

Localizing Vaccine Production in Saudi Arabia: International Legal Dynamics and Challenges

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Abstract

The localization of vaccine manufacturing is an important aspect for Saudi Arabia, as it relies on healthcare imports during crises. Under its Vision 2030 framework, Saudi Arabia is making efforts to modernize its healthcare system and localize the production of vaccines. However, Saudi Arabia needs to participate in strengthening the international legal framework in this endeavor. The extant legal agreements, like TRIPS, facilitate technology transfer; however, they also impose strict conditions on intellectual property (IP) protection. This study employs a qualitative methodology to analyze Saudi and international legal documents, agreements, and frameworks, and examines their influence on the localization of vaccine manufacturing in Saudi Arabia. The study findings indicate that there are challenges related to IP protection, international regulatory issues, and jurisdictional matters that hinder collaboration. However, Saudi Arabia can overcome them by promoting regional and multi-lateral agreements that can facilitate technology transfer and international collaborations. The study further indicates that to balance international commitments with national priorities, modifications to the legal framework, collaboration with other countries, and the establishment of cross-border partnerships are necessary.

Keywords

Vaccine Localization, International Law, Intellectual Property Rights, Regulatory Challenges, Saudi Arabia, Saudi Vision 2030

1. Introduction

The localization of vaccine production has become an increasingly important goal in health governance across the globe. Localization refers to the capability to produce vaccines through the necessary stages in the home country, where produc-

tion and regulatory frameworks are established (Kumraj et al., 2022). A lack of local production can become an issue for countries that rely on imports, especially for critical vaccines, in handling international crises. Countries around the world are making efforts to localize the production of critical products. For countries like Saudi Arabia, localized production of critical products (like vaccines) is necessary to enhance the health security of their residents (Halwani et al., 2023) and to enhance sustainable development (Singh et al., 2022a, 2022b; Al-Mamary & Singh, 2025). Consequently, countries like Saudi Arabia are making efforts to enhance the localization of vaccine manufacturing by streamlining their legal structures and related mechanisms (like international legal agreements) (Singh & Alshammari, 2020; Alshehri et al., 2023).

International legal agreements can play a crucial role in helping countries like Saudi Arabia meet global standards for vaccine production. These agreements facilitate knowledge exchange in a standardized manner to meet the needs of various stakeholders, including transnational companies, local governments, and global regulatory bodies (Tawfik et al., 2022a; Alshammari & Singh, 2018). However, these agreements could also pose challenges for countries like Saudi Arabia that seek to localize vaccine production (Dzau et al., 2025). On the one hand, these agreements facilitate the transfer of technology. Technology transfer enables countries to acquire modern technologies and develop international collaborations to meet international standards (Da Fonseca et al., 2023). On the other hand, they create legal challenges in technology transfer, making it difficult to develop locally critical products (like vaccines). Therefore, countries like Saudi Arabia need to consider global health standards, trade commitments, and intellectual property (IP) restrictions, as well as the local population's need to access affordable vaccines (Mirza et al., 2023a; Al-Eitan et al., 2025).

IP rights are an important aspect of international legal agreements in the area of vaccine manufacturing. International legal agreements dealing with IP rights, such as the Trade-Related Aspects of Intellectual Property Rights (TRIPS), endeavor to protect innovative ideas and encourage nations to conduct vaccine research. However, TRIPS also makes it challenging for developing countries like Saudi Arabia to produce essential vaccines locally (Chan et al., 2025). Therefore, countries like Saudi Arabia need techno-legal mechanisms to produce vaccines locally that do not contravene international IP rights. These mechanisms include collaborations with transnational companies, entering into license agreements, working with both the public and private sectors, and strengthening human capital development (Alam et al., 2022; Abubakar et al., 2024; Alam et al., 2025) inside the country to generate the necessary skillset for the local production of vaccines. However, these mechanisms should be well-planned and executed strategically in line with the nation's vision, so that all stakeholders benefit from them.

