score in biosimilar among respondents was 3.81 (± 0.86) out of a maximum possible score of six (Chong et al., 2022).

4.3 Incentives

It is crucial to improve the appeal of the biosimilar insulin market in order to incentivize other biosimilar manufacturers to join the market, especially as the patents for several long-acting insulin analogues expire. This will benefit all important groups involved (Godman et al., 2021). Implementing reimbursement for biosimilar, setting specific prescribing targets, and promoting competition among manufacturers, including incentivizing local production (Godman et al., 2021). Promoting the increased use of biosimilar drugs instead of original and patented medications within a specific category to save resources without

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compromising the quality of care (Godman et al., 2021b). The recommendations for countries with expanding healthcare coverage (CEHCs) suggest implementing stringent quality standards for tender inclusion, consolidating procurement processes to handle larger volumes, and adopting a cautious approach to tendering in order to effectively achieve their objectives in developing their healthcare systems (Maniadakis et al., 2018b). Studies have shown that in Japan, hospitals and clinics meeting biosimilar prescription targets received additional financial support, leading to a 10% increase in biosimilar prescriptions and a 12% reduction in overall healthcare expenditures (Itoshima et al., 2024). A similar model in Malaysia, where financial rewards or subsidies are provided for hospitals exceeding a set biosimilar adoption threshold, could encourage greater usage. To promote the early introduction of generic/biosimilars drugs, enhancing the capacity of local production and offering incentives to local producers to enter the export market is necessary. This can be achieved through agreements to purchase a specified quantity of drugs and other incentives aimed at fostering price competition during the procurement process. A key issue is the pricing disparity between biosimilars and their biologics. While biosimilars are generally priced 20-30% lower than originators, the cost savings have not been substantial enough to incentivize widespread prescribing (Hamzah et al., 2020).

4.4 Pricing rules and dynamic

The overall procurement prices remained relatively stable over the years, except for 2014 when the quantity-weighted average price ratio (QWAPR) and expenditure-weighted average price ratio (EWAPR) decreased by 14% and 9% respectively, compared to 2010. A comparison with International Reference Prices (IRP) revealed that Malaysian government procurement prices were often higher than global benchmarks. For instance, certain medicines had procurement prices exceeding the IRP by up to 21 times, indicating inefficiencies in cost management (Hamzah et al., 2020)**.** The prescribing of biosimilars is primarily influenced by two key factors: cost differences and the implementation of comprehensive pharmacovigilance activities. Cost differences and pharmacovigilance activities primarily influence the prescribing of biosimilars in Malaysia. A survey among Malaysian oncologists found that 40% cited patient preferences and 34% pointed to the non-availability of biosimilars in hospitals as major barriers to their adoption (Chong et al., 2022). Cost and value concerns restricted their usage in Malaysia (Godman et al., 2021). The widespread adoption of biosimilars in Malaysia can be attributed to their affordability and local manufacturing capabilities (Godman et al., 2021). Buyer prices, unlike supplier prices, can be tailored to the government, regional procurement agency, or international organization that conducted the competitive bidding or tender process (Hamzah et al., 2020).

4.5 Purchasing mechanism

There was evidence suggesting that pooling or joint tenders were more effective in attracting bidders and reducing prices. There is a severe lack of research on the effects of procurement through tendering in countries with expanding healthcare coverage (CEHCs), with only six publications found on this topic. Multiple authors concur those efficient tendering leads to a decrease in prices and aids in containing costs in the short term. In Malaysia, tenders are requested for products that surpass a budget of US$250 million per hospital. According to a recent report on tendering, it was found that tendering can help control costs if it is implemented within a strong legal and organizational structure, and if appropriate stakeholder management is in place to protect users from potential risks (Maniadakis et al., 2018b). The majority of the approved product purchase list (APPL) items consisted of local products, accounting for 70% of the total. In contrast, half of the national tenders were for originator products. The Ministry of Health (MOH) facilities, including hospitals, specialized medical institutions, health clinics, and community clinics, are directly provided by the appointed supplier. These facilities are procured through both national tenders and direct purchases made by individual facilities. In 2016, the pharmaceutical spending of MOH was divided as follows: 37% for the approved product purchase list (APPL) (presumably a specific organization), 43% for national tender, and 20% for direct purchases. Although nearly 70% of national tenders consist of imported products, there was no notable disparity in prices between APPL and national tenders when compared to International Reference Prices (IRPs). This could be attributed to the advantages of economies of scale and confidential price discounts associated with national tenders, which allow for prices that are comparable to those of APPL products (Hamzah et al., 2020). In general, the registration requirements for BTPs and biosimilar products align with international regulatory practices (Khoo et al., 2017a).

4.6 Policy Elements Impacting Biosimilar Market Sustainability

The findings, summarized in Table 2, highlight the strengths and challenges of Malaysia's biosimilar policies.

