Scientific Research Publishing

Beijing Law Review, 2025, 16(4), 2147-2160
https://www.scirp.org/journal/blr
ISSN Online: 2159-4635
ISSN Print: 2159-4627

Local Vaccine Manufacturing in Saudi Arabia: Examining the Role of National Legal Frameworks and Strategic Policies

Tareq S. Alshammari

Department of Law, College of Shariah and Law, University of Ha'il, Ha'il, Kingdom of Saudi Arabia
Email: ts.alshammary@uoh.edu.sa

How to cite this paper: Alshammari, T. S. (2025). Local Vaccine Manufacturing in Saudi Arabia: Examining the Role of National Legal Frameworks and Strategic Policies. *Beijing Law Review, 16,* 2147-2160.
https://doi.org/10.4236/blr.2025.164108

Received: September 15, 2025
Accepted: October 26, 2025
Published: October 29, 2025

Abstract

This research aims to identify and evaluate the key legal issues in local vaccine production in Saudi Arabia, as outlined in the provisions of Vision 2030. It examines how evolving domestic legal frameworks—including sectoral laws, regulatory reforms, and national policies—enable or limit successful vaccine localization. Through qualitative documentary analysis, the study finds that Saudi Arabia's legal reforms have significantly improved the regulatory environment, enabling the rapid development of local partnerships and manufacturing capacity. However, Vision 2030, while driving broad policy change, is ultimately a high-level catalyst. The effective realization of local vaccine manufacturing depends on granular legal adaptation, stronger enforcement, sustained interagency coordination, and continual legal learning. These legal advances have important implications for public health law, boosting resilience, access, and system reliability. The paper concludes with policy recommendations for maximizing the opportunities and addressing the persistent barriers encountered in Saudi vaccine law as the country continues its journey toward health sovereignty.

Keywords

Legal framework, Localization, Public Health Law, Saudi Arabia, Vaccine Manufacturing, Vision 2030

1. Introduction

Saudi Arabia has implemented measures to regulate the pharmaceutical industry, given its significant importance in the country's healthcare system. At the outset, pharmaceutical regulations in Saudi Arabia primarily focused on ensuring the

safety, efficacy, and quality of all pharmaceutical products (Tawfik et al., 2022a). This matched international standards, such as those recommended by the World Health Organization (WHO) and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use. With an oversight role, the Saudi Food and Drug Authority (SFDA) ensured these regulations were in place and that pharmaceutical products attained the required safety and quality standards before they were allowed into the market for distribution and sale.

In the early stages, Saudi pharmaceutical and health law was predominantly responsive, externally modeled, and designed for safety, but little more in terms of the legal language for biotechnical or vaccine innovation (Mani & Goniewicz, 2024). As the global map of health threats evolved (like COVID-19 and other threats), it became increasingly clear to Saudi Arabia that it was time to move away from general regulations. Similar transition was observed in other sectors, such as cybersecurity law (Alshammari & Singh, 2018; Singh & Alshammari, 2020; Singh & Alshammari, 2021), digital legal modernization (Singh & Alshammari, 2021; Singh & Alwaqaa, 2023; Singh & Alodaynan, 2023; Alhulail & Singh, 2023), economic legal restructuring (Alam et al., 2022; Singh et al., 2022a, 2022b; Abubakar et al., 2024; Alam et al., 2025), etc. The healthcare transformation occurred when "localization" became the national priority. The ability to produce and distribute nationally became a public health and national security issue.

As time has passed, Saudi Arabia's legal frameworks regarding vaccine production have become increasingly complex and detailed. In Saudi Arabia, legislative efforts have built upon the initial regulatory foundations to create more specific legal codes that address the details of vaccine production (Alshehri et al., 2023). These laws cover many parts of the industrial process, from getting raw materials to getting finished goods to customers. They also have rules for approving and licensing vaccine manufacturing facilities to make sure they fulfill the necessary safety and quality criteria. These legal standards are very important for helping local businesses and biotech corporations work together, which is in line with national health goals. The law changes show a clear commitment to the ability of local manufacturing and stress the need for a domestic pharmaceutical market in Saudi Arabia's pharmaceuticals sector (Alshehri et al., 2023). These changes make local rules better by making it easier to get things approved and ensuring better quality control.

Even though Saudi Arabia's localization strategy has made headway, issues with implementation and the way that jurisdictional conflicts work together have always been important roadblocks (Alzahrani & Harris, 2021). Following the rules is a big difficulty when it comes to shifting vaccine production to other nations. It is challenging to get local and sectoral norms to agree with each other. Saudi Arabia requires a strong legal system that helps local businesses, has an impact on global legal challenges, and handles difficulties with rules. Consequently, the current study examines the legality of localizing vaccine manufacturing in Saudi Arabia, focusing on the interaction of domestic legislation, regulatory reforms, and

policy adjustments within the Vision 2030 framework.

