FROST & SULLIVAN

DUOPHARMA

2022 COMPANY OF THE YEAR

Malaysia
Biosimilars Industry

Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. Duopharma Biotech Berhad excels in many of the criteria in the biosimilars space.

Biosimilars and Growing Industry Acceptance

Biosimilars are approved biological medicines that are similar to drugs of biological origin (e.g., vaccine, blood, blood components, somatic, gene therapy, and recombinant therapeutic proteins) in quality, safety, and effectiveness. Biosimilars take a maximum of 10 years to develop, costing between $100 million and $200 million, while the cost of developing an original drug is estimated at $2.6 billion with a development time of more than a decade. Therefore, biosimilar drugs can have lower list prices, which is of benefit to manufacturers, as they receive incentives to lower the product price to maintain or increase market share with the rising number of treatment options for a particular disease or condition.

Based on a 2019-2020 WHO survey of participants in 20 countries, biosimilar development in many countries, including Malaysia, still faces challenges. National regulatory authorities face resource shortages, leading to short-term measures, such as relying on information from other regulators or joint reviews. Malaysia relies on the expertise of countries with previously approved biologics and biosimilars to facilitate drug approval. However, it is difficult to replace the original drug with a biosimilar. The use and acceptance of biosimilars is an issue for physicians and patients, not regulatory bodies. Therefore, promoting the feasibility and advantages of biosimilars will improve market acceptance.

© Frost & Sullivan 2022

Compared to generic drugs, biosimilars are more complex, difficult to manufacture and have a lengthy approval process, which can hamper commercialization and increase costs[1]. Strict manufacturing requirements for biosimilars pose additional challenges to production continuity. For example, single-use bioprocessing bags offer technical and economic benefits, such as sturdiness, sterility, and ease of handling. However, the shortage of such bags may limit the activities of pharmaceutical companies, ranging from cell culture and material transportation to drug filling.

Duopharma Biotech commits to improving the status of biosimilar development. The company educates the medical community through online and offline seminars, educational meetings, and scientific associations to increase the acceptance of biosimilars by experts, doctors, and patients. Duopharma Biotech keeps reviewing and expanding its product portfolio to meet health and wellness needs. With its 3 franchises, Diabetes Care, Cancer Care, and Renal Care, the company's Ethical Specialty Business (ESB) is committed to providing improved access to quality healthcare through biosimilars. Currently, 5 Duopharma Biotech biosimilar products are available as affordable solutions for healthcare professionals and patients to manage diabetes, cancer, and renal anemia, including one additional product for Cancer Care Franchise (launched in 2021).

Addressing Unmet Needs & Best Practices Implementation

In Malaysia, cancer is the fourth most common cause of death, with approximately 37,000 cases reported annually. According to Health Ministry's Malaysian Study on Cancer Survival (MySCan), almost 37,000 cancer cases reported in Malaysia are estimated to increase to 55,000 by 2030. In addition, the disease is responsible for 12.6% of deaths in government hospitals and 26.7% in private hospitals[2]. Malaysia is not self-sufficient in oncology drugs and relies heavily on imports; consistent supply and research of oncology drugs and therapies will help improve the situation. The country faces an unstable supply and high imported drug prices. A self-paid use of such prescription drugs for chronic diseases increases the economic burden and reduces adherence to drug compliance, resulting in a deterioration of health[3]. Enhanced local manufacturing of oncology medication is necessary not only for the security of supply but also to ensure the affordability of treatment.

In ASEAN, one of Duopharma Biotech's competitive advantages lies in its uniquely diverse product portfolio, which allows it to compete with other market participants. Duopharma Biotech has launched biosimilars Zuhera and Krabeva for the Cancer Care Franchise; Insugen and Basalog One for the Diabetes Care Franchise. In addition, ERYSAA® (biosimilar of Epoetin Alfa), Duopharma Biotech's first biosimilar, received its halal certificate from the Korea Muslim Federation (KMF) in 2020 and 2021. It is the world's first halal-certified biosimilar used for dialysis patients. In 2020, Duopharma Biotech was awarded the tender for ERYSAA® by the Ministry of Health (MOH) to supply all government facilities/hospitals in Malaysia. ERYSAA® has won the National Kidney Foundation tender for 2 years since 2021.

[1] "Regulatory Explainer: Everything You Need to Know About Biosimilars," The Regulatory Affairs Professionals Society (RAPS)
[2] "Duopharma Biotech – On a Mission to Provide Cancer Therapeutics," The PetriDish
[3] "Breast Cancer and Chronic Myloid Leukaemia Community Welcome Manufacturing of Relevant Drugs at Malaysia's First HAPI Facility," USM News Portal

In 2021, the installation of a pre-filled syringe (PFS) production line and the necessary ancillary infrastructure to fill and finish Epoetin (EPO) manufacturing in Duopharma (M) Sdn Bhd, Klang, for ERYSAA® will ensure supply for the local market. In 2021, Basalog One won a strategic 2-year pool-procurement tender to supply MOH, Ministry of Defence (MINDEF), Pusat Perubatan Universiti Kebangsaan Malaysia (PPUKM), Hospital Universiti Sains Malaysia (HUSM), and Universiti Teknologi MARA (UiTM) with insulin glargine till 12 September 2023. Despite other biosimilars available in the market, Zuhera is the preferred drug prescribed to patients, especially in the private sector. Zuhera's accounts for 59% of the IV trastuzumab market.

