White Paper

Localization of Pharmaceutical Manufacturing in Middle East and North Africa Region

An Evolving Landscape of the Healthcare Ecosystem

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Executive Summary

Localization of the pharmaceutical sector encompasses the local production and concentration of different aspects of the pharmaceutical value chain in a specific region. Local production leads to self-sufficiency, fulfilling domestic needs and empowering national healthcare systems—key pillars of a sustainable economy. The drive toward localization is mainly to adapt to changing market dynamics and the desire to achieve self-reliance and economic resilience. Economic benefits come from foreign direct investment, reduced import costs, low labor costs, exports to different countries, and a reduction in government spending on certain sectors. Localization also impacts the development of the skilled labor force, knowledge- and-technology-driven industries, and research and development—driving innovation and global competition.

The COVID-19 pandemic has caused a fundamental change in the global pharmaceutical industry's operations. As with any other sector, the pharmaceutical industry has been impacted by the pandemic and is undergoing a paradigm shift in the post-COVID-19 recovery path. These challenging times have brought to the fore the extreme reliance of the Middle East and North Africa (MENA) countries on global pharmaceutical markets and imports of essential medicines and healthcare products. Inevitably, governments across these markets have been forced to renew their focus on pharmaceutical localization efforts to overcome the severe impact of disrupted global supply chains and bolster their domestic pharmaceutical manufacturing capabilities.

One of the ways in which the pharmaceutical sector is undertaking localization, in addition to localized manufacturing, is through partnerships and joint ventures with local companies—an initiative that is highly encouraged by local governments. The MENA region is uniquely positioned in this regard and has seen concerted efforts toward localization in the past decade. Using directives from government reform programs, several policies and regulations have been devised that incentivize the localization of pharmaceutical industries and promote locally manufactured drugs. The benefits include quick approval and registration, easy licensing, and better pricing for locally produced drugs—both generics and branded. Localization policies also offer the benefit of ownership for local businesses in specific countries, as well as a myriad of other incentives for multinational companies when they partner and establish joint ventures with local manufactures. One of the most important advantages of localization is the ability of foreign pharmaceuticals to gain faster and wider access to markets for their innovative and new drugs—reaching wider and more diverse patient populations and addressing unmet health care needs.

Pharmaceutical localization is a part of the comprehensive Vision 2030 for the Kingdom of Saudi Arabia (KSA), Egypt and Vision 2040 for

Oman, and similar programs for other MENA region countries. These initiatives provide the basic framework and guidance for long-term localization goals for all sectors, including the pharma industry, and define legislation and policies for shaping the health care landscape in the region. Of note, MENA region localization initiatives have gained momentum and fostered many successful efforts by multinational pharmaceutical companies; however, the process has its share of challenges that need to be addressed in order for localization to be successful. Countries in the region are identifying barriers and addressing shortcomings, gradually advancing towards an effective model of pharmaceutical localization for the MENA region. As local governments and agencies hone and streamline their policies and processes for localization, several new investment opportunities are expected to emerge in key segments of the pharmaceutical value chain that will transform the pharmaceutical landscape of the region.

This paper presents IQVIA's analysis of localization and highlights three key topics:

- Outlining the current state of pharmaceutical sector's localization in the MENA region
- Identifying short- and long-term investment opportunities in the region
- Assisting pharmaceutical industry stakeholders in considering long-term strategic planning to maximize the benefits of localization initiatives

In terms of countries covered, the paper draws on a broad range of experience from both emerging and developed markets. Specific attention is paid to the experience pertaining to the biggest markets in the MENA region, including Saudi Arabia, Algeria, and Egypt. All these data and future directives will help the pharmaceutical sector understand, assess, and prioritize the allocation of resources across the region. "Going local" is not just a buzz word but demands long-term perspective and setting priorities—combined with ongoing formalized metrics that track benefits.

Introduction

Localization as a phenomenon has existed for a long time, ensuring adaption and customization of products and services to a market and region. A comprehensive process, localization employs appropriate systems to customize products, services, and technologies portrayed as developed locally, within the same culture, and with the desired local look and feel. Countries seek localization to enhance their domestic industrial capacity and promote economic growth. From the long-term perspective, localization allows governments to be autonomous, self-sufficient, and self-reliant to meet the growing needs of their population. Establishing local industries and increasing domestic production is the cornerstone of a thriving economy, driving regional and global competition, as well as influencing and further enhancing the global standing of an economy [1-4]. The development and growth of specialized industries such as the pharmaceutical industry provides opportunities to leverage local talent and human resources for technology and innovation-driven solutions [5, 6].

