OPEN ACCESS

Saudi Journal of Medicine
Abbreviated Key Title: Saudi J Med
ISSN 2518-3389 (Print) | ISSN 2518-3397 (Online)
Scholars Middle East Publishers, Dubai, United Arab Emirates
Journal homepage: https://saudijournals.com

Original Research Article

Local Manufacturing of Insulin in Saudi Arabia: Advancing Healthcare and Economic Growth

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DOI: https://doi.org/10.36348/sjm.2025.v10i08.008 | **Received:** 19.06.2025 | **Accepted:** 25.08.2025 | **Published:** 28.08.2025

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Abstract

Diabetes mellitus (DM) is a significant public health and economic concern in Saudi Arabia, affecting more than 20% of adults. Insulin remains a cornerstone in DM management, but the country relies significantly on imported products. Hence, this results in high healthcare expenditures and variable availability. In line with Vision 2030, Saudi Arabia has prioritized the localization of insulin manufacturing to ensure sustainable access, reduce import dependency, and enhance national health security. This paper explores the clinical, economic, and policy implications of localizing insulin production in the Kingdom. The current work used a case study methodology to assess the feasibility, challenges, and strategic opportunities for the domestic production of innovative insulins, such as Degludec and IDegAsp. The study supports the development of public-private partnerships, investment in biotechnology infrastructure, and regulatory reform to foster a robust local biopharmaceutical ecosystem. By 2027, Saudi Arabia aims to meet 50% of its insulin demand through local production, making it the first country in the GCC region to produce innovative insulin. This initiative is expected to promote affordability and position the Kingdom as a leader in insulin innovation.

Executive Summary

- **INTRODUCTION**

Diabetes is a significant health issue in Saudi Arabia, where it affects more than 20% of adults. The growing diabetic population has created a pressing demand for effective and accessible DM therapies like insulins which considered a cornerstone in the management of DM. Innovative insulins have reshaped DM management, offering improved convenience and patient adherence. Imported insulin presents substantial affordability and accessibility difficulties. Saudi Arabia's Vision 2030 proposes to localize insulin production, assuring a sustainable supply and lowering healthcare expenses.

Key Findings

- **Increasing DM prevalence :**Saudi Arabia is witnessing a sharp rise in DM cases, with the condition becoming one of the most pressing health challenges in the country.
- **Economic burden:** Imported insulin has an enormous financial burden on patients and the healthcare system.

- **Challenges in Accessibility:** Availability of new generation of insulins is difficult despite government subsidies due to changing worldwide costs and supply chain vulnerabilities.
- **Vision 2030 objectives:** The government has prioritized indigenous pharmaceutical manufacture and aims to produce 50% of the domestic insulin needed by 2027.
- Local production is anticipated to enhance access to medications for the Saudi population by reducing costs associated with imports and improving the availability of essential drugs. This increased accessibility is crucial for addressing public health needs, particularly for non-communicable diseases (NCDs) such as DM and cancer.

DISCUSSION

This paper highlights the necessity of:

1. Enhancing local production capabilities by building revolutionary insulin manufacturing facilities to reduce dependence on imports.
2. Improving supply chain resiliency that includes guaranteeing a consistent and continuous insulin supply by domestic production.
3. Economic and healthcare impact by lowering healthcare expenditures while improving patient outcomes through affordable insulin access.
4. The start in production of new generations of insulin like Degludec and IdegAsp will improve the outcomes of our patients while reducing the prices and ensure the availability.
5. Regulatory and policy support via strengthening policies to encourage investment in local biopharmaceutical production.
6. Workforce development by training and equipping local professionals to sustain insulin production and innovation.

Proposed Solutions

A comprehensive approach is essential for achieving insulin self-sufficiency. Key recommendations include:

- **Public-Private Partnerships (PPPs):** collaborate to establish local insulin production.
- **Investment in biotechnology:** establish research and innovation hubs. Localizing insulin manufacturing is one of the key pillars of KSA national biotech strategy given its importance within the healthcare system.
- **Implement pricing and reimbursement strategies** to balance insulin, especially new generations, affordability with profitability for manufacturers.
- **Infrastructure development:** establish industrial factories with worldwide quality requirements.