To meet these evolving challenges, Saudi Arabia needs to update its health regulations in line with international standards. Additionally, it needs to collaborate effectively with other countries, especially the Gulf Cooperation Council (GCC)

nations. This could be useful as GCC nations have collaborated among themselves in the past to form international legal agreements and develop shared digital systems (Singh & Alshammari, 2021; Alhamad & Singh, 2022; Singh & Kumari, 2023; Singh & Aziz, 2025). Therefore, these international legal agreements could provide an enabling framework for Saudi Arabia to localize its vaccine production.

Consequently, the present study addresses the following research questions:

RQ1: How do international legal agreements influence local vaccine manufacturing in Saudi Arabia?

RQ2: What are the legal challenges that emerge in the localization of vaccine manufacturing in Saudi Arabia?

2. Literature Review

International legal agreements could play a crucial role in providing a guiding framework for local manufacturing, especially in Saudi Arabia, which is undergoing significant transformation under its Vision 2030 program. International legal agreements can help the local industry gain access to cutting-edge technology and the global market; however, they also impose constraints that pose challenges to local manufacturing. The local industry needs to develop competencies quickly to compete in the global sphere under these international legal agreements; otherwise, it might not be able to localize vaccine production effectively (Suri & Marini, 2024).

Trade-Related Aspects of Intellectual Property Rights (TRIPS) is a well-known international legal agreement that protects Intellectual Property (IP) and helps nations share technology (Perehudoff et al., 2022). TRIPS can facilitate technology transfer, which can be crucial for developing nations like Saudi Arabia, especially in the area of vaccine manufacturing. TRIPS can help nations like Saudi Arabia develop new ideas (Abreu et al., 2025) and develop their creative potential (Alhulail & Singh, 2023; Singh & Alwaqaa, 2023). However, TRIPS also enforces IP protection mechanisms vigorously (via protecting patents), which makes the localization of vaccine manufacturing difficult. This is because TRIPS ensures that companies that have invested in research and development do not incur a loss on their original ideas and get a reasonable profit on their investments. Thus, TRIPS prevents local producers from copying the original patents. In effect, TRIPS protects the IP of the original creators, whereas it also hampers local vaccine production by making it difficult to improvise on the original ideas. Furthermore, developing nations like Saudi Arabia also face infrastructure and trained human resource constraints (Kumari & Singh, 2022), which complicate their efforts to develop local capabilities. Therefore, local producers require strategic partnerships with major international pharmaceutical companies to overcome these constraints, which TRIPS can enable.

Prior research shows that international agreements (like TRIPS) enable the transfer of technology and help companies comply with international IP laws (Raslan, 2024; Martínez-Zarzoso & Coka, 2025; Rehman et al., 2025). These inter-

national agreements present opportunities for Saudi local companies to work with international companies to develop local vaccine manufacturing capabilities. However, local Saudi companies need to walk a tightrope so that they can meet international commitments to protect IP while keeping costs down to meet the needs of domestic consumers. International legal agreements (like TRIPS) prioritize the protection of IP rights; therefore, they complicate local efforts to produce affordable vaccines for the local population (Mirza et al., 2023b). Thus, countries like Saudi Arabia need to develop a legal framework that ensures these conflicting objectives are balanced, which means local enterprises get access to cutting-edge technology (to overcome their technology and human resource issues) while protecting the rights of international IP holders. Such a legal framework can enable local enterprises to produce affordable vaccines locally that meet international standards and respect international IP holder rights (Ngum et al., 2024; Nunes et al., 2024).

However, there are challenges in developing an effective legal framework in Saudi Arabia. One of the primary difficulties is protecting the rights of the international IP holder. This is because local producers need access to critical information and tools for local vaccine production; however, it is a difficult balance to protect the rights of the international IP holder and provide local producers with the information they need to produce affordable vaccines locally. Considering these challenges, Tawfik et al. (2022b) asserted that strict IP restrictions impose considerable legal and financial troubles on local manufacturers; therefore, they find it difficult to produce affordable goods. This is the issue that affects local vaccine manufacturers in Saudi Arabia. Therefore, the legal framework needs to have provisions to overcome these challenges. One method is to develop vaccines locally under strict technology transfer licenses. These licenses can protect the IP and enable local production. However, the legal framework of the nation should have enabling provisions so that a deal can be negotiated between international and local companies (Patel et al., 2023).

