

Malaysia pharma digest

Q3 2024



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Malaysia Q3 report is out!

In this report, you will find an exclusive article on localization forces driving the insulin market in Malaysia.

The competitive landscape: Biocon, Pharmaniaga, GSK, Novo Nordisk... what these companies have been up to in Q3?

Get also an overview on recent market approvals.

*USD 1.7
billion*

Projected annual revenue for 2024 (Statista)

277

Approved pharma manufacturers (KKMNOW, Gov. Malaysia)

525

As in Vision 525, Pharmaniaga's new strategic plan aimed at strengthening public sector business, building biopharmaceutical capability, optimizing cost aggressively, growing the private sector, and reinventing Indonesia market.

INSULIN SUPPLY AND LOCALIZATION OF PRODUCTION: MALAYSIA'S CASE.

103 years after its discovery, insulin is reinventing itself: from pricing readjustments in major markets to the increasing usage of biosimilars. Historic players like Novo Nordisk and Eli Lilly seek growth outside insulin, with successes notably in obesity management drugs (Wegovy...), paving the way for initiatives led by local manufacturers.

This may redistribute the cards in mid-size markets. Governments are keen on enhancing their sovereignty over medicines supply and tend to favor national champions in this quest.

A case in point is Malaysia, which has been hit by an unprecedented shortage of human insulin.

Pharmaniaga threatens a duopoly

Malaysia is currently supplied by Biocon and Novo Nordisk. Biosimilar maker Biocon already supplies 80% of Malaysia's human insulin. However, it has been facing manufacturing issues in its Johor plant in the last few months, notably with a Form 483 issued by USFDA. Novo Nordisk does not have any production unit in Malaysia and thus exports the remaining 20% to the country.

The competitive landscape is being reshaped with Pharmaniaga's foray into insulin production. Pharmaniaga has announced the launch of the first locally owned insulin facility to serve the needs of 4,4 million patients with diabetes. The state-of-art facility based in Puchong has been granted an EU GMP certification so far and is expected to produce an annual 30 million doses of insulin. Vaccines for 13 diseases will also be manufactured in Puchong.

A lot remains to be done for Pharmaniaga. The company still must get the regulatory approvals, and some questions emerge on the partnerships that will enable the company to produce insulin. We only know from Pharmaniaga's [Integrated report 2023](#) (p.21) that the "group will collaborate with strategic partners from South Korea, Thailand, China and India to facilitate technology transfer and reach."

Will it be worth for major players to keep supplying Malaysia?

Further south, in Malaysia, close to Singapore's frontier, US-based device maker Insulet has celebrated the grand opening of its new facility, where Omnipod 5, its tubeless insulin pump will be manufactured. It took a USD 200 million investment to build this 400,000 square-foot plant, that will start with 350 employees and is estimated to be at full steam in 2026 with 1,000 employees.

In South Africa, Novo and Aspen have signed in 2023 a manufacturing agreement to supply insulin. In an unexpected move in June 2024, Novo did not renew its supply contract with SAPHRA for 14 million pens, reportedly prompting patients to switch to vials and syringes.

In Indonesia, a natural export spot for Malaysia, Novo has announced a [deal](#) with local manufacturer BioFarma to pack insulin and provide "expertise in diabetes treatment and insulin production".

In Egypt, Eli Lilly has [partnered](#) with Egypt-based Eva Pharma to complete an insulin facility in Cairo.

Such initiatives show that the global competitive landscape is shifting towards a localization of insulin production. The fact that countries know they will rely on their own source of insulin will impact the prices and possibly push major companies to collaborate with local producers.

Latest news



Competitive landscape

GSK launches Herpes Zoster Vaccine in Malaysia

GSK has launched its HZV vaccine (non-live, recombinant subunit vaccine) aimed at preventing shingles and post-herpetic neuralgia for adults 50+.

[Biospectrum Asia](#)

Human insulin shortages: Minister blames Biocon

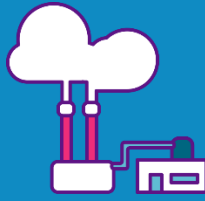
Minister of Health Dzulkefly Ahmad has blamed Biocon for not meeting its contractual obligations in supplying the country with human insulin. This friendly reminder comes after the much-commented insulin shortages in Malaysia and throws into question Biocon's strategy: the biosimilars maker will have to position itself in the country's question of national sovereignty.