CONCLUSION

Localized insulin production is intended to improve Saudi Arabia's health security, economic strength, and patient care. By producing pharmaceuticals locally, KSA can retain more capital within the country rather than spending it on imports. Localizing production allows for strategic stockpiling of essential medicines and active pharmaceutical ingredients, which can serve as a buffer against supply chain interruptions. This approach does not only secure access to critical medications but also fosters a more responsive healthcare system capable of addressing local health needs promptly. With manufacturing facilities situated within the country, pharmaceutical companies can adapt their production lines more rapidly to meet the needs of the population, ensuring that essential medicines are available when needed. By addressing production, accessibility, and regulatory challenges, the Kingdom can ensure a steady supply, reduce healthcare expenditures, and improve outcomes for millions of diabetic people. By 2027, Saudi Arabia is set to become the first producer of a biologic innovator insulin in the GCC region.

Keywords: Diabetes mellitus, Insulin localization, Vision 2030, Saudi Arabia, Biopharmaceutical manufacturing, Health economics.

INTRODUCTION

Diabetes is one of the most pressing public health concerns in the globe due to its startlingly high prevalence. Diabetes is a serious issue in Saudi Arabia, where it affects over 20% of adults. The serious consequences of this chronic condition, such as blindness, kidney failure, neuropathy, and cardiovascular abnormalities, lead to severe morbidity, mortality, and financial costs [1–4].

Insulin therapy is essential for managing DM, especially for those with type 1 (T1DM) and advanced type 2 (T2DM). Finding reasonably priced insulin, however, is still a significant problem everywhere, especially in Saudi Arabia, where a sizable amount is imported. Given its high cost and potential supply chain disruptions, local insulin production ensures long-term access to this life-saving medication [1–5].

Saudi Arabia prioritizes localizing pharmaceutical manufacturing in line with Vision 2030 to improve healthcare security, lessen reliance on imports, and promote economic growth. One important endeavor to lower costs, increase accessibility, and establish the Kingdom as a leader in the production of biopharmaceuticals is local insulin manufacturing. This initiative is expected to cover 50% of the country's insulin needs by 2027, create thousands of jobs, and contribute billions to the national economy [6,7].

This paper explores local insulin production's economic, clinical, and healthcare implications in Saudi Arabia.

METHODOLOGY

The current case study aimed to evaluate the feasibility, challenges, and benefits of the local production of insulin in Saudi Arabia. It provided a comprehensive analysis of the economic, healthcare, and policy implications of insulin production within the framework of Saudi Vision 2030.

The research evaluated the current status of insulin manufacturing. It also, identified barriers to its production, and assessed opportunities for local production. The study focused on existing pharmaceutical manufacturers, technology transfer initiatives, and government collaborations.

A desk research and literature review were carried out to contextualize Saudi Arabia's pharmaceutical sector within the best international practices, highlighting key regulatory and economic factors that influence local production.

In addition, a policy analysis studied documents of Saudi Vision 2030, public health initiatives, and pharmaceutical regulations to assess governmental support for the local production of insulin. Furthermore, a market analysis, using public health databases and industry reports, evaluated the current insulin demand status, pricing trends, and import dependency.

Expert meetings were conducted to gather insights from pharmaceutical manufacturing, biotechnology, and public health policy specialists, as well as healthcare specialists, including endocrinologists, diabetologists, internists, and practitioners.

1. Vision 2030 and Healthcare Transformation

The Saudi Kingdom Vision 2030, a comprehensive plan that encompasses society, economy, and ambition, plays a pivotal role in the transformation of the healthcare sector. Increasing the life expectancy of Saudi people to 80 years by 2030 is the primary goal of this vision. The Kingdom is committed to improving the quality of life (QOL) for its citizens. Also, the Kingdom does its best to address the escalating burden of chronic diseases, such as DM. A key strategy to achieve this is by promoting healthcare sustainability, which involves reducing reliance on imported products and encouraging local manufacturing. This is crucial for ensuring a consistent supply of key essential medications [6,8].