Developing an effective international legal agreement can help to overcome these challenges, as it can resolve several issues of conflict. It requires effective cooperation between national and international governments as well as alignment in their legal frameworks around international cooperation and technology transfer (Mashingia et al., 2023). However, this process is easier said than done. This is because the multiple standards in various countries can make it difficult for local manufacturers to follow the rules. It becomes difficult, time-consuming, and costly for local companies to follow multiple sets of rules from various nations. Multiple sets of rules also have the potential to create conflict between international and local companies, which may result in legal battles and court cases. Things get even more complicated when there are multiple regulatory authorities in various countries to enforce the rules. In the case of vaccines, multiple regulatory bodies and rules make it difficult to produce and distribute vaccines affordably. Also, global technology transfer processes under international agreements (like TRIPS) can be

slow and resource-consuming, which places pressure on local manufacturers. Therefore, [Alzahrani and Harris \(2021\)](#) assert that countries should enter into international agreements and harmonize the rules and regulatory framework to solve legal jurisdictional issues. Further, [Chejor et al. \(2024\)](#) and [Thompson et al. \(2023\)](#) suggest that nations should build infrastructure, skills, and quality control systems around their international legal framework to ensure smooth implementation. Such mechanisms can ensure that international legal agreements can help in the localization process.

3. Methodology

The methodology used in this research is qualitative to examine the international legal dynamics for localizing vaccine manufacturing in Saudi Arabia. This study used a qualitative methodology as it is considered pertinent for examining the legal documents and drawing conclusions. Accordingly, we qualitatively examine the role of relevant international agreement(s) and legal framework(s) to generate knowledge for localizing vaccine manufacturing in Saudi Arabia.

The study conducts a qualitative analysis of the legal documents to decipher the similarities and differences between the national (Saudi) and international legal frameworks. The national (Saudi) laws and regulations were examined using the SFDA materials ([SFDA, 2025](#)) and the documents of the Saudi Ministry of Health ([MoH, 2025](#)). To study the international agreements and legal frameworks, we examined documents from the World Health Organization ([WHO, 2025](#)), the World Trade Organization ([WTO, 2025](#)), and the TRIPS documents. The Saudi documents were selected because they provide important and relevant information about the Saudi legal framework, and the international documents provide pertinent and crucial information about the international legal framework and guidelines. The selected documents were screened beforehand and then analyzed comprehensively. The purpose of the legal document review was to identify the areas of support (legal areas that promote localization) and divergence (legal areas that pose challenges to localization) regarding the localization of vaccine manufacturing in Saudi Arabia.

4. Findings

4.1. International Legal Agreements' Influence on Local Vaccine Manufacturing (RQ1)

4.1.1. Compliance with International Legal Frameworks

Local producers in Saudi Arabia need to ensure compliance with international legal frameworks (e.g., TRIPS), and it is strategically essential for vaccine manufacturers to abide by both domestic and international regulations ([Perehudoff et al., 2022](#); [Tawfik et al., 2022b](#)). Compliance with regulations is not just a legal necessity but also necessary for obtaining the much-needed technology transfer from established international companies. This can help local companies grow and enhance their manufacturing capabilities. Furthermore, compliance with lo-

cal and international regulations enables local companies to meet their legal and financial obligations without unnecessary hassles. Companies can automate certain processes for ease of compliance, which can help them adapt to regulatory changes. Moreover, local enterprises can train their staff, encourage them to attend international workshops and conferences, and develop collaborative international networks to meet compliance requirements and facilitate knowledge sharing. Such initiatives can also help local enterprises meet international standards, such as those set by the WHO and WTO.