4.7 Positive Policy Elements

Malaysia has made significant progress in biosimilar regulation, aligning its guidelines with international best practices, particularly the European Medicines Agency (EMA) and World Health Organization (WHO) standards (Sani et al., 2020). This regulatory foundation ensures biosimilar safety and efficacy while fostering market confidence (Abas, 2011; Sani et al., 2020). Additionally, structured training programs have been introduced to educate healthcare professionals, improving their understanding of biosimilar prescribing and administration (Chong et al., 2022; Mohd Sani et al., 2023a). The implementation of biosimilars promotes competitive pricing, making biosimilars more affordable (Hamzah et al., 2020). Furthermore, government procurement contracts provide market stability and ensure widespread access to biosimilar treatments in both public and private healthcare settings (Maniadakis et al., 2018a).

The adoption of biosimilars in Malaysia also benefits from the growing global experience in biosimilar use. The increasing number of successful biosimilar cases worldwide, particularly in Europe and the United States, offers valuable lessons that Malaysia can incorporate into its own policies (Paul et al., 2024). By leveraging global best practices, Malaysia can further refine its

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Malaysian Journal of Science 44 (Special Issue 1): 8-18 (December 2025)

regulatory frameworks to enhance biosimilar acceptance among healthcare providers and patients.

4.8 Policy Challenges

Despite these positive developments, several barriers continue to restrict the full potential of biosimilars in Malaysia. The absence of localized treatment guidelines results in uncertainty among prescribers, which slows adoption rates (Fischer et al., 2016). Delays in market entry due to lengthy and complex approval processes further hinder access to cost-effective biosimilars. (Hoang et al., 2024). Additionally, awareness and education gaps persist; while healthcare professionals receive some training, pharmacists and physicians often lack in-depth biosimilar knowledge, and patient education remains insufficient (Chong et al., 2022; Mohd Sani et al., 2022a, 2023a). Without proactive educational initiatives, skepticism regarding biosimilar safety and effectiveness may continue. The comparison with other Asian countries highlights the need for stronger policy interventions. For instance, in South Korea and Thailand, structured incentive programs and educational initiatives have accelerated biosimilar adoption at a greater pace (Kang et al., 2021).

One of the key concerns among prescribers is interchangeability (Barbier & Vulto, 2021). While biosimilars are rigorously evaluated for safety and efficacy, many physicians remain hesitant to switch patients from originator biologics to biosimilars due to a lack of conclusive real-world data (Chong et al., 2022; Sarnola et al., 2020; Thongpooswan et al., 2024). More extensive post-marketing surveillance and real-world studies could address this uncertainty by providing additional evidence on biosimilar safety and efficacy.

Financial disincentives further complicate adoption. Unlike countries with high biosimilar uptake, Malaysia lacks strong financial motivations for hospitals, prescribers, and patients to choose biosimilars over originator biologics (Mohd Sani et al., 2023a). Without incentives such as rebates, reimbursement schemes, or financial support for local biosimilar manufacturers, biosimilars struggle to gain market traction (Maniadakis et al., 2018a; Mohd Sani et al., 2023a). Additionally, biosimilar pricing policies in Malaysia do not sufficiently encourage competition. The lack of mandatory price reductions for originator biologics upon biosimilar entry reduces the cost-saving potential of biosimilars and limits patient access to these more affordable alternatives.

Pricing and procurement policies also create challenges. While reference pricing helps control costs, Malaysia has not implemented mandatory price reductions for originator biologics upon biosimilar entry. (Chen et al., 2024). This weakens the price competition needed to increase biosimilar adoption. Furthermore, the reliance on single-winner tendering systems limits market diversity, creating monopolistic environments where price reductions are minimal and procurement flexibility is constrained (Mohd Kasim et al., 2024). Internationally, multi-winner tenders have been shown to improve price competitiveness and ensure long-term sustainability (Németh et al., 2023), suggesting that Malaysia could benefit from revising its procurement processes.

4.9 Potential Policy Solutions

To address these issues, several strategic interventions could be considered. First, the development of localized biosimilar treatment guidelines would provide clear, evidence-based directives for prescribers, ensuring consistency in clinical decision-making. By incorporating region-specific treatment data, these guidelines could improve physician confidence in biosimilars and accelerate their adoption (Shubow et al., 2022). Additionally, real-world studies should be prioritized to address concerns about interchangeability and long-term efficacy (Leonard et al., 2019).

Second, targeted educational campaigns should be launched for both healthcare professionals and patients. By leveraging digital platforms, workshops, and professional training programs, knowledge gaps can be reduced, fostering greater confidence in biosimilar usage (Laurisz et al., 2023). Public education campaigns should also emphasize the safety, efficacy, and cost-effectiveness of biosimilars to encourage broader acceptance (Cazap et al., 2018).