Moreover, the Kingdom of Saudi Arabia is actively bolstering its domestic pharmaceutical production capability through a multifaceted plan aligned with Vision 2030. This plan includes encouraging foreign investment, promoting technology transfer, establishing strategic partnerships with multinational pharmaceutical companies, and expanding local production capabilities for both generic and innovative drugs. The Kingdom has launched several initiatives, including the National Industrial Development and Logistics Program (NIDLP) and the Made in Saudi Program, to promote localization, regulatory streamlining, workforce development, and research and development (R&D) innovation. All these integrated strategies will significantly boost the share of pharmaceuticals manufactured locally and help establish Saudi Arabia as a leading regional hub for pharmaceutical production by 2030 [6,8].

Vision 2030, with its strong emphasis on economic diversification and boosting the industrial sector, recognizes the pharmaceutical industry as a key strategic pillar. The National Industrial Development and Logistics Program (NIDLP) is important and strategic to this objective. It is expected to meet approximately 40% of the pharmaceutical market demand through local manufacturing, significantly increasing the share of pharmaceuticals manufactured domestically and positioning Saudi Arabia as a key regional hub for pharmaceutical production by 2030 [6,8].

Localizing pharmaceutical manufacturing reduces dependence on imported drugs. It also strengthens the supply chain resilience and lowers production costs. Consequently, this improves drug affordability and ensures that essential medicines reach patients more quickly and reliably. All these elements will be reflected in increased treatment adherence, reduced care delays, and ultimately improved patient outcomes and public health resilience. This establishes Saudi Arabia as a competitive regional hub for pharmaceutical production, encouraging sustainability and long-term prosperity [6,8].

2. Diabetes Landscape in Saudi Arabia

The growing prevalence of DM in Saudi Arabia (Figure 1) has created a pressing demand for effective and accessible insulin therapies, the cornerstone of DM therapy. As DM prevalence continues to rise sharply in the country, it has become one of the most significant health challenges. However, with the development and implementation of improved insulin therapies, there is hope for a more efficient and reliable DM management system [9].

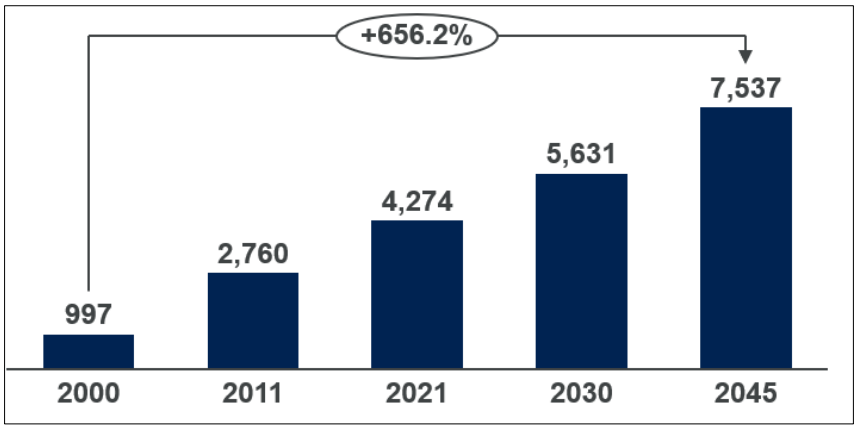

Figure 1: Diabetes estimates (20-79 y), 000' people, 2000 to 2045 [10]

The Saudi Insulin Market is growing (Figure 2 depicts anti-diabetic drugs, including insulin). Diabetes is becoming more common, and advances in insulin delivery methods have considerably improved patient adherence. Government programs, particularly those under the Vision 2030 program, focus on increasing healthcare spending and infrastructure development. Localized insulin manufacturing, such as the agreement with Novo Nordisk to produce insulin locally for Degludec and IDegAsp, aims to reduce supply chain disruptions and ensure consistent insulin product availability [11].