Localization stems from the desire of local governments to attract an increased flow of foreign direct investment (FDI), create local jobs, and strengthen the local economy, either for a given industry, sector, or general area of economic activity [5].

"Going local": Pharmaceutical sector's perspective

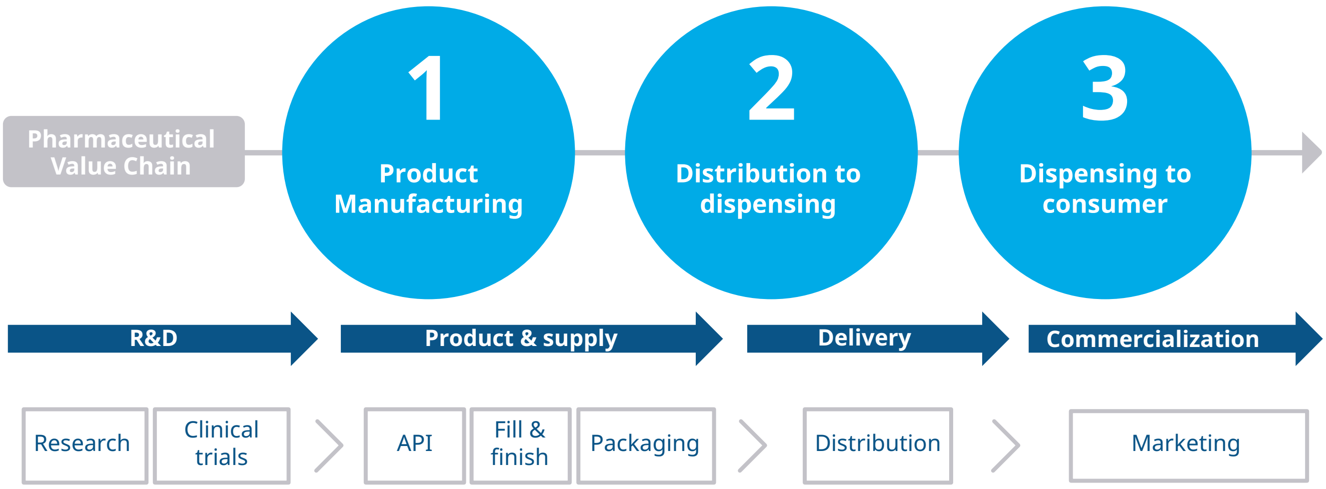
Globally, the pharmaceutical industry is witnessing rapid growth, and the intense competition in business is driving the industry toward localization[6, 7]. Most large international pharmaceutical companies have their footprint and operate in several countries[8-10]. These market dynamics are forcing companies to evolve and strategize their market access and profitability by increasing productivity and growth[8-10]. Economic benefits encourage local governments to compel global pharmaceuticals to invest in various models of localization and share financial benefits [6].

Certain countries are considered "pharmerging markets"*, as their pharmaceutical sales are rapidly growing in comparison to established markets. To meet this growing need and manage cost and revenue, pharmaceutical companies need to adopt localization at every step of their value chain in these markets[6, 8]. The pharmaceutical value chain is defined as the set of activities that begin with the manufacturing of a medical product and end with its final delivery to the patient under medical care[11].

Different localization models are being applied at various stages across the pharmaceutical value chain. These important steps are product manufacturing, distribution via the supply chain, and dispensing to consumers (Figure 1)[11].

Footnote *: "Pharmerging markets" are defined as countries that have less than US$ 30k gross domestic product (GDP)/capita but more than US$ 1 billion (bn) in absolute prescription medicine market growth potential between 2014 and 2019. These markets have a rapid growth profile. Pharmerging markets include the following countries: China, India, Brazil, Russia, South Africa, Argentina, Mexico, Chile, Venezuela, Colombia, Romania, Poland, Ukraine, Turkey, Kazakhstan, Saudi Arabia, Nigeria, Algeria, Egypt, Pakistan, Bangladesh, Vietnam, Philippines, Thailand, Indonesia. Established markets are the USA, UK, Germany, France, Italy, Japan, etc.[12].