Financial incentives should also be introduced to encourage market growth. These could include reimbursement programs for hospitals and prescribers who prioritize biosimilar prescribing, tax incentives for manufacturers to encourage local production, and direct financial support for patients to offset treatment costs (Bond et al., 2023; Itoshima et al., 2024; Lobo & Río-Álvarez, 2021). Implementing mandatory price reduction policies for originator biologics upon biosimilar entry would enhance cost competitiveness, further driving biosimilar adoption.(Chen et al., 2024). Additionally, tiered pricing structures, where biosimilars receive greater price advantages over originators, could further incentivize their use. Addressing biases in the literature review process, the study acknowledges potential selection biases in retrieved articles and calls for real-world studies to complement existing policy assessments. The review process highlights the necessity of transparent evaluation criteria in biosimilar procurement to avoid potential biases in market accessibility.

Finally, procurement reforms should be prioritized. Transitioning from a single-winner to a multi-winner tendering system would increase market diversity, ensure fair competition, and enhance cost-efficiency (Mohd Kasim et al., 2024; Németh et al., 2023). By encouraging multiple suppliers to participate in government tenders, Malaysia can create a more dynamic biosimilar market that benefits both the healthcare system and patients. Encouraging regional procurement collaborations could also help Malaysia negotiate better prices and secure a stable supply of biosimilars.(Hamzah et al., 2020).

5. Conclusion

The sustainability of the biosimilar market in Malaysia is shaped by a complex array of policy factors that govern market entry, adoption rates, and long-term viability. Despite being one of the early adopters of regulatory frameworks for biosimilars, Malaysia's current market continues to encounter significant challenges that impede its comprehensive advancement. To enhance sustainability, policymakers should implement localized treatment guidelines, expand educational initiatives for

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healthcare providers and patients, introduce structured financial incentives, and refine procurement frameworks to encourage market competition. Specifically, integrating biosimilar incentives into Malaysia's National Medicines Policy and adopting multi-supplier tendering models could help optimize market conditions. The review suggests that, even with a strong regulatory framework in place that meets international standards, there are ongoing challenges. These include insufficient awareness among healthcare providers and patients, a lack of adequate financial incentives, and restrictive pricing dynamics, all of which hinder the wider acceptance of biosimilars.

The regulatory advancements in Malaysia have profoundly impacted the biosimilar landscape. However, their effectiveness relies on supplementary approaches, including clearer treatment protocols, continuous monitoring of market trends, and refined approval processes to reduce delays in market access. The improvement of the regulatory framework by implementing uniform biosimilar substitution policies, strengthening pharmacovigilance, and ensuring effective post-market surveillance is crucial for increasing market confidence among healthcare providers and patients. Furthermore, improving alignment with international standards, particularly in terms of pricing and procurement strategies, could play a significant role in cultivating a more competitive and transparent market environment.

An essential element affecting sustainability is the degree of awareness and education present among stakeholders, such as physicians, pharmacists, and patients. Recent investigations indicate varying levels of understanding among healthcare professionals, underscoring that a significant proportion of pharmacists and prescribers lack sufficient training concerning biosimilars. Addressing this issue requires the implementation of targeted educational initiatives designed to enhance confidence in the prescribing and substitution of biosimilars. Furthermore, educational programs focused on patients can address misunderstandings regarding the safety and effectiveness of biosimilars, resulting in enhanced acceptance and use.

Economic incentives significantly influence the sustainability of biosimilars. The lack of robust financial incentives for prescribers and healthcare institutions has led to a more gradual pace of adoption. Policymakers must investigate the potential of competitive price policies, prescription quotas, and reimbursement schemes in order to encourage the larger use of biosimilars. Moreover, encouraging local manufacturing by means of incentives to businesses would greatly increase market competitiveness, hence reducing prices and improving access.

Pricing regulations and procurement mechanisms serve as critical elements that shape market dynamics. Despite Malaysia's adoption of reference pricing strategies for cost management, the prevalence of single-winner tendering systems has limited price competition and diminished market diversity. The shift towards multi-winner tenders and the establishment of long-term procurement contracts could promote a pricing environment that is fair and sustainable. Moreover, regulations requiring price reductions for original biologics might make reasonably priced alternatives more enticing, hence boosting the market for biosimilars in the public and private sectors of medicine.

Overall, the Malaysian biosimilar industry has significant potential; yet, targeted legislative adjustments will help to increase its long-term viability. Enhancing regulatory clarity, broadening educational initiatives, establishing strong financial incentives, and refining pricing and procurement approaches will be crucial for cultivating a competitive and sustainable market. By addressing these gaps, Malaysia has the potential to enhance access to cost-effective biosimilar treatments, lower healthcare expenses, and improve patient outcomes, thereby securing lasting advantages for the healthcare system.

6. Acknowledgement

This paper is a part of a PhD thesis in Biopharmaceuticals. It is under the Faculty of Pharmaceutical Sciences of UCSI University, Kuala Lumpur Campus, Malaysia.

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