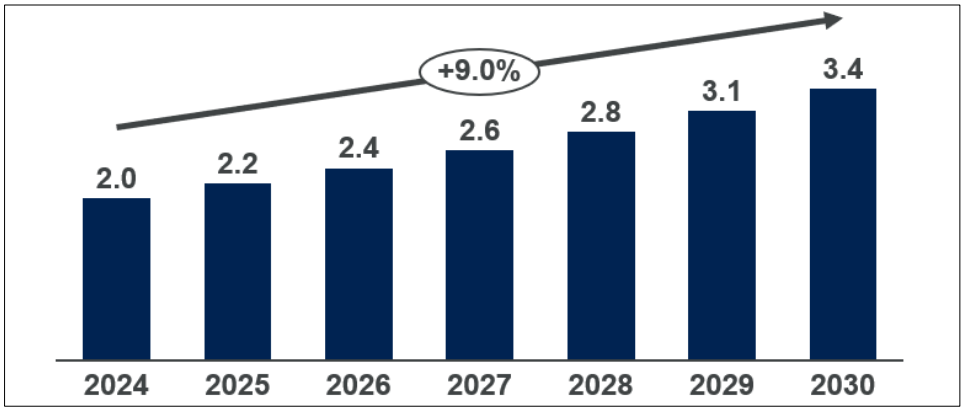

Figure 2: Saudi Arabia Diabetes Drug Market, $ Bn, 2024 to 2030 [11]

3. The Strategic Push for Local Pharmaceutical Manufacturing

The Kingdom plans to increase local pharmaceutical production to approximately 80% by 2040. Prioritization of vaccines, biosimilars, and biotherapeutics was set to enhance the self-sufficiency of these products. Efforts emphasize the development of local capital through the integration of high-tech solutions, expanding manufacturing facilities, and training programs. The collaboration with multinational pharmaceutical corporations is not just crucial, it's a cornerstone in our journey towards self-sufficiency. This collaboration ensures the transfer of high-tech knowledge and adherence to global standards. The Ministries of Health, Industry, and Investment each contribute to regulatory assistance and policy creation. Healthcare professionals and researchers provide the scientific experience, while pharmaceutical companies drive local production and innovation. All these efforts align with Vision 2030's [6].

The Ministry of Industry and Mineral Resources has set a significant goal to localize 80% to 90% of the government's insulin procurement needs, aiming to enhance self-sufficiency, reduce imports, and ensure a stable supply. A significant step toward this goal is the partnership between Lifera and Novo Nordisk. Through Lifera's subsidiary, SaudiBio, the two companies have agreed to localize insulin production. This collaboration will not only enable the Kingdom to become the first producer of biologic innovator insulin in the GCC region by 2027 but also position Saudi Arabia as a regional leader in advanced pharmaceutical manufacturing, a feat we can all take pride in [12–17].

4. Economic and Healthcare Benefits of Local Manufacturing

The indigenous production of insulin in Saudi Arabia has profound implications for the healthcare landscape, economic development, and the pharmaceutical business as shown in the following Table [8,18–21].

Aspect	Key Points	Impact
Healthcare Impact	- Self-sufficiency in insulin production - Stable supply during crises (e.g., COVID-19) - Improved affordability and accessibility - Enhanced patient safety	- Reduced dependency on imports - Better management of chronic diseases like DM - Consistent availability of insulin
Economic Benefits	- Job creation (11,000 jobs by 2030) - Contribution to non-oil GDP ($34.6 billion by 2040) - 50% reduction in insulin prices - Retains capital within the country	- Boosts economic diversification - Improves healthcare affordability - Strengthens local economy
Pharmaceutical Sector Development	- Establishing Saudi Arabia as a regional pharmaceutical hub - Encouraging research and development - Collaborations between local institutions and multinational companies	- Fosters innovation - Strengthens pharmaceutical infrastructure - Positions Saudi Arabia as a biotechnology leader
Regulatory Support	- Expedited SFDA registration systems - Fast-tracked approvals for locally manufactured drugs - Tax incentives and customs duty exemptions	- Faster access to medications - Competitive advantage for local manufacturers - Improved profit margins for companies
Supply Chain Resilience	- Strategic stockpiling of essential medicines - Local adaptation of production to healthcare demands - Protection against global supply chain disruptions	- Reliable supply of critical medications - Rapid response to public health emergencies - Enhanced healthcare security