It is essential to note that Saudi Arabia is undergoing a significant transformation due to its Vision 2030 government initiative (Rehman et al., 2025). Saudi Arabia has put a number of legal reforms in place as part of its Vision 2030. These legal measures also include protections for local manufacturing, knowledge and innovation management, and the readiness of medical crisis response systems (AL-Eitan et al., 2025; Alghamdi, 2025). This study aims to investigate the effect of Saudi legislation, regulatory frameworks, and interagency norms on the advancement of domestic vaccine production in Saudi Arabia. Accordingly, the current research endeavors to answer the following research questions:

RQ1: How does Vision 2030 influence the legal strategies regarding local vaccine manufacturing?

RQ2: How do Saudi domestic laws and related regulations support local vaccine manufacturing?

RQ3: What are the implications of local vaccine manufacturing for public health law in Saudi Arabia?

2. Literature Review

The laws in Saudi Arabia that govern vaccine production have changed a lot throughout the years. At first, the main focus was on the rules that govern the making of drugs in general. But vaccinations are not the same as other drugs. Vaccines usually involve complicated biological processes and need strict quality control to make sure they are safe and work. Tawfik et al. (2022a) assert that more advanced legal frameworks are essential to tackle the distinct issues associated with vaccine manufacturing. New legal remedies to these specific difficulties are frequently based on hope, but problems with implementation and the way that different jurisdictions interact with each other are often big obstacles (Alzahrani & Harris, 2021). One of the legal issues that comes up when vaccine manufacturing is moved to different places is following the rules. These problems show how hard it is to make local and sectoral standards work together in a world that is changing quickly (Tawfik et al., 2022b).

Saudi Arabia's laws around making vaccines have changed over the years as a result. The legal reforms show a clear commitment to the ability of local production. This is shown in the research of Alshehri et al. (2023), who stressed the necessity for legal reform to boost the local pharmaceutical market in the Saudi Arabian drug industry. These legal changes are meant to strengthen domestic rules by making the approval process easier and better quality control through specified requirements.

According to Alshehri et al. (2023), Saudi Arabia established regulatory foundations to develop more specific legal codes tailored to the details of vaccine development. These encompassed various aspects of the production process, from sourcing raw materials to distributing finished products. Recently, Saudi Arabia has introduced guidelines to streamline the approval and licensing of

vaccine manufacturing facilities under the Vision 2030 framework (Halwani et al., 2023). These Saudi legal enhancements have a positive influence on facilitating the local vaccine manufacturing and public health in Saudi Arabia (Alshehri et al., 2023).

The establishment of a pertinent legal framework can provide a solid foundation to support vaccine manufacturing; however, the development of effective compliance mechanisms is equally important. Ensuring compliance (for example, with the vaccine legal framework) requires solid enforcement mechanisms and a capacity for effective monitoring and regulation (Kumari & Singh, 2022; Alhamad & Singh, 2022). Mirza et al. (2023) note that gaps often exist in the enforcement mechanisms that regulate the vaccine production process. As Al-ghaith et al. (2020) point out, a primary issue is ensuring compliance with regulations throughout the entire supply chain. This includes manufacturers, suppliers, distributors, and other stakeholders involved in the vaccine production process. Another parameter involves aligning local regulations with international standards. Although Saudi Arabia's legal frameworks typically align with international standards, some discrepancies still exist in certain areas, which can present challenges for local manufacturers (Niazi, 2023; Singh & Kumari, 2023).

Local vaccine production is vastly important for public health law in Saudi Arabia. This move is important because it enhances the country's capacity to produce vaccines and, simultaneously, assumes wider legal and regulatory frameworks that would ensure the country's health security. Recent studies have begun to fill the knowledge gaps regarding the potential impacts of local vaccine production on public health law. Yet, an in-depth legal analysis is typically directed toward appreciating these implications and, in turn, creating an effective legal framework. As noted by Mirza et al. (2023), much of pharmaceutical policy remains to be further researched, especially concerning local vaccine production. Niazi (2023) mentioned that localization should be supported by adequate legal measures to ensure the availability of vaccines for all sections of the population, particularly vulnerable groups. The legal systems of Saudi Arabia require significant change to support these principles, with full support for local vaccine production.

Fair access and distribution of vaccines is a key part of the law of public health (Alrasheedy et al., 2024). Legal provisions should outline the liability in case of adverse reactions and, more importantly, ensure that victims have access to compensation. This should be one of the major factors that will maintain public trust in vaccines produced within Saudi Arabia and simultaneously ensure that manufacturers are held liable for their products. The question of liability extends to the question of side effects of locally produced vaccines. Local vaccine production has major implications for public health law. As noted by Mirza et al. (2023), this includes raising regulatory standards for national health security. Niazi (2023) emphasized that localization should be supported by legal measures to ensure access to all, particularly vulnerable groups. Liability in case of adverse reactions must be

addressed clearly (Kang et al., 2024). Al-ghaith et al. (2020) highlighted that quality control is critical to national supply continuity and safety. Legal systems should also deal with the cost of locally made vaccines. Alzahrani & Harris (2021) advocated that localized production should consider economic impacts on consumers.

