



جامعة ميدأوشن

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عنوان البحث

**Public Perception and Adoption of Locally Manufactured Biologic Drugs in Saudi Arabia: A
Consumer Survey**

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1. Introduction

Biologics are some of the most impactful drugs in the age of modern medicine for patients with cancer, autoimmune diseases, and rare genetic disorders. Biologics differ from traditional chemical-based drugs, as they are produced using living cells, which demand complex manufacturing techniques and stringent regulatory oversight to guarantee their safety, efficacy, and reliability.

Accordingly, Saudi Arabia is focusing on its local biologic medication production as part of Saudi Vision 2030 to mitigate import dependency, minimize healthcare expenditure, and claim a leading role in the regional pharmaceutical market. New regulatory frameworks for the approval of biologics and their production have been introduced by the Saudi Food and Drug Authority (SFDA). However, there is a big challenge to that: Public trust and consumption of locally made biological drugs.

Despite the cost savings potential, improved accessibility, and a ripple effect on the national economy when utilizing domestically manufactured biologics, many Saudi consumers still view imported biologics as of higher quality based on established global brand names, regulatory approvals from the FDA (United States) and EMA (Europe), and experience from clinical trials. By analyzing the several elements affecting consumer trust, physician attitudes, economic variables, and regulatory difficulties, this study investigates these aspects to enable a better knowledge of their needs by authorities, medical professionals, and pharmaceutical businesses.

2. Problem Statement

This market of biological drugs is the most challenging of the three, and Saudi Arabia is trying hard to localize the production in the country; however, the adoption rate is low due to a few significant barriers.

Depend on patients: Patients link imported biologics to higher safety and efficiency.

Impact of Physicians: Physicians often prefer to prescribe biologic brands with a track record of success.

Economic and Healthcare System Obstacles: Including Biologics in the insurance guidelines does not motivate the local biologics economy, as the charges and scopes are usually more significant for international brands.

Tentative Conclusion: SFDA has already moved ahead with international/global adhering (FDA, EMA, WHO) standards; however, it is somewhat unclear whether SFDA significantly appealed to the public or how its approval process compared with international/regulatory approval.

Awareness and Education: Few public education campaigns exist, so adoption of locally produced biologics is low.

By means of a consumer survey and expert interviews, this study explores these aspects related to Saudi biologics in order to grasp the attitudes, obstacles, and possible remedies to build confidence in Saudi-made biologics.

3. Research Objectives

Evaluates the barriers to adoption and public perception of locally manufactured biologics medicines.

Specific objectives include:

- Assess consumers' knowledge of biologic drugs produced in the Kingdom of Saudi Arabia.
- Trust in the domestic vs. foreign versions of the biologics.
- Explore physician utilization of local versus international biologics.
- Economic factors (including pricing, insurance coverage, and financial incentives)
- Impact of SFDA regulation on trust of the public
- Propose policies to broaden acceptance of Saudi-produced biologic pharmaceuticals.

4. Research Hypotheses

This analysis tests the hypotheses below:

4.1 Consumer Awareness & Trust

- Consumer awareness has no significant effect on trusting locally made biologics.
- A direct correlation exists between increased consumer awareness and trust in Saudi-made biologics.
- Saudi consumers trust Biologics that are imported more than Biologics that are made locally.
- Works by medicinal product categories and regulatory agencies.

4.2 Economic & Insurance Factors

- KMPs do not influence consumer WTA Saudi biologics.
- Local biologics are sold at lower prices, resulting in higher adoption rates.
- Recycling the Expanded—Saudi Biologics coverage positively impacts consumer adoption.

4.3 Regulative Frameworks & Public Trust

- SFDA approvals receive lower trust from consumers than FDA/EMA certifications.
- Saudi biologics gain greater public trust if they receive international certifications (WHO, FDA, EMA).
- Consumer confidence is significantly determined by regulatory transparency and public education.

5. Literature Review

5.1 Trust in biologics from the public perspective

Pharmaceutical trust is primarily based on brand, regulatory, and clinical trial transparency (Jones & Smith, 2020). Previous research demonstrates that patients in emerging markets prefer imported drugs due to perceptions of higher-quality manufacturing processes and regulatory scrutiny (Kim & Park, 2021).

SFDA approval is essential for establishing trust in Saudi Arabia. However, the study found that most respondents considered the FDA and EMA the first indicators of the drug's safety and efficacy (Alharthi, 2021).

5.2 Physician's Role in Biologic Adoption

Physicians have a key impact on patient preferences for biologics. Patel and Kumar show in their research (2020) that physician endorsement has proved to be decisive in shaping patient perception and efficacy of new biologic drugs. However, many Saudi physicians may be reluctant to prescribe local biologics due to limited clinical trial data and a history of reliance on imported brands.

5.3 Economic Barriers

The cost of biologics significantly influences patient adoption. Price-sensitive consumers were shown to be more likely to switch from imported to locally produced biologics if the price was significantly lower than imported drugs (Wang & Li, 2019). However, in Saudi Arabia, insurance policies tend to favor international brands, thus diminishing the affordability incentive for local products (SFDA Report, 2021).

5.4 Regulatory Perceptions and Public Confidence

Public confidence in biologics depends on regulatory bodies like the SFDA, FDA, and EMA. In a study from the Middle East, Ahmed (2020) mentioned that such patients are more inclined towards biologics recognized by international organizations like WHO, FDA, and EMA. Furthermore, well-led awareness campaigns (ideally spearheaded by the government) and physician endorsement work against skepticism towards locally produced biologics (FDA Reports, 2021).

5.5 Public Education Matters

Biologic Drug Adoption: The Role of Consumer Awareness Many Saudi patients were unaware about biologics, making them reluctant to switch to locally manufactured drugs away from imported ones (Al-Qahtani, 2021). Public education campaigns contribute to increased biosimilar usage, as has been documented through biosimilar uptake in countries like South Korea and the UAE (Smith & Brown, 2022).

6. Research Methodology

6.1 Study Design

A mixed-methods approach will be used in this study:

- Quantitative Surveys (500 of Saudi consumers).
- Qualitative Expert interviews (50 healthcare providers: physicians, pharmacists, regulators).

6.2 Sampling Method

- Stratified Random Sampling (so that there are no demographic disparities).
- Quota Sampling (Ensuring a balance of consumers familiar versus unfamiliar with biologics).

6.3 Data Analysis

Using the Chi-square test to explore relationships between consumer trust and awareness.

- T-tests & ANOVA: Examining Physician Attitude Towards the Local vs Imported Biologics.
- Regression analysis: Economic and insurance impact.
- Factor analysis: Measuring confidence in regulators and approval.

7. Expected Outcomes

- Understand major obstacles to biologics drug uptake.
- Give regulatory insights to align SFDA with global agencies.
- Advise on local biologics marketing strategies.
- Propose policies to increase adoption rates.

8. Research Limits

This study has certain limitations that might affect its findings and interpretations. Understanding these constraints is important to ensure transparency and inform future research efforts.

8.1 Sample Size and Representation

- The study is based on 500 consumer respondents and 50 healthcare professionals; therefore, the findings may not fully generalize to the experience of the wider Saudi population.
- Responses from health care professionals may not be representative of specialists, limiting generalizability to primary care providers and pharmacists who may influence patient choices.

8.2 Geographic and Demographic Scope

- The survey primarily targets consumers and healthcare professionals in urban areas, who have more access to biological therapies and regulatory knowledge.
- There may be different levels of trust, economic concerns, and awareness in rural and remote populations that are not captured in the current study.

8.3 Consumer Awareness Bias

- Since local consumers have relatively less exposure to locally produced biologics, response bias may challenge this assumption when appraising trust and uptake.
- Social desirability bias might additionally play a role in responses, as participants gravitate towards answers that align with perceived expectations instead of actual preferences.

8.4 Availability of Economic and Insurance Resources

- The study assumes no insurance coverage or pricing structure changes, but updates in government policy, insurance reimbursement, or subsidy programs could affect adoption patterns.
- Differences in private vs. public insurance coverage were not thoroughly explored, which may affect patients' cost-based decisions.

8.5 Comparative Limitations

- The study evaluated Saudi Arabia's biologics industry versus globally (FDA, EMA) yet provided no detailed juxtaposition with GCC markets (UAE, Qatar, Egypt), wherein biologics uptake might mirror national trends.
- Lacking longitudinal data to monitor changes in attitudes over time.

8.6 Time Constraints

- The study is cross-sectional, collecting responses from the same time point.
- A longitudinal study must determine how perceptions, regulatory adaptations, and adoption rates vary.

9. Conclusion

Saudi Arabia can lead the region's biological production. Overcoming public trust issues, economic barriers and regulatory perceptions will be key. The research findings will provide policymakers, healthcare providers, and pharmaceutical companies with data-driven recommendations on stimulating more specific local use of biologics in the future.

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11. Appendix: The Consumer Survey

Public Perception and Acceptance Towards Locally Manufactured Biologic Drugs in Saudi Arabia

Section 1: Basic Details

Age Group:

☐ 18-24

☐ 25-34

☐ 35-44

☐ 45-54

☐ 55+

Gender:

☐ Male

☐ Female

Educational Level:

☐ No formal education

☐ High school diploma

☐ bachelor's degree

☐ master's degree or higher

Employment Status:

☐ Working in health services (doctor, pharmacy, inspector)

☐ In a different sector

☐ Unemployed

☐ Retired

Have you ever taken a biologic drug?

☐ Yes

☐ No

Does anyone in your household currently take biologic drugs?

☐ Yes

☐ No

☐ Unsure

Section 2: Awareness & Knowledge of Biologic Drugs

Do you know much about biologic drugs?

☐ No, I am not familiar with them

☐ Yes, but I am not sure what they are

☐ No, I have never heard of them

Do you know the difference between biologic and chemical-based drugs?

☐ Yes, I know the difference

☐ No, I am unsure

Do you know that Saudi Arabia is now making its biologic drugs?

☐ Yes

☐ No

Do you believe the biologic drugs in the Kingdom of Saudi Arabia are up to international quality standards?

☐ Yes

☐ No

☐ Unsure

Section 3: Use of Local Biologics

How confident are you in the quality of biologic drugs produced in Saudi Arabia?

☐ Strongly trust

☐ Somewhat trust

☐ Neutral

☐ Somewhat distrust

☐ Strongly distrust

If your physician prescribed a Saudi-manufactured biologic drug, would you use it?

☐ Yes, without hesitation

☐ Yes, but only if markedly less expensive

☐ No, give me the imported biologics

What is your greatest concern about taking Saudi-manufactured biologic drugs?

- ☐ Quality and safety
- ☐ Efficacy against imported alternatives
- ☐ Failure of clinical trials transparency
- ☐ Physician recommendations

Would you be more likely to use a local biological drug if: (Please select all that apply)

- ☐ SFDA approved it and complied with FDA/EMA regulation
- ☐ It was cheaper than importing alternatives
- ☐ Your doctor recommended it

Section 4: Economics & Insurance Considerations

Well, demand for the local biologic drugs you make is very price sensitive.

- ☐ Very important
- ☐ Somewhat important
- ☐ Neutral
- ☐ Not important

If your health insurance covered a Saudi-made biologic drug, would you take it?

- ☐ Yes
- ☐ No

What role should the government play in facilitating locally produced biologic drug adoption? (Select all that apply)

- ☐ Reducing costs for patients
- ☐ Awareness and the public
- ☐ Enhance regulatory oversight

Section 5: Public Awareness & Education

Are you aware of any government campaign that promotes Saudi-made biologics?

- ☐ Yes
- ☐ No

What information would increase confidence in using local biologics? (Select all that apply.)

- ☐ Science publications and clinical trial data
- ☐ Health care professional advice
- ☐ Government campaigns and regulatory endorsements

Do you want to know more about locally developed biologic products in Saudi?

- ☐ Yes
- ☐ No

Section 6: Open questioners

- What would make you feel more confident in using locally produced biologic drugs?
- All other comments or concerns for locally manufactured biologic drugs in Saudi Arabia.