

# Saudi Arabia pharma digest

MAY-OCTOBER 2024



José Moutinho



# Saudi report is out

In this report you will find an exclusive report on Saudi Arabia's path to self-sufficiency.

News on top Saudi players: Tabuk, MS Pharma, Avalon, and Janjoom... and global pharma players.

You will also find the notable market authorizations in this market!

*USD 11  
billion*

*Estimated market review  
(2023)*

*206*

*Approved pharma and  
medical devices factories*

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Many thanks to all those who have given feedback.

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# IS SAUDI ARABIA ON THE PATH OF SELF-SUFFICIENCY?

The Public Investment Fund (PIF) has established its Vision 2030 to enable Saudi Arabia's private sector to find new investment opportunities, both domestically and internationally. How does Vision 2030 affect the kingdom's pharma strategy?

The Saudi Public Investment Fund (PIF) has set its agenda to reach 40% of domestic manufacturing by 2030. The cornerstone of this strategy will be Lifera, a PIF-funded biopharma company, aimed at building manufacturing capacity in KSA. Partnerships have been signed to scale up local biomanufacturing: vaccines ([Sanofi](#) and [Arabio](#)), insulin ([Sanofi](#), [Novo](#)). US-based CDMO National Resilience has also established a joint venture focused on sterile injectables and other parenteral products.

To support the country's ambitions, another company is positioned: Vaccine Industrial Company (VIC), founded in 2022. USD 133 million have been engaged to build a vaccine factory in Sudair City, with a yearly production capacity of 30 million vaccine packages. 150 jobs have been announced to manufacture flu, Covid-19, chickenpox, pneumococcal and meningitis vaccines. VIC has signed an equity deal with Emergex Vaccines, positioned Phase I for infectious diseases such as betacoronaviruses and dengue fever. The deal involves a potential fill & finish tech transfer.

Saudi Arabia also seeks partners from BRICS countries: Minister of Industry and Mineral Resources Bandar Al-Khorayef has visited the Butantan Institute's operations in Brazil. Following this visit, the Saudi kingdom wishes to boost collaboration with Brazil, potentially involving tech transfers.

Al-Khorayef is also [urging](#) Chinese companies to invest in the Saudi industry, notably pharma.

*National sovereignty, half or full measures?*

Vision 2030 has entered the minds in all the private sector prompting companies to quickly switch gears. Reaching national sovereignty also means that Saudi Arabia seeks to shine in the Islamic world, through exportation. In the public sector, Saudi FDA has taken steps to protect the market with the establishment of new pharmaeconomic guidelines, mandatory for international companies to enter the market. Novel drugs will be subjected to stricter rules in terms of real-world evidence and economic impact.

Will these efforts be enough to reach the goals set up? On paper, producing all insulin and vaccines on your soil is a great deal, but being limited to fill & finish can only be temporary if the true objective is national pharma independence. The multiplication of signals the authorities' wish to benefit from the most complete tech transfer.

Finally, the Saudi's ambition to shine in the Islamic world will face the strong position of other key countries. Saudi Arabia will have to compete with Egypt in Africa and Indonesia in Southeast Asia, countries that are more advanced in terms of production (Vacsera, PT BioFarma...).

*José Moutinho*



# Competitive landscape



## **MS Pharma launches Ravegza (ranibizumab) in Saudi Arabia**

MS Pharma has announced the launch of Ravegza (FYB201), a Lucentis (ranibizumab) biosimilar, in the Saudi market. Aimed at treating retinal diseases (diabetic retinopathy, wet age-related macular degeneration), Ravegza has been co-developed by Bioeq, a JV between Formycon AG and Polpharma Biologics.

[MS Pharma](#)

## **Sanofi launches a treatment against cGVHD**

Niven Al-Khoury, GM General Medicines at Sanofi KSA and Gulf countries, has announced the launch of Rezurock (belumusodil mesylate) against chronic graft versus host disease.