To overcome the regulatory, administrative, and financial challenges of critical sectors vital to its economy, Saudi Arabia formulated the Vision 2030 government program. The economic pillars of Vision 2030 are inseparable from its legal goals. It intends to create an enabling environment for investment and the growth of non-oil sectors (Nair et al., 2024). Among the significant features is the enactment of new policies and regulations that promote the enhancement of biotechnology and pharmaceutical industries, which enhance the country's capacity for local vaccine production. Vision 2030 calls for changes to the legislative system, which include making regulatory procedures better. Vision 2030 sets the stage for legal changes. Vision 2030's legal changes include tax breaks, easier licensing processes, and the promotion of strategic research and development (R&D) collaborations (Singh & Alhulail, 2023; Singh & Aziz, 2025). The Digital Health Strategy and the National Industrial Development and Logistics Program are two ways that Vision 2030 has affected the legal framework. Both of them encourage biotechnology to move forward and the legal framework to be brought up to date (Alarifi et al., 2025). Vision 2030's legislative frameworks make it easier for new technologies to work together (Mani & Goniewicz, 2024). Vision 2030 has begun a necessary movement for Saudi Arabia to produce its own vaccines. Saudi Arabia has established R&D centers under Vision 2030, focusing primarily on biotechnology. There are both legal and financial reasons for new vaccination concepts to support these centers (Mani & Goniewicz, 2024). Vision 2030 has brought about the formation of a necessary legal framework, revisions to regulations, financial incentives, and strategic partnerships that all work together to build a strong local vaccine manufacturing capability.

Saudi Arabia has endeavored to make the norms and laws tougher, develop a clear legal framework for developing vaccines. In 2025, Saudi Arabia set up a new legal framework for the Saudi Food and Drug Authority (SFDA) to ensure that laws and regulations are followed. Therefore, this new SFDA legislative framework was created in 2025 by changing and adding to the old statute from 2007 (Meysan, 2025). The SFDA's original laws were published as Royal Decree No. M/6 (25/1/1428H) (GAFDS, 2007). Changes to the laws up to 2025 can be found on the Istitlaa consultation platform (Istitlaa, 2025). Also, the 2025 legislative framework was added to by the Executive Regulation of the Food Law, the Regulations and Requirements for Conducting Clinical Trials on Drugs (Version 3.0), and the Data Requirements for Submission of Human Drugs (Version 4.0) (SFDA, 2025).

This new legal framework is meant to make medicines, medical equipment, and other health-related goods safer, more useful, and more effective. The new law gives the SFDA the power to make rules, monitor safety, and operate the process.

Article 3 of the new SFDA law makes it clear that the SFDA is responsible for giving people vaccines. The new SFDA statute gives the SFDA the power it needs to do its job well (Meysan, 2025). The SFDA sets the rules for issuing approval and licenses to places that develop vaccines. The SFDA makes sure that vaccinations are safe and work properly in Saudi Arabia by making sure that the right steps are taken in the production process (Covarrubias et al., 2022; Arab et al., 2025). The SFDA has to grant the go-ahead for vaccine producers to commercialize their products. This guarantees that vaccines are both safe and efficacious (Alhossan et al., 2022). The SFDA has strict rules for vaccine makers about quality control, validation, and regularly sending in clinical study data and reports. The SFDA has reached WHO maturity level 4, which is a big deal because it is one of the most respected groups in the world for vaccines and drugs. These kinds of reforms could help Saudi Arabia become a regional center for developing vaccines and be less dependent on imports, which is in line with the goals of its Vision 2030 program.

The localization of vaccine production has major effects on Saudi Arabia's public health laws. It can help the country make sure that all residents have equitable access to vaccines and also make the country's health security better by boosting its ability to make vaccines at home. A law that ensures such local manufacturing would strengthen regulatory standards and promote greater self-sufficiency, thereby reducing dependence on imported vaccines and a fragile global supply chain. Public health priorities support local production facilities to ensure that legal provisions are aligned with national health strategies, promoting sustainable access to essential vaccines.

3. Methodology

The methodology used in this research is broadly qualitative, involving a systematic analysis of all legal texts and frameworks related to vaccine production. Hence, it involves a detailed scrutiny of national legislation, local regulations, and Vision 2030 directives. The qualitative approach is chosen due to its ability to capture the complexities and interrelations between diverse legal provisions, providing a nuanced view of the legal environment.

The analysis specifically encompassed primary national legal instruments pertaining to public health and pharmaceutical regulation (e.g., Royal Decrees and Council of Ministers' Decisions); regulatory texts issued by the SFDA (e.g., guidelines regarding licensing, clinical trials, Good manufacturing practices (GMP)); and strategic policy charters under Vision 2030, including the National Industrial Development and Logistics Program (NIDLP) and health security initiatives.