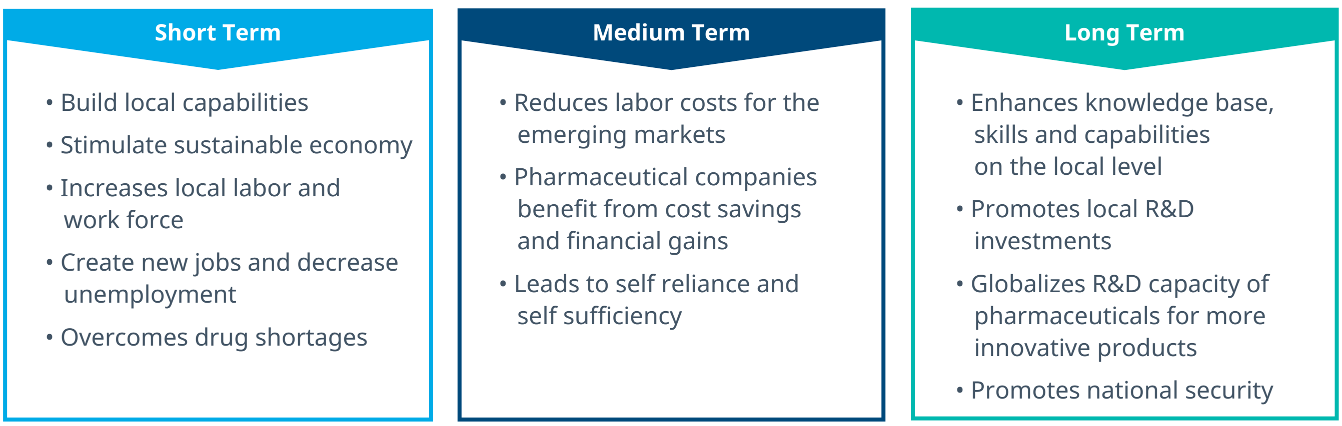
Figure 1. Steps in pharmaceutical value chain



Localization in pharmerging markets: An overview

Governments in developing and pharmerging markets have restructured their programs and policies to adapt to growing health care needs. Pharmaceutical companies in emerging markets and the Middle East and North Africa (MENA) region recognize that a significant portion of their new clients are either government-sponsored or government-based health care providers; as a result, companies' localization strategies should focus on achieving short-, medium-, and long-term goals in evolving pharmaceutical markets[6, 13, 14] (Figure 2).

Figure 2. Localization goals for pharmaceutical industries



Pharmaceutical companies have taken initiatives toward localization in the largest emerging markets and started building a manufacturing footprint through joint ventures with local companies (Figure 3).

Figure 3. Localization benefits for pharmaceutical companies in pharmerging markets

Brazil

Pfizer partnership with Teuto

- Portfolio of 250 drugs for middle-class latin America, gained distribution networks to rural areas, set up manufacturing, sales and finance
- Exchanged 43 medicine dossiers; introduced generics, branded generics and launched six anti-inflammatory drugs

Argentina

GSK acquired Laboratorios Phoenix

- Increased generic drugs portfolio and gained manufacturing unit to become the third largest pharmaceutical in the county

Luye Pharma partnered with Loboratorios Phoenix

- Improved its production costs and access to market

Russia

Pfizer partnerships with NovaMedica

- Production of >30 drugs for bacterial, fungal infections and inflammatory diseases
- Drugs entered essential drug list (EDL) and in reimbursement program like Population Drug coverage (ONLS) and 7 Nosologies (7N)

China

Santen (Japan) partnered with Chongquing Kerul for MSD's ophthalmology drug

- 20% increase in compounded annual growth rate (CAGR) compared to previous five years
- Supplied high-quality products at reasonable cost to the patients

Government localization initiatives such as fast-track approval for new drugs, 25% price preference for locally manufactured drugs, financial assistance to local manufacturers, and favorable insurance reimbursement plans have enabled pharmaceutical companies to expand their drug portfolios and increase local coverage and access tenders in the pharmerging markets of Russia, Brazil, Argentina, and China —enabling revenue growth[5, 6, 15] (Figure 3). The Russian government mandates that drugs listed on the vital and essential drugs list must be locally manufactured[16]. Amended procurement rules in 2015 ensure that only drugs manufactured locally in Russia or any other Eurasian Economic Union member state can be purchased. Further, to strengthen localization efforts, the Russian government plans to invest around 4 billion (bn) rubbles (RUB) over the next three years[16]. Similarly, in Brazil, the government offers a range of financial schemes to local manufacturers through the National Development Bank, BNDES. In addition, technology transfer aggrements through the Productive Development Partnership initiative, as well as a 35% lower price for local generics with simple and expedited approval, accelerate market access[17].

Governments across pharmerging markets show a keen desire to grow their local pharmaceutical market and are driving efforts toward localization within the value chain.

Where Is MENA Region in Terms of Localization?

The MENA region includes over 18 countries with a common culture and a similar health sector framework. The MENA region has steadily developed its pharmaceutical market, with more than 140 pharmaceutical companies operating in the region, accounting for approximately 2% of the world's pharmaceutical market. The region has shown remarkable growth over the last few years, and is estimated to reach around US$