4.1.2. Technology Transfer and Global Partnerships

Global partnerships can enable technology transfer (Abreu et al., 2025), which can be critical for developing vaccines locally. Local Saudi manufacturers can develop partnerships with global vaccine manufacturers and biotechnology companies. This can help them gain access to critical technology and know-how. Such partnerships can enable them to develop affordable vaccines that meet global standards as well as enhance their industrial competitiveness (Alhulail & Singh, 2023). Partnerships with global players also help local companies gain critical supply lines, finances, and technical knowledge, which helps them innovate according to local conditions. Such partnerships also enable global players to establish a local footprint in a new territory, where they might not have reached otherwise. Therefore, these partnerships present a win-win situation for local and global enterprises and help them build capacity as well as develop sustainable business models in alignment with global standards and regulations (Ngum et al., 2024; Nunes et al., 2024).

4.1.3. Negotiation Strategies and Mutual Benefits

The local Saudi enterprises need to negotiate with global players in areas of mutual benefit. These areas include access to local markets (for global players) and technology transfer (for local players) (Martínez-Zarzoso & Coka, 2025; Rehman et al., 2025). While the local players need access to advanced technology, the global players also need access to the Saudi market through partnerships with local players. Both parties should recognize the mutual benefits and conduct business in this regard. As an example, the Saudi MoH and SaudiVax (local players) collaborated with Sanofi (a French multinational pharmaceutical company) to enhance local pharmaceutical production. Both parties negotiated this in accordance with TRIPS and considered the IP and technology transfer aspects (Da Fonseca et al., 2023). Such agreements lay the groundwork to prevent any disagreements and provide a working framework, which helps both parties achieve mutually beneficial goals in accordance with the regulations. These international agreements also help advance the Saudi Vision 2030 goals of local job creation, training Saudi human resources in using modern technology, and improving public health. Such agreements could be very useful in the area of vaccine manufacturing and can be mutually beneficial for local as well as global players. There is good scope for Saudi Arabia to enter into mutually beneficial partnerships in this regard with Gulf Co-

operation Council (GCC) countries, as regional agreements are easier to negotiate, given that these countries share similar cultures and legal frameworks.

4.1.4. Intellectual Property Rights and Risk Management

The IP rights of international players should be respected in letter and spirit so that there can be effective technology transfer (Tawfik et al., 2022b; Perehudoff et al., 2022). Global players can only feel comfortable with effective technology transfer when they are assured that their technology will not be compromised. Therefore, it is important to develop an environment of trust and strengthen the governing legal framework (Mirza et al., 2023b). Such mechanisms can minimize risks for all parties, meet the national interests of Saudi Arabia, and enable local Saudi enterprises to meet their global obligations in line with international standards.

4.1.5. Multi-Stakeholder and Regulatory Engagement

It is important to engage with multiple stakeholders (such as government agencies, local and international industries) (Raslan, 2024). This kind of engagement with multiple stakeholders enhances the value of mutual agreements and leads to long-lasting agreements that are beneficial to all parties. Furthermore, disagreements around the sticky issues can be resolved by such agreements. The involvement of government agencies in this process can enable the formulation of an enabling regulatory environment, which can lead to the smooth conduct of business among all parties. Therefore, Saudi Arabia should engage with multiple stakeholders and participate in the development of a regional or multilateral regulatory framework, which can be beneficial for the localization of vaccine manufacturing in Saudi Arabia.

4.2. Legal Challenges in the Localization of Vaccine Production (RQ2)

4.2.1. Intellectual Property Rights and Management

It is important to manage the issues related to IP rights in letter and spirit, especially for nations like Saudi Arabia. This is because Saudi Arabia lacks local expertise and needs effective technology transfer agreements (Tawfik et al., 2022b; Perehudoff et al., 2022). Therefore, legal mechanisms need to be developed to protect IP rights. Further, there is a need to develop effective and trustworthy partnerships between local and global players. Global players should receive fair compensation for technology transfer and should be confident that the transferred technology will not be misused (Martínez-Zarzoso & Coka, 2025; Rehman et al., 2025). There should be legal mechanisms in place that ensure technology transfer serves its intended purpose and that shared information is held confidentially (Raslan, 2024). The issues around compulsory licensing should be managed professionally and legally (Perehudoff et al., 2022; Tawfik et al., 2022b). The Saudi government should ensure that IP laws are followed in letter and spirit by local enterprises (Mirza et al., 2023b). Regulatory mechanisms should be made robust to encourage the participation of global players in the Saudi health market for the

localization of vaccine manufacturing. Such mechanisms can help Saudi Arabia manage IP issues effectively, promote the participation of international players in the Saudi market, facilitate technology transfer, and promote the localization of vaccine manufacturing in Saudi Arabia.