The analysis employed the comparative legal method through a review of relevant policies, frameworks, and legal documents. Therefore, this methodological framework is crucial in providing an account of the similarities and variations in the legal texts, facilitating a proper comprehension of the legal constraints and opportunities in the localization of vaccine production.

4. Findings

4.1. Vision 2030's Influence on Legal Strategies (RQ1)

4.1.1. Vision 2030, Legal Drive, and Technology Integration

Vision 2030 is a comprehensive plan for Saudi Arabia that aims to reduce its dependence on oil and create a sustainable economy based on innovation (Al-Mamary & Singh, 2025). Vision 2030 aims to create an atmosphere that helps different parts of the Saudi economy grow. A key part of this vision is to improve the biotechnology and pharmaceutical industries in making vaccines in the same place. The legal frameworks under Vision 2030 enable the use of cutting-edge technologies like big data analytics and artificial intelligence to speed up vaccine development and improve quality control (Alghamdi, 2025). The National Strategy for Digital Transformation underlines how crucial it is to employ technology in healthcare, which is highly important for manufacturing vaccines. This plan underlines how important it is to have a robust digital infrastructure to help with research, development, and production (Mani & Goniewicz, 2024).

4.1.2. Regulatory Frameworks and SFDA Role

The SFDA assists local producers by teaching them more about regulations, which lets them compete with big firms from other countries while still meeting global standards, in line with the aims of Vision 2030 (Arab et al., 2025). The National Industrial Development & Logistics Program makes the industrial sector stronger by helping local firms make things better. Vision 2030 gives local businesses a number of legal ways to get aid. The SFDA framework monitors the process of making vaccines, which must be very safe and effective. Vaccines that meet certain requirements, such as those for public health emergencies, can be licensed fast (Meysan, 2025). Local rules are brought up to date with global standards, as those defined by the World Health Organization and the World Conference on Harmonization (Alhossan et al., 2022). GMP requirements have been made easier to follow so that quality and safety criteria are satisfied (Covarrubias et al., 2022).

4.1.3. R&D and Scientific Development

The laws and policies of Vision 2030 are supposed to help make vaccines effectively. These regulations and legislation put a lot of focus on R&D. The Scientific and Technological National Agency supports research that will help the country meet its health goals. This agency encourages colleges, research centers, and private businesses to work together. It endeavors to make Saudi Arabia a player in the global biotechnology industry by putting in place laws that encourage R&D (Alshehri et al., 2023).

4.1.4. SEZs and Fiscal Incentives

Saudi Arabia has created special economic zones (SEZs) as part of its Vision 2030 plan to attract investors from inside and outside the country by offering tax breaks, simpler rules, and modern infrastructure (Alam et al., 2025). Setting up SEZs is one approach to get people to invest in developing vaccines in the area.

Businesses in SEZs pay less in corporate taxes. Exempting and cutting taxes (such as corporate tax) that make vaccines in Saudi Arabia is a financial incentive given to the firms (Alam et al., 2022). The Saudi government provides grants and funding programs that help companies in the biotechnology sector (such as to produce vaccines locally) (Nair et al., 2024).

4.1.5. Strategic Partnerships and Innovation Ecosystems

Under the Vision 2030 framework, strategic partnerships promote innovation and self-reliance in localizing vaccine manufacturing. Saudi Arabia encourages local firms to form partnerships with international biotech companies to transfer knowledge and best practices (Alshehri et al., 2023). These partnerships are structured through joint ventures or licensing agreements. Setting up innovation hubs under Vision 2030 supports these collaborations (Mani & Goniewicz, 2024). Partnerships with academia give access to research and skilled labor. Public-private partnerships enable resource sharing and risk mitigation (Abubakar et al., 2024). Legal support forms the contractual basis. These partnerships enhance local expertise and position Saudi Arabia in global vaccine production.

4.2. Domestic Laws Supporting Vaccine Production (RQ2)

4.2.1. Streamlining Vaccine Approval Laws

Saudi Arabia has introduced a new legal framework under the revamped SFDA law (2025) to address past delays in vaccine approvals. Previously, regulatory processes were slow and misaligned with public health emergencies. The traditional approval methods caused significant delays. The reforms aim to shorten timelines by allowing early dialogue between manufacturers and regulators, enabling conditional approvals based on preliminary data with post-marketing surveillance (Meysan, 2025). The SFDA has established a specialized team to manage vaccine approvals, collaborating with global authorities to align with international standards. Digital systems have also enhanced transparency and speed up submissions (Kumari & Singh, 2022; Alhamad & Singh, 2022).

4.2.2. Quality Assurance and Regulatory Oversight

Legal reforms emphasize strict quality control to ensure the safety and efficacy of vaccines. New measures require thorough validation during all stages—preclinical, clinical, and post-marketing. Under quality assurance (QA) initiatives, manufacturers are subject to regular audits and inspections, with penalties for noncompliance (Arab et al., 2025). Saudi Arabia collaborates with global agencies to adopt best practices and enhance domestic standards, with the broader aim of improving its export potential and strengthening its position in the global vaccine market (Covarrubias et al., 2022; Alhossan et al., 2022).