5. Challenges and Barriers in Local Manufacturing

Establishing a successful domestic insulin manufacturing business in Saudi Arabia necessitated close collaboration with global pharmaceutical corporations to promote technology transfer and experience sharing. Collaborations with industry, such as Novo Nordisk, allowed the Kingdom to benefit from proficient production techniques and best practices. The collaborations were critical in the development of technical capabilities for producing insulin locally. Conformance to global quality standards, such as those set forth by WHO (World Health Organization) and the FDA (United States Food and Drug Administration), was critical for ensuring safety, efficacy, and worldwide competitiveness. [22,23].

Investment in advanced facilities and qualified personnel training was needed to overcome technological barriers in biosimilar production. The Saudi Food and Drug Authority's (SFDA) stringent regulatory monitoring guaranteed that domestically made insulin met rigorous quality and safety standards. These efforts were critical in establishing Saudi Arabia as a regional leader in pharmaceutical manufacturing [23–26].

How to make insulin affordable while profitable was an important issue that necessitated negotiations between global partners and stakeholders. Also, effective supply chain management was also required to ensure constant production. Moreover, rigorous clinical trials and real-world evidence were required to address the doubts regarding locally made insulin. Additionally, doctors-patient trust is necessary to help patients accept locally produced insulin. Furthermore, rigorous testing and regulatory approval processes alleviated worries and emphasized the advantages of local production. These measures aided the Kingdom's healthcare objectives and reaffirmed the country's commitment to achieving self-sufficiency [23–26].

a. Clinical and Economic Evaluation of New Generations Long-acting Insulin

Ultra long-acting basal insulin analogues were developed to improve glycemic control with a lower risk of hypoglycemia compared to older insulins like NPH, Insulin detemir, Insulin Glargine. These analogues achieve similar HbA1c outcomes while reducing hypoglycemia risk by 20%–50%. The lower hypoglycemia rates lead to cost savings, better adherence, fewer complications, and reduced healthcare expenses [27,28].

Newer basal insulins like insulin Degludec and glargine U300 offer longer duration of action and more stable glucose control than first-generation analogues. They significantly lower hypoglycemia risk, making them safer options for long-term use [27].

Insulin Degludec provides similar HbA1c reduction to glargine and detemir but improves fasting plasma glucose and reduces overall and nocturnal hypoglycemia. A meta-analysis by (Dong et al., 2022) of 20 RCTs (19,048 patients) confirmed these findings, showing Degludec's greater reduction in fasting plasma glucose and lower hypoglycemia rates without increased severe hypoglycemia risk [29]. According to Ratner et al.'s meta-analysis, equivalent glycemic control was

achieved with 10% lower insulin units compared to glargine U100, without compromising efficacy. This highlights the potential for improved efficiency and cost-effectiveness through local manufacturing, ultimately contributing to better patient outcomes and a more resilient healthcare system [30].

Phase III trials and crossover studies (SWITCH 1 and SWITCH 2) demonstrated that Degludec consistently reduces hypoglycemia risk compared to glargine U100 while achieving equivalent glycemic control [30]. The SWITCH PRO trial further confirmed that Degludec improves time in range and reduces nocturnal hypoglycemia in patients at risk of hypoglycemia [31].

The CONCLUDE trial found no significant difference in overall symptomatic hypoglycemia between Degludec U100 and glargine U300, but Degludec significantly reduced nocturnal and severe hypoglycemia rates, suggesting advantages in nighttime glycemic stability. Degludec achieved target HbA1c levels with a 12% lower end-of-trial insulin dose compared to insulin glargine U300, without compromising glycaemic control [32].