Since 2012, Duopharma Biotech established a strategic partnership with the biosimilar manufacturer Biocon insulin supply and the contract to supply Ministry of Health, Malaysia is valid until 2025. Duopharma Biotech plans to utilize the existing fill-and-finish facility for bulk biosimilar/vaccine manufacturing to fulfill medical needs in Malaysia. In addition, the company is aiming to start producing biosimilars in Malaysia. With VentureTech's investment of $3.6 million in the project, the facility is expected to complete in 2024.

Financial Performance

In 2021, the increase in sales and tender awards of Duopharma Biotech biosimilars demonstrated the popularity of its products and market competitiveness.

ERYSAA®'s performance is particularly encouraging in 2021. The medicine is for renal anemia, and its sales have grown by 52%. Approximately 49% of dialysis centers and hospitals have prescribed ERYSAA® for patients in the same year. Duopharma Biotech has a 35% to 36% market share of ERYSAA® in Malaysia and is on a growth trajectory. The existing MOH tender until 2023 helps Duopharma Biotech convert more dialysis patients in MOH-approved facilities to ERYSAA®.

> *"In ASEAN, one of Duopharma Biotech's competitive advantages lies in its uniquely diverse product portfolio, which allows it to compete with other market participants. Duopharma Biotech has launched biosimilars Zuhera and Krabeva for the Cancer Care Franchise; Insugen and Basalog One for the Diabetes Care Franchise. In addition, ERYSAA® (biosimilar of Epoetin Alfa), Duopharma Biotech's first biosimilar, received its halal certificate from the Korea Muslim Federation (KMF) in 2020 and 2021. It is the world's first halal-certified biosimilar used for dialysis patients."*
>
> ***- Dr. Maeirah Ashaie, Consultant***

Besides, in 2021, sales of Basalog One, an insulin glargine, have grown 10% and 22% in the government and private sectors, respectively. Revenue from Zuhera, a breast cancer treatment, grew 10% (RM5.59 million in 2021). With its price advantage, Zuhera was quite popular with healthcare professionals and patients and was awarded a year Pusat Perubatan Universiti Malaya (PPUM) tender (December 2021 until 2022) with an estimated value of RM669,000. For Insugen, MOH accepted the tender offer from Duopharma Biotech to supply Insugen and issued a 3-year Letter of Award (LOA). The LOA is from 29 April 2022 to 28 April 2025, with a total contract value of RM375,174,320.00.

Customer Purchase & Service Experience

Duopharma Biotech's quality policy outlines its commitment to building trust by offering products and services that satisfy customers' expectations and comply with local and overseas regulatory and quality requirements. The quality policy requires Duopharma Biotech to understand and fulfill customer requirements, provide a high standard of service to internal and external customers, continuously engage and delight customers and stakeholders, and improve processes, products, and services continuously.

Duopharma Biotech uses several means to improve the customer purchase experience. For example, the on-time in-full (OTIF) index helps pay close attention to the completeness of delivery to customers. Through timely drug delivery, Duopharma Biotech aims to reduce customer rejection, preventing drugs from being wasted. According to the index, goods must be delivered to customers within 24 hours after placing an order. The OTIF performance of Duopharma Biotech can reach a maximum of 97%[4]. In 2021, the OTIF of the warehouse reached 98.8%, surpassing the set KPI. The company conducts a Voice of Customer survey for feedback with targeted customers from various channels, including consumer healthcare, ethical classic, ethical specialty, government business, private hospitals, and exports. In 2021, the customer satisfaction index achieved a score of 98%, much higher than 90% in 2020 and slightly higher than 97% in 2019. Customers may return products for many reasons, such as approaching the use-by date or wrong orders. Duopharma Biotech's team records and analyzes returned goods information to understand the reasons for the return and reduce the internal and external gap. In 2021, the return value of consumer healthcare and ethical business was 1.4% and 0.3%, respectively, better than in 2020 and well below the maximum values.

> *"Duopharma Biotech's quality policy outlines its commitment to building trust by offering products and services that satisfy customers' expectations and comply with local and overseas regulatory and quality requirements. The quality policy requires Duopharma Biotech to understand and fulfill customer requirements, provide a high standard of service to internal and external customers, continuously engage and delight customers and stakeholders, and improve processes, products, and services continuously."*
>
> ***- Dr. Maeirah Ashaie, Consultant***

Duopharma Biotech has a dedicated team of product specialists trained to promote and share biosimilar knowledge to offer customers the best purchase and service experience. In addition, integrated teams from regulatory, medical, quality assurance and control, customer relationship management, and warehouse departments support customer needs.