[Linkedin](#)

## **Tabuk Pharmaceutical deals with Formosa Pharmaceuticals, Biocon, Hanmi.**

Tabuk Pharmaceuticals has announced an exclusive licensing agreement with Taiwan-based Formosa Pharmaceuticals for commercialization of Clobetasol Propionate Ophthalmic Suspension in key MENA regions. This medicine is aimed at treating pain after ophthalmic surgery.

The Saudi company has also partnered with Biocon, to commercialize GLP-1 products in the Middle-East. As marketing rights owners, Tabuk will oversee registration, importation and promotion of diabetes and weight management drugs made by Biocon. The deal also includes an option on a potential tech transfer from Biocon.

Tabuk has also entered a exclusive licensing agreement with Korean player Hanmi, to facilitate the export of Hanmi's flagship products in the MENA region. The deal involves existing and potential new medicines.

[PR Newswire Pharmaceutical Technology Hanmi](#)

## **Bayer opens a new regional office in Djeddah**

In line with its commitment to better serve the region and with the crown's Vision 2030, Bayer has opened its new offices in Djeddah.

[Souq Al Dawaa](#)

## **Lallemand partners with Avalon Pharma in respiratory healthcare**

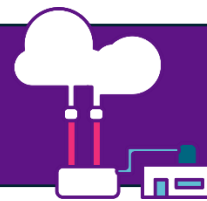
This partnership includes the launch of Salinose Bagonvalve

[Lallemand](#)

## **Eisai sets up subsidiary in Riyadh**

Active in the Kingdom since 1960 through local partners, Eisai starts fully-fledged operations in Riyadh to support sales and marketing activities for Methycobal, Fycomba (from October 2024), Lenvima and Halaven (from April 2025).

[Eisai](#)



## **Saudi Arabia's ambition to localize insulin production**

Minister of Industry and Mineral Resources Bandar bin Ibrahim Alkhorayef has announced Saudi Arabia's ambition to localize 80-90% of insulin and attract key investors in healthcare. Today, alongside the historic insulin competitors Novo, Sanofi and Eli Lilly, biosimilar players like Biocon and Saja hold market authorizations for insulin in Saudi Arabia.

[Arab News](#)

## **SFDA approves Avalon Pharma new production lines in Riyadh**

SFDA has approved Avalon Pharma's new production lines at Plant n°2 in Riyadh. The new registered line will have a production capacity of 270 million capsules and tablet per year, and 22 million semi-solids. Avalon is specialized in consumer healthcare and generic prescription medicines. We have also learned that Avalon Pharma has obtained banking facilities from Emirates NBD Bank, worth 70 million riyals.

[Zone Bourse](#)

## **Jamjoom's plan to open a new ophthalmology production line in Algeria**

In its quest to further the development of a new ophthalmology production line in Algeria, Janjoom Pharmaceuticals has issued a corporate guarantee to its joint venture.

[Janjoom Pharmaceuticals](#)

## **Jamjoom to establish a drug production facility in Uzbekistan**

Jamjoom is investing in Uzbekistan through a new drug production facility that will commence operations in Q3 2025. Talks also include the registration of 30 drugs that Jamjoom will produce in Uzbekistan.

[Daryo \(Uzbekistan\)](#)

# Regulatory

## **SFDA issues guidelines for the evaluation of economic studies**

The objective of these guidelines is to establish pharmaeconomic evaluation methods into decision-making processes for pricing and reimbursement of novel drugs. In fact, this move is aimed at developing a value-based pricing framework and will be mandatory by July 2025. It is estimated that greater resources will be needed in Saudi Arabia, to deal with these new requirements.

[Consultancy-Me](#)

## **SFDA's approval required for advertising**

Pharma companies, notably in the OTC space, must now seek approval from Saudi FDA before advertising.