4.2.3. Intellectual Property and National Alignment

Intellectual Property (IP) regulations protect the rights of inventors and firms involved in vaccine development (Niazi, 2023). Legal IP protection for local production of vaccines incentivizes R&D. The Saudi legal framework includes IP protec-

tions to ensure trust between local and international partners. Revamped SFDA legal framework (2025) encourages vaccine development aligned with national health needs and provides mechanisms for oversight, monitoring, and accountability (Alshehri et al., 2023). These initiatives help Saudi Arabia enhance self-sufficiency in healthcare and support its goal of becoming a regional biotech hub, contributing to global health security (Tawfik et al., 2022a; Halwani et al., 2023). Saudi Arabia links its legal structure with international intellectual property treaties, particularly the TRIPS Agreement of the World Trade Organization. TRIPS safeguards pharmaceutical discoveries to enhance their appeal and facilitates knowledge transfer; nevertheless, it simultaneously enforces patent protection requirements that may hinder local manufacturers from creating generics or biosimilars (Tawfik et al., 2022a).

4.3. Public Health Law Implications of Local Manufacturing (RQ3)

4.3.1. Legal Foundations for Local Vaccine Production

Saudi Arabia has revamped the SFDA legal framework to support local vaccine production, including provisions for setting up manufacturing plants, ensuring quality control, and promoting technology transfer (Meysan, 2025). These legal reforms address public health priorities by enhancing domestic production and facilitating rapid responses to health crises. SFDA regulations enforce safety standards, which are critical to overcoming vaccine hesitancy (Alrasheedy et al., 2024). Digitization and regulatory adjustments further streamline processes, ensuring timely vaccine approval and distribution (Kumari & Singh, 2022; Alhamad & Singh, 2022). This legal infrastructure plays a crucial role in enhancing national health security and bolstering the healthcare system's resilience (Alarifi et al., 2025).

4.3.2. Public Access, Equity, and Affordability

Local manufacturing reduces dependence on imports and enhances vaccine availability (Tawfik et al., 2022a). Laws supporting domestic production contribute to lower vaccine costs—up to 25% less. Since the Saudi government subsidizes healthcare, this cost reduction is helpful for the Saudi government to modernize its health services effectively (Nair et al., 2024). Legal mandates ensure distribution to underserved populations, including rural and low-income communities, promoting vaccine equity (AL-Eitan et al., 2025; Alrasheedy et al., 2024). Such developments ensure quicker access, fairer distribution, and better coverage during health emergencies.

4.3.3. Strengthening System Responsiveness and Oversight

Legal frameworks guide national vaccination programs by coordinating policy formulation, storage, and logistics for delivery. SFDA-led inspections and quality checks ensure adherence to high standards, protecting public health and reinforcing trust in local vaccines (Arab et al., 2025). Provisions for data collection on vaccination rates, adverse events, and public health outcomes help target interven-

tions where needed (Kang et al., 2024). The revamped SFDA legal framework (2025) supports flexible responses to new challenges—which is demonstrated by expedited approvals during health emergencies—ensuring that vaccine production and distribution remain adaptive to emerging threats (Meysan, 2025). This legal evolution positions Saudi Arabia to better manage future health crises with strengthened preparedness and accountability (Alarifi et al., 2025).

To enhance the legal harmonization between local and international norms, extensive research on suggested legal innovations is impeded by significant impediments to implementation and existing jurisdictional conflicts. The primary concerns were the safeguarding of intellectual property and adherence to legislation; these legal obstacles require meticulous management. Meticulously established collaboration agreements can mitigate jurisdictional issues and enhance efficacy.

5. Conclusion

Through the strengthening of domestic manufacturing capabilities, the localization of vaccine manufacturing under Vision 2030 has significant implications for public health laws in Saudi Arabia, as it can help the country ensure equal access to vaccines among all citizens and improve its national health security (AL-Eitan et al., 2025). Evidence and analysis in this study demonstrate a unique shift in domestic law from generalist, static regulations to sectoral codes (Alshehri et al., 2023). The new SFDA legal framework 2025 ensures that local manufacturing makes provisions stronger for regulatory standards and greater self-sufficiency, thereby reducing reliance on imported vaccines and the global supply chain (Arab et al., 2025).

Vision 2030 seeks to reduce reliance on oil and establish an innovative, sustainable economy (Mani & Goniewicz, 2024). Enhancing the localization of vaccine manufacturing in the pharmaceutical and biotechnology industries is a crucial component of Vision 2030. Encouraging cooperation between academic institutions, research institutes, and commercial businesses, Vision 2030 acknowledges R&D in the legal and policy framework. Tax breaks and simplified regulations in SEZs attract investment (Nair et al., 2024). Under Vision 2030, strategic alliances promote information sharing, innovation center development, and collaboration between regional businesses and global biotech enterprises.