[Code Blue](#)

Novo continues to supply insulin to Malaysia

The Danish giant, buoyed by the recent success of Wegovy, is streamlining its manufacturing network to serve markets globally. In Malaysia, Novo has announced that its supply of insulin remains stable. So far, Novo represents 20% of the country's insulin supply.

[Code Blue](#)



Manufacturing

Insulet debuts a new device manufacturing facility

The leader in tubeless insulin pump technology strengthens its global footprint, with a USD 200 million investment. Insulet will cover 400,000 square-foot area in Johor Bahru, with hopes to employ 1,000 people in 2026.

Pharmaniaga launches the first country first locally owned insulin and vaccines plant

This announcement comes in a context of global supply crunch affecting medicines in general. Pharmaniaga tries to address this issue by launching in Puchong a state-of-art facility able to cover Malaysia's needs: 4,4 million Malaysians require 24,7 million doses of insulin annually, a figure expected to grow to 5 million by 2030. 30 million doses of insulin are expected. Pharmaniaga also aims to produce vaccines for 13 types of diseases.

[Pharmaniaga](#)

Schott opens a new production facility in Kulim

The specialty glass maker strengthens its manufacturing network in Malaysia. This enhanced production capacity integrates augmented reality (AR).

[Biospectrum Asia](#)

NEW PRODUCTS APPROVED (JUNE-OCTOBER 2024)

BIOLOGICS

IDB Resources	Besremi	Manufactured by PharmaEssentia in Taiwan, Besremi (Ropeginterferon alfa-2b) is used to treat polycythemia vera.
Roche	Lunsumio	Lunsumio (mosunetuzumab) is a 1 mg/ml solution for infusion to treat refractory or relapsed follicular lymphoma in adults.
Astellas	Padcev	Padcev (enfortumab vedotin) is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy. It has been approved for its 20 and 30 mg versions.
Astrazeneca	Soliris	Soliris (eculizumab) is a humanized monoclonal antibody is indicated in adults and children for paroxysmal nocturnal haemoglobinuria, atypical haemolytic uremic syndrome, refractory generalized myasthenia gravis; and neuromyelitis optica spectrum disorder for adults only.
Astrazeneca	Ultomiris	Ultomiris (ravulizumab) is indicated for paroxysmal nocturnal haemoglobinuria, atypical haemolytic uremic syndrome and generalized myasthenia gravis.

BIOSIMILARS

Kotra Pharma	Vaxcel Enoxaparin	Manufactured by Nanjing King Friend, Kotra's version of enoxaparin has been authorized in 3 dosages, in prefilled syringes.
Kalbe	Avamab	A bevacizumab biosimilar manufactured by GH Genelix in Spain
Celltrion	Yuflyma	An adalimumab biosimilar pre-filled pen approved in its 10mg/0.1ml Solution dosage for injection.
Duopharma	Kauliv	KAULIV 20 micrograms/80microliters solution for injection. A teriparatide biosimilar used to treat osteoporosis

GENERIC MEDICINES

Glenmark	Ezzicad S	Glenmark's ezetimibe version has been approved in 3 versions.
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Pahang Pharmacy	Rosmi	Manufactured by Cadila Healthcare in India, Rosuvastatin generic approved in 10 and 20 mg versions
Synervv	Rovusastatin	Manufactured by Unimedica Laboratories in India, this generic has been approved in 5, 10 and 20 mg versions.
Seacross	Plerixafor	Manufactured by Sichuan Huyiu in China, this version of Sanofi's Mozobil treats graft versus host disease
Healok	Ryfintum 15	Manufactured by Inventia Healthcare in India, this version of Bayer's Rivaroxaban has been approved in its 15 mg version.

NEW CHEMICAL ENTITIES

Pfizer	Cibinqo	Approved in 3 dosages (50, 100, 200 mg), Cibinqo is a medicine used to treat adults and adolescents from 12 years of age with moderate to severe atopic dermatitis
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VACCINES

GSK	Shingrix	Shingrix powder and suspension for injection.
GSK	Arexvy	Arexvy is indicated for the prevention of lower respiratory tract disease caused by RSV in older adults (60+).

OTC

Haleon	Panadol Actifast Caplet 500 mg	Manufactured by Wyeth Pharmaceuticals in China, this is a new line extension for Panadol.
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Data retrieved from NPRA's public platforms

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