[Saudi Gazette](#)

## **Bahrain NHRA and SFDA sign MoU**

The deal has been signed to establish mutual recognition and strengthens mutual recognition between the 2 drug authorities.

[Bahrain News Agency](#)

# NOTABLE MARKET AUTHORIZATIONS

MAY 2024 ONWARDS

## BIOLOGICS

Novo Nordisk	Sogroya	Solution for injection in pre-filled pen. After 2 earlier authorizations in 2023, another strength has been authorized (10). This long-acting growth hormone comes at a price of SAR 3072 in pharmacy.
LFB	Cevenfacta	Manufactured by Sanofi SRL (Italy), Cevenfacta is aimed at preventing bleeding in patients undergoing surgery.
Abbvie	Epkinly	Manufactured by Vetter in Germany, Epkinly has been approved in two strengths (4 and 48 mg/ml), to treat lymphoma.

## BIOSIMILARS

Biocon	Krabeva	Priced at SAR 698,45 for a vial, this bevacizumab biosimilar offers the more competitive price compared to Roche's originator, Zirabev (Pfizer) and Mvasi (Amgen) versions.
AJA Pharmaceutical	Ligra	Priced at 258,05, and manufactured by Novocol in Canada, Ligra is a liraglutide biosimilar.

## GENERIC MEDICINES

Boston Oncology Arabia	Pomalidomide BOS	Manufactured by Natco, Pomalidomide BOS is approved in 4 versions, and will compete with BMS' originator Imnovid and other generics from Sudair.
Boston Oncology Arabia	Cabozantinib BOS	Priced at SAR 13761,05, and manufactured by Natco, Cabozantinib BOS is aimed at treating renal carcinoma. Generic version of Ipsen's Cabometyx,
Sudair	Daglozin	A Farxiga generic, manufactured by MSN Laboratories in India
Sudair	Ensutine	A Ribomustin generic, manufactured by Dr. Reddy in India
Tabuk Pharmaceuticals	Teralas	Manufactured by Pharmacare Premium (Malta), Teralas joins the existing teriflunomide line-up among which originator Aubagio.
Adel-Ahmed Al Shaeir Pharmaceutical Company	Levogand	Manufactured by Acme Generics LLP in India, Levogand is the 2d Levotyrox generic approved in Saudi Arabia, after Aspen's version.
Seacross	Azafor	A Mozobil (Sanofi) generic, Azafor is manufactured by Sichuan Huyiu Pharma in China.
Apotex	Trovapt	Priced at SAR 2172,50, Trovapt is manufactured by Apotex in Canada and is a generic of Sanofi's Aubagio.
Sudair	Empaglifozin SPC	Manufactured by Dr. Reddy in India, Sudair's empaglifozin will be priced at 135.15

Altaif	Specrodoce	Manufactured by Shilpa Medicare in India, Specrodroce (docetaxel) is a generic of Sanofi's Taxotere.
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## NEW CHEMICAL ENTITIES

Pierre Fabre	Nerlynx	Indicated for breast cancer, Nerlynx (Neratinib) consists of film-coated tablets for oral use.
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Sanofi	Rezurock	Indicated for graft vs host disease (GVHD), Rezurock (belumosudil mesylate) will come at a price of SAR 34581.50
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Labatec	Tymlos	Indicated for osteoporosis, Tymlos (abaloparatide), will come at a price of SAR 1564.15
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Eli Lilly	Mounjaro Kwikpen	Coming in 6 dosages, Mounjaro Kwikpen is indicated for weight loss. Price: 1261.40
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Servier	Irinotecan	Indicated for advanced colorectal cancer, Irinotecan (onivyde pegylated liposomal)
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Pfizer	Litfulo	Indicated for alopecia, Litfulo (ritlecitinib) is priced at SAR 3605.85.
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## OTC

Avalon	Avogestic	Avogestic (diethylamine salicylate) is a topical analgesic priced at SAR 13,85 a box in pharmacies.
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