Saudi Arabia has implemented policies to regulate the pharmaceutical sector, with a focus on quality, safety, and efficacy. These measures underscore the importance of a domestic pharmaceutical industry and facilitate partnerships between local businesses and biotech enterprises. The new SFDA framework for 2025 deals with delays in vaccination approvals. The new SFDA rules help Saudi Arabia reach its goal of becoming a regional biotech powerhouse and ensure that vaccine development meets public health needs.

There are provisions in the new SFDA framework for building plants, keeping an eye on quality, and sharing information. These rules make it easier to respond

rapidly to health emergencies and increase local manufacturing. The SFDA makes safety rules to get people to be vaccinated. Getting approval and sending out goods has become easier because of digitization and changes to the procedures. Vaccines are easier to get when they are made locally, and there is less need to import them. Laws that ensure vaccines get to people who need them, such as people in rural or low-income areas, help make immunizations more fair. People are more inclined to trust local vaccines because the SFDA monitors them for quality and safety (Kang et al., 2024). The new SFDA 2025 law will speed up approvals in an emergency, ensuring that manufacturing and distribution can keep up with new demands. This update in the law makes people more responsible and prepared (Alarifi et al., 2025).

This paper offers an extensive analysis of the legal implications of localizing vaccine production, including domestic legislation, regulatory reforms, and legal adjustments in accordance with Vision 2030. Saudi Arabia's emphasis on localization aids in the development of vaccines that meet both regional and international standards (Tawfik et al., 2022a). SFDA is considered one of the best regulatory organizations, and it has attained level 4 of WHO maturity. If Saudi Arabia follows the ideas in Vision 2030, these kinds of improvements could make it a regional center for vaccine production, which would make it less dependent on imports.

6. Recommendations and Future Research

Saudi Arabia should concentrate on incorporating contemporary legal trends and technologies into its vaccine production system. It should do an assessment to see if digital health technology may help make vaccination distribution systems more efficient and make it easier to follow the rules. Legal scholars and policymakers should collaborate to enhance the localization of vaccine production in Saudi Arabia. Saudi Arabia's legal and policy framework should make sure that its health laws are strict and that people can get the vaccines they need sustainably.

Looking ahead, several key areas likely require additional research and development. These efforts could enhance the effectiveness of Saudi Arabia's legal frameworks for vaccine production. The regulatory process could include new technologies and ideas. Using digital technologies like blockchain and AI can make regulation more open and efficient. This can make it easier to monitor and enforce compliance. Future research should examine these developing technologies and their implications for the healthcare sector in Saudi Arabia, especially with the localization of vaccine production. Moreover, subsequent research could seek to empirically evaluate the effectiveness of recent legislative reforms, for instance, by measuring variances in vaccine clearance delays or assessing local production rates.

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

References

Abubakar, A. A., Al-Mamary, Y. H., Singh, H. P., Singh, A., Alam, F., & Agrawal, V. (2024). Exploring Factors Influencing Sustainable Human Capital Development: Insights from Saudi Arabia. *Heliyon, 10,* e35676. https://doi.org/10.1016/j.heliyon.2024.e35676

Alam, F., Singh, H. P., & Singh, A. (2022). Economic Growth in Saudi Arabia through Sectoral Reallocation of Government Expenditures. *Sage Open, 12,* 1-13. https://doi.org/10.1177/21582440221127158

Alam, F., Singh, H. P., Singh, A., Al-Mamary, Y. H., Abubakar, A. A., & Agrawal, V. (2025). Human Capital Spending and Its Impact on Economic Growth in Saudi Arabia: An NARDL Approach. *Sustainability, 17,* Article No. 4639. https://doi.org/10.3390/su17104639

Alarifi, A. M., Alshahrani, N. Z., Jokhdar, H., & Asiri, A. M. (2025). Advancing Health through Sustainable Development Goals-Saudi Arabia's Mid-Journey Progress and Insights. *Journal of Epidemiology and Global Health, 15,* Article No. 48. https://doi.org/10.1007/s44197-025-00385-y

AL-Eitan, L. N., Almahdawi, D. L., Abu Khiarah, R. A., & Alghamdi, M. A. (2025). Bridging Gaps in Vaccine Access and Equity: A Middle Eastern Perspective. *Vaccines, 13,* Article No. 806. https://doi.org/10.3390/vaccines13080806

Al-Ghaith, T., Almoteiry, K., Alamri, A., Alluhidan, M., Alharf, A., Al-Hammad, B., Aljaffali, I., Seiter, A., Pisani, E., Herbst, C. H., El-Saharty, S., & Alazemi, N. (2020). *Strengthening the Pharmaceutical System in the Kingdom of Saudi Arabia: Towards a Medicine Policy to Support Vision 2030 (Health, Nutrition and Population Discussion Paper).* World Bank. https://doi.org/10.1596/35846

Alghamdi, A. A. (2025). Medication Safety in Saudi Arabia: Evaluating the Current Situation and Identifying the Areas for Improvement. *Pharmacy, 13,* Article No. 50. https://doi.org/10.3390/pharmacy13020050