Real-world data, including the CONFIRM study, showed that Degludec provided a greater reduction in HbA1c when compared with glargine U300, the change in the rates of hypoglycemia demonstrated a 30% lower rate of hypoglycaemia with Degludec vs glargine U300, and increases treatment persistence compared to glargine U300 [27]. The UPDATES study in Saudi Arabia confirmed these benefits, demonstrating improved glycemic control and reduced hypoglycemia without safety concerns with 1.2% point reduction from baseline after treatment with Degludec, reduction in incidence of nocturnal (89%) and non-severe hypoglycaemia (96%). In addition, resources utilizations associated with severe hypoglycaemia were dropped in both insulin-naïve and insulin-experienced patients after Degludec initiation [33].

A retrospective study at King Abdulaziz University Hospital found that switching to Degludec significantly reduced HbA1c and insulin dose requirements without increasing hypoglycemia risk (34). Cost-effectiveness analyses from several countries indicate that Degludec improves QALYs and reduces hypoglycemia-related costs, making it a cost-effective option for DM management [35–39].

Second-generation basal insulin analogues like Degludec have longer half-lives and lower glycemic variability than glargine U300, with better hypoglycemia outcomes. Also, Degludec can be used in a wide range of patient population like pediatrics starting from 1 year and pregnancy. Local cost-utility analyses in Saudi Arabia support Degludec's cost-saving potential, reinforcing its role in optimizing DM care in the region [40].

The study by Evans et al. assessed the cost-effectiveness of insulin Degludec/insulin aspart (IDegAsp) compared to biphasic insulin aspart 30 (BIAsp 30) in patients with T2DM using a 5-year model from a Danish healthcare perspective. Drawing on data from two phase 3a clinical trials, the analysis revealed that IDegAsp offers a favorable cost-effectiveness profile, with an incremental cost-effectiveness ratio (ICER) of 81,507.91 Danish Kroner per quality-adjusted life year (QALY). This finding was primarily attributed to the significant reduction in severe hypoglycemic events and lower insulin dose requirements associated with IDegAsp. Sensitivity analyses confirmed the robustness of the results, with the ICER remaining well below the commonly accepted threshold of 250,000 DKK per QALY. The probabilistic analysis further supported these findings, showing a 99.5% probability that IDegAsp is cost-effective compared to BIAsp 30. The study concludes that IDegAsp represents a cost-effective treatment alternative, driven by both clinical and economic benefits [41].

The combination insulin IDegAsp demonstrated non-inferior HbA1c reduction versus BIAsp 30, with better fasting plasma glucose control, lower insulin requirements, and reduced hypoglycemia rates [42]. A systematic review confirmed that IDegAsp simplifies insulin regimens while maintaining glycemic control and lowering hypoglycemia risk. IDegAsp offers similar HbA1c control (treat to target design studies) with a significantly lower insulin dose by 16% at end of trial vs BIAsp 30 [43].

A real-world study across six countries, including Saudi Arabia, showed that switching to IDegAsp significantly improved HbA1c, fasting plasma glucose, and hypoglycemia rates in adults with T2DM, as well as reduced resource utilization associated with DM and its complications after the use of IDegAsp in Saudi Arabia. IDegAsp significantly reduces the risk of hypoglycemia vs BIAsp 30 in patients with T2D during treatment maintenance by 84% Reduction of severe hypoglycemic events, 61% Reduction of non-severe nocturnal hypoglycemic events. In the Saudi cohort only, IDegAsp reduced HbA1c by 2% with mean change in FPG by -59.5mg/dl from baseline with consistent high safety profile in terms of non-severe nocturnal and severe hypoglycemia. [44]. Cost-effectiveness modeling in China further supported IDegAsp's benefits in improving life years and QALYs while reducing hypoglycemia-related costs [45].

b. Roadmap for Local Manufacturing Strategic Actions and Policy Recommendations

The following goals and policies aim to transform Saudi Arabia into a self-sufficient pharmaceutical hub, boosting healthcare resilience, economic growth, and innovation in line with Vision 2030.