4.2.2. Regulatory Harmonization and Convergence

The effective collaboration between local and global players requires the harmonization of regulations at the government level. This is because local and global players need to satisfy the requirements of their host governments, and in the case of a conflict between regulations, it becomes challenging for both players to collaborate effectively. There could be differences in regulations related to clinical trials, safety rules, quality issues, etc. (Mashingia et al., 2023). These issues prevent collaboration between local and global players, even though such collaboration could be a win-win situation for both parties. Therefore, it is important that the host countries' governments work together to create an enabling regulatory framework. Saudi Arabia can work collaboratively with the GCC and other countries' governments in this regard to formulate an effective regulatory framework. It is possible to form Mutual Recognition Agreements (MRAs) among interested nations. Such multilateral agreements can enhance companies' confidence in the regulatory framework and help strengthen healthcare systems (Alzahrani & Harris, 2021) (especially related to vaccine development and distribution). There is also a need to use technology to develop an e-regulatory framework that promotes knowledge sharing, technology transfer, and expedites approvals (Chejor et al., 2024; Thompson et al., 2023; Alshehri et al., 2023). Various stakeholders should be able to use the e-regulatory framework for effective collaboration and to streamline process alignment (Patel et al., 2023). Therefore, such regulatory harmonization can enable the localization of vaccine manufacturing in Saudi Arabia.

4.2.3. Regional and Cross-Border Cooperation

The collaboration between local and global players can only be effective if there is regional and cross-border collaboration among nations (Ngum et al., 2024) (for example, Saudi Arabia and the GCC, or multilateral agreements). When there is a macro-alignment between the regulatory frameworks of nations, it provides an effective environment for enterprises to collaborate (Nunes et al., 2024). Global players will feel confident in technology transfer agreements when they see an enabling macro environment (in the form of multilateral agreements). Regional and multilateral cooperation can also lead to a streamlined regulatory framework, which helps to lower costs and expedite vaccine development approvals. Such cooperative agreements also facilitate technology transfer, access to finances (loans), and lead to foreign direct investment (FDI). This can be critical for vaccines, which require expertise (technology transfer) as well as finances (loans) (Raslan, 2024). Such agreements also ensure that IP owners' rights are protected across borders, they receive fair compensation for their innovation, and local players can utilize technology to meet national goals (Martínez-Zarzoso & Coka, 2025).

4.2.4. Collaborative Networks and Stakeholder Platforms

It is important to develop collaborative networks that bring together multiple stakeholders (such as local and global players, regulatory agencies, governments, experts, etc.). Such collaborative networks can streamline communications and develop mutually beneficial solutions (Ngum et al., 2024; Nunes et al., 2024). The localization of vaccine manufacturing presents several challenges, such as technological, legal, and financial issues. Collaborative networks can help to overcome the challenges around these issues and develop an environment of trust (Raslan, 2024). This is important for healthcare systems in general and for the localization of vaccine manufacturing in particular.

5. Conclusion

Saudi Arabia needs to forge international legal agreements for the localization of vaccine manufacturing in the country. The Saudi local players lack access to technology, healthcare infrastructure, and trained human resources who can develop cutting-edge systems (Mirza et al., 2023b). Due to these limitations, they find it difficult to innovate to develop cutting-edge systems (Abreu et al., 2025), especially in healthcare. Therefore, they require technology transfer from global players. The global players also require access to a large market like Saudi Arabia, which they otherwise might not reach. Therefore, the international legal agreements present a win-win situation for both parties (Suri & Marini, 2024; Perehudoff et al., 2022). Furthermore, the collaboration between the local and global players develops shared ownership, facilitates knowledge sharing, facilitates access to finances (loans), and overcomes several structural barriers (Ngum et al., 2024; Nunes et al., 2024). However, the collaboration between the local and global players will not be useful unless the macro environment is suitable for mutual trade. This is the gap that the regional and multilateral legal agreements can fulfill.