Alhamad, I. A., & Singh, H. P. (2022). Digital Technologies and Information Translucence in Healthcare Management: An Institutional Theory Perspective for Adopting Electronic Incidence Reporting Systems. *Revista Amazonia Investiga, 11,* 30-38. https://doi.org/10.34069/ai/2022.57.09.3

Alhossan, A., Alsaran, A. K., Almahmudi, A. H., Aljohani, Z. S., Albishi, M. R., & Almutairi, A. K. (2022). Adverse Events of COVID-19 Vaccination among the Saudi Population: A Systematic Review and Meta-Analysis. *Vaccines, 10,* Article No. 2089. https://doi.org/10.3390/vaccines10122089

Alhulail, H. N., & Singh, H. P. (2023). Impact of Multimedia Technology on University Students Learning Agility and Creativity. *Revista Amazonia Investiga, 12,* 189-199. https://doi.org/10.34069/ai/2023.70.10.17

Al-Mamary, Y. H., & Singh, H. P. (2025). Modeling Sustainable Entrepreneurship and Green Economic Growth: The Role of Policy, Digital Innovation, Resource Efficiency, Infrastructure, Entrepreneurial Intentions, and Innovative Capacity. *Next Research, 2,* Article ID: 100859. https://doi.org/10.1016/j.nexres.2025.100859

Alrasheedy, A. A., Alharbi, A. T., Alturaifi, H. A., Alkhamis, R. A., Almazyad, R. S., Almozaini, S. S. et al. (2024). Community Pharmacists' Knowledge, Beliefs, and Perceived Barriers toward Vaccination Services at Community Pharmacies: A Cross-Sectional Study from Saudi Arabia. *Human Vaccines & Immunotherapeutics, 20,* Article ID: 2414551. https://doi.org/10.1080/21645515.2024.2414551

Alshammari, T. S., & Singh, H. P. (2018). Preparedness of Saudi Arabia to Defend against Cyber Crimes: An Assessment with Reference to Anti-Cyber Crime Law and GCI Index. *Archives of Business Research, 6,* 131-146. https://doi.org/10.14738/abr.612.5771

Alshehri, M. et al. (2023). Legal Frameworks Impacting Pharmaceutical Localization in Saudi Arabia: A Policy Review. *Middle East Health Policy Journal, 12,* 103-117.

Alzahrani, A., & Harris, M. (2021). Vision 2030 and the Evolution of Healthcare Law in Saudi Arabia. *Journal of International Legal Studies, 29,* 87-102.

Arab, O. O., Aldayan, M., Almowaizri, K., Alghamdi, A., Alghamdi, J., & Alharf, A. (2025). Descriptive Analysis of Good Clinical Practice Inspection Findings from the Saudi Food and Drug Authority. *Therapeutic Innovation & Regulatory Science, 59,* 295-303. https://doi.org/10.1007/s43441-024-00731-5

Covarrubias, C. E., Rivera, T. A., Soto, C. A., Deeks, T., & Kalergis, A. M. (2022). Current GMP Standards for the Production of Vaccines and Antibodies: An Overview. *Frontiers in Public Health, 10,* Article ID: 1021905. https://doi.org/10.3389/fpubh.2022.1021905

GAFDS (2007). *General Authority for Food and Drug System*. https://laws.boe.gov.sa/BoeLaws/Laws/LawDetails/dd7a7d7d-a92d-431b-9ec3-a9a700f28a46/1

Halwani, A. A., Balkhi, B., Alamoudi, A. A., Almozain, N. H., Alajmi, A. M., Noorwali, A. et al. (2023). Current Status and Vision of Local Pharmaceutical Industries in Saudi Arabia: The Focus on Nanomedicines. *Saudi Pharmaceutical Journal, 31,* Article ID: 101674. https://doi.org/10.1016/j.jsps.2023.06.007

Istitlaa (2025). *Amendments to the General Food and Drug Authority Law and Food Law (Public Consultation)*. National Competitiveness Center. https://istitlaa.ncc.gov.sa/en/health/sfda/SFDALAW/Pages/default.aspx

Kang, C. R., Choe, Y. J., Moon, J., Kim, D., Kim, T., & Lee, J. (2024). Comparison and Consideration of Vaccine Injury Compensation Programs in the Republic of Korea, Japan, and Taiwan Region. *Osong Public Health and Research Perspectives, 15,* 479-488. https://doi.org/10.24171/j.phrp.2024.0129

Kumari, R., & Singh, H. P. (2022). Role of Incident Reporting System in Healthcare Management: A Case of Multispecialty Tertiary Hospital in India. *International Journal of Information Movement, 6,* 12-18. http://www.ijim.in/paper-3-role-of-incident-reporting-system-in-healthcare-management-a-case-of-multispeciality-tertiary-hospital-in-india/

Mani, Z. A., & Goniewicz, K. (2024). Transforming Healthcare in Saudi Arabia: A Comprehensive Evaluation of Vision 2030's Impact. *Sustainability, 16,* Article No. 3277. https://doi.org/10.3390/su16083277

Meysan, H. A. (2025). *The New SFDA Law: A Transformational Regulatory Framework for Food, Drug, and Health Oversight in Saudi Arabia*. Hammad & Al-Mehdar Law Firm. https://hmco.com.sa/the-new-sfda-law-a-transformational-regulatory-framework-for-food-drug-and-health-oversight-in-saudi-arabia/

Mirza, K., Al-Ruwaili, F., & Daghistani, M. (2023). Challenges in Regulatory Compliance for Locally Manufactured Vaccines in Saudi Arabia. *Saudi Legal Review, 18,* 44-59.