CONCLUSION

Local insulin manufacture in Saudi Arabia is an essential step toward healthcare sustainability and improved patient care. This program attempts to limit insulin imports and provide a consistent, inexpensive supply. It is consistent with Saudi Arabia's Vision 2030. The project is projected to reduce insulin prices by 50%, lowering the financial burden on patients and the healthcare system. It will generate around 11,000 jobs and contribute $54 billion to the national GDP, enhancing Saudi Arabia's position in regional biopharmaceutical production. By 2027, indigenous manufacturing will meet 50% of insulin demand, with the goal of reaching 80% by 2040. Government support, investments, and worldwide alliances to improve technology and production capacity will be critical to success.

RECOMMENDATIONS

To successfully implement and sustain the local manufacturing of insulin in Saudi Arabia, a comprehensive, multi-stakeholder approach is essential. The following recommendations outline key strategies for optimizing healthcare benefits, economic growth, and long-term self-sufficiency in insulin production:

1. Strengthening Local Manufacturing Capacity
Invest in Advanced Biopharmaceutical Technologies: Establish state-of-the-art facilities with cutting-edge biotechnology to ensure high-quality insulin production that meets global standards. **Develop a Skilled Workforce:** Expand training programs in pharmaceutical sciences, biotechnology, and regulatory affairs to equip local professionals with the necessary expertise.

Enhance Supply Chain Resilience: Strengthen local supply chains for raw materials and active pharmaceutical ingredients (APIs) to reduce dependency on imports.
2. Improving Affordability and Accessibility of Insulin
Implement Pricing Regulations and Subsidies: Establish price control mechanisms to ensure insulin remains affordable for all patients, particularly those with low income. **Expand Distribution Networks:** Improve logistics and healthcare infrastructure to ensure insulin reaches patients across all regions, including remote and underserved areas. **Integrate Insulin into National Healthcare Coverage:** Include locally manufactured insulin in government health insurance programs and support private-sector reimbursement policies. It is recommended to emphasize the potential of local insulin manufacturing to improve patient access to innovative insulin therapies such as insulin degludec and IDegAsp. Localization can significantly reduce production and distribution costs, thereby enhancing affordability. This improved access can facilitate broader adoption of advanced insulin regimens, support better glycemic control, and ultimately lead to improved patient outcomes and a more sustainable healthcare system.
3. Driving Economic Growth and Job Creation
Promote Public-Private Partnerships (PPPs): Encourage collaboration between government agencies, private pharmaceutical companies, and academic institutions to drive innovation and efficiency in insulin production. **Support Research and Development (R&D):** Allocate funding for research initiatives focused on improving insulin formulations, drug delivery systems, and next-generation DM treatments. **Create Incentives for Local and Foreign Investors:** Offer tax benefits, grants, and regulatory support to attract investment in the pharmaceutical sector and strengthen Saudi Arabia's position as a biopharmaceutical hub.
4. Strengthening Regulatory and Quality Assurance Frameworks
Ensure Compliance with International Standards: Align local insulin production with global regulatory frameworks such as the WHO, FDA, and EMA to facilitate regional and international market expansion. **Enhance Pharmacovigilance and Quality Control:** Implement robust monitoring systems to track insulin efficacy, safety, and patient outcomes. **Accelerate Regulatory Approvals for Local Production:** Streamline approval processes for locally manufactured insulin while maintaining strict safety and efficacy standards.
5. Expanding Regional and Global Market Reach
Position Saudi Arabia as a Biopharmaceutical Export Hub: Develop policies to facilitate the export of locally manufactured insulin to the Middle East, Africa, and other emerging markets. **Foster Regional Collaborations:** Establish agreements with neighboring countries for technology sharing, regulatory harmonization, and joint research initiatives. **Develop Strategic Global Partnerships:** Engage with international pharmaceutical leaders to bring expertise, investment, and innovation into the Saudi insulin manufacturing sector.
6. Enhancing Public Awareness and DM Management Programs
Launch National DM Awareness Campaigns: Educate the public on DM prevention, early diagnosis, and proper insulin usage to improve patient outcomes. **Integrate Insulin Therapy into Primary Healthcare Services:** Train general practitioners and primary care providers to enhance DM management and insulin prescription practices. **Encourage Lifestyle Modification Programs:** Promote national initiatives focusing on nutrition, physical activity, and weight management to reduce DM prevalence and insulin dependency.

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