This study examined two research questions. RQ1 examined the influence of international legal agreements on vaccine manufacturing in Saudi Arabia. TRIPS is an enabling international framework that facilitates the protection of IP and enables technology transfer (Perehudoff et al., 2022). However, it places strict requirements on local manufacturers to protect the IP rights of the global players related to technology transfer. Thus, local players have to comply with international legal frameworks and global standards (Tawfik et al., 2022b). Local players have to form collaborations with global players for technology transfer (Abreu et al., 2025). This can be critical for the transfer of critical healthcare technology to produce vaccines as well as to gain access to finances and trained human resources (Ngum et al., 2024; Nunes et al., 2024). Therefore, local players need to negotiate with global players on the twin benefits: technology transfer (local players) and access to the local market (global players) (Martínez-Zarzoso & Coka, 2025; Rehman et al., 2025). Local players can form agreements with global players under various established frameworks (like TRIPS) to reach these mutually beneficial objectives. However, for such agreements to work in letter and spirit, it is important for local players to ensure that the IP rights of the global players are re-

spected in letter and spirit (Tawfik et al., 2022b; Perehudoff et al., 2022). Therefore, there should be an environment of trust as well as a governing legal framework (Mirza et al., 2023b). To foster trust, various stakeholders should be engaged to form legal agreements (such as government agencies, local and international players) (Raslan, 2024). There should also be a harmonious regulatory framework that facilitates these legal agreements.

The second RQ (RQ2) examined the challenges that emerge in the localization of vaccine manufacturing in Saudi Arabia. One of the important issues is IP rights management because without effective legal mechanisms, global players will hesitate to develop partnerships with local players regarding technology transfer. Therefore, there should be effective legal mechanisms that protect IP rights, ensure fair compensation for them, and ensure that the legal framework is followed in both letter and spirit. A necessary regulatory framework should be in place so that conflicts between local and global players are resolved. There should also be necessary regulatory harmonization and convergence between nations. This is because local and global players can effectively collaborate in the critical area of vaccine manufacturing when there is an enabling macro environment. The differences in regulatory frameworks of various nations can be a hindrance to effective collaboration. Therefore, Saudi Arabia needs to forge international legal agreements at the regional (GCC) as well as the international level (multilateral agreements). Such agreements can facilitate cross-border cooperation, technology transfer, and lead to FDI. Furthermore, there should be collaborative networks where various stakeholders can collaborate freely and resolve their differences in a mutually beneficial manner (Ngum et al., 2024; Nunes et al., 2024).

6. Limitations, Recommendations, and Future Research

This study has some limitations that future research can address. This study used a qualitative methodology to examine two kinds of documents: Saudi legal documents (like SFDA (SFDA, 2025) and MoH (MoH, 2025)) and international legal documents (WHO (WHO, 2025) and WTO/TRIPS (WTO, 2025)). The utilization of these documents can lead to selection bias, as there were limitations to accessing documents related to trade practices, licensing, and business practices (both local and international). Future research can address these limitations by using two methods. A questionnaire can be designed and given to policymakers and industry practitioners (Saudi and international). Further, in-depth individual interviews can be conducted with policymakers and Saudi and international practitioners to understand these aspects.

This study examined the aspects of local vaccine manufacturing in Saudi Arabia through the lens of international agreements. However, there is a need to align local and international regulations. Future research should address this limitation by harmonizing the two aspects so that the local and international legal frameworks are aligned. Future research can also examine how local vaccine production affects the health and well-being of Saudi residents. Furthermore, future research

can examine the effect of international legal agreements on the economic growth and national security of Saudi Arabia. Future research can also consider emerging healthcare technologies, such as artificial intelligence in healthcare and healthcare analytics, and examine how Saudi Arabia can make strides in these areas.

Conflicts of Interest

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

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