Brand Equity

Duopharma Biotech educates the healthcare fraternity on the safety and quality of biosimilars. In the last 2 years, the company participated in several major scientific events organized by medical societies, such as the Malaysian Endocrine and Metabolic Society, Malaysian Oncology Society, and Malaysian Society of Nephrology. The company held online educational sessions and scientific events focusing on Basalog One,

[4] "Duopharma Biotech Aims to Lead Malaysia's Green Pharmaceutical Initiative," Revonmedia

Zuhera, ERYSAA®, and Krabeva. In addition, it conducted virtual plant tours of the HAPI plant and the fill-and-finish facility in Klang for healthcare professionals. Acceptance of Duopharma Biotech brands by healthcare professionals has increased, and patients are increasingly being treated with Basalog One, Zuhera, and ERYSAA®.

Duopharma Biotech will conduct more biosimilar education webinars to connect with healthcare professionals in various disciplines and educate patients. These company webinars will improve the number of Key Opinion Leaders and specialists advocating and supporting the use of biosimilars to improve healthcare. It aims to continue the extension of its alliances with current collaborators, such as Biocon, and engage in new collaborations to improve its market presence and diversify its products and technology.

Conclusion

Duopharma Biotech has established itself as a leading manufacturer of biosimilars in Malaysia. The company benefits patients with its diverse product portfolio and strong market performance. In the future, it aims to provide more products at lower costs. With its strong overall performance, Duopharma Biotech Berhad earns Frost & Sullivan's 2022 Malaysia Company of the Year Award in the Biosimilars industry.

© Frost & Sullivan 2022

What You Need to Know about the Company of the Year Recognition

Frost & Sullivan's Company of the Year Award is its top honor and recognizes the market participant that exemplifies visionary innovation, market-leading performance, and unmatched customer care.

Best Practices Award Analysis

For the Company of the Year Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Visionary Innovation & Performance

Addressing Unmet Needs: Customers' unmet or under-served needs are unearthed and addressed by a robust solution development process

Visionary Scenarios Through Mega Trends: Long-range, macro-level scenarios are incorporated into the innovation strategy through the use of Mega Trends, thereby enabling first-to-market solutions and new growth opportunities

Leadership Focus: Company focuses on building a leadership position in core markets and on creating stiff barriers to entry for new competitors

Best Practices Implementation: Best-in-class implementation is characterized by processes, tools, or activities that generate a consistent and repeatable level of success

Financial Performance: Strong overall business performance is achieved in terms of revenue, revenue growth, operating margin, and other key financial metrics

Customer Impact

Price/Performance Value: Products or services provide the best value for the price compared to similar market offerings

Customer Purchase Experience: Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

Customer Ownership Experience: Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

Customer Service Experience: Customer service is accessible, fast, stress-free, and high quality

Brand Equity: Customers perceive the brand positively and exhibit high brand loyalty

© Frost & Sullivan 2022

About Frost & Sullivan

Frost & Sullivan is the Growth Pipeline Company™. We power our clients to a future shaped by growth. Our Growth Pipeline as a Service™ provides the CEO and the CEO's growth team with a continuous and rigorous platform of growth opportunities, ensuring long-term success. To achieve positive outcomes, our team leverages over 60 years of experience, coaching organizations of all types and sizes across 6 continents with our proven best practices. To power your Growth Pipeline future, visit Frost & Sullivan at http://www.frost.com.

The Growth Pipeline Engine™

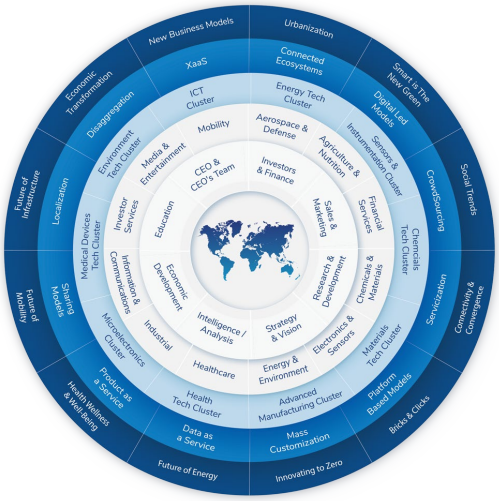
Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator™.
Learn more.

Key Impacts:

- **Growth Pipeline:** *Continuous Flow of Growth Opportunities*
- **Growth Strategies:** *Proven Best Practices*
- **Innovation Culture:** *Optimized Customer Experience*
- **ROI & Margin:** *Implementation Excellence*
- **Transformational Growth:** *Industry Leadership*

The Innovation Generator™

Our 6 analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.



Analytical Perspectives:

- Mega Trend (MT)
- Business Model (BM)
- Technology (TE)
- Industries (IN)
- Customer (CU)
- Geographies (GE)