Nair, K. S., Mughal, Y. H., Albejaidi, F., & Alharbi, A. H. (2024). Healthcare Financing in Saudi Arabia: A Comprehensive Review. *Healthcare, 12,* Article No. 2544. https://doi.org/10.3390/healthcare12242544

Niazi, S. K. (2023). A Proposed Global Medicines Agency (GMA) to Make Biological Drugs Accessible: Starting with the League of Arab States. *Healthcare, 11,* Article No. 2075. https://doi.org/10.3390/healthcare11142075

Rehman, A., Ara, A., & Singh, H. P. (2025). How Green HRM Practices, Organisational Citizenship Behaviour towards Environment, Technological Competence and Resistance to Change Influence the Environmental Performance of Saudi Universities. *Future Busi-*

ness Journal, 11, Article No. 224. https://doi.org/10.1186/s43093-025-00657-w

SFDA (2025). *Laws and Regulations*. Saudi Food and Drug Authority. https://www.sfda.gov.sa/en/regulations

Singh, A., Singh, H. P., Alam, F., & Agrawal, V. (2022a). Role of Education, Training, and E-Learning in Sustainable Employment Generation and Social Empowerment in Saudi Arabia. *Sustainability, 14,* Article No. 8822. https://doi.org/10.3390/su14148822

Singh, H. P., & Alhulail, H. N. (2023). Information Technology Governance and Corporate Boards' Relationship with Companies' Performance and Earnings Management: A Longitudinal Approach. *Sustainability, 15,* Article No. 6492. https://doi.org/10.3390/su15086492

Singh, H. P., & Alodaynan, A. M. M. (2023). The Role of Educational Technology in Developing the Cognitive and Communicative Skills of University Students: A Saudi Arabian Case. *International Journal of Advanced and Applied Sciences, 10,* 157-164. https://doi.org/10.21833/ijaas.2023.07.017

Singh, H. P., & Alshammari, K. (2021). Impacts of Digital Technology-Enabled Personalized and Adaptive Learning on Student Learning Performance: A TOE Framework for Saudi Arabia. *International Transaction Journal of Engineering, Management, & Applied Sciences & Technologies, 12,* 1-12. https://doi.org/10.14456/ITJEMAST.2021.262

Singh, H. P., & Alshammari, T. S. (2020). An Institutional Theory Perspective on Developing a Cyber Security Legal Framework: A Case of Saudi Arabia. *Beijing Law Review, 11,* 637-650. https://doi.org/10.4236/blr.2020.113039

Singh, H. P., & Alwaqaa, M. A. M. (2023). The Educational Technology's Impact on Youth Creativity and Innovation: A Case of Ha'il Region of Saudi Arabia. *Revista Amazonia Investiga, 12,* 144-154. https://doi.org/10.34069/ai/2023.66.06.14

Singh, H. P., & Aziz, A. A. (2025). Impact of Intelligent Learning Assistants on Creativity of University Students: A Self-Determination Theory Perspective. *Future Business Journal, 11,* Article No. 122. https://doi.org/10.1186/s43093-025-00544-4

Singh, H. P., & Kumari, R. (2023). Digital Technologies in Healthcare Management: A Study of Influence of National Culture for Adoption of Electronic Health Records in India and Australia. *Archives of Business Research, 11,* 206-217. https://doi.org/10.14738/abr.118.15354

Singh, H. P., Singh, A., Alam, F., & Agrawal, V. (2022b). Impact of Sustainable Development Goals on Economic Growth in Saudi Arabia: Role of Education and Training. *Sustainability, 14,* Article No. 14119. https://doi.org/10.3390/su142114119

Tawfik, E. A., Tawfik, A. F., Alajmi, A. M., Badr, M. Y., Al-Jedai, A., Almozain, N. H. et al. (2022b). Localizing Pharmaceuticals Manufacturing and Its Impact on Drug Security in Saudi Arabia. *Saudi Pharmaceutical Journal, 30,* 28-38. https://doi.org/10.1016/j.jsps.2021.12.002

Tawfik, H., Alghamdi, N., & Basudan, R. (2022a). Regulatory Frameworks for Pharmaceuticals in Saudi Arabia: A WHO-Compliance Analysis. *Global Drug Policy and Health, 6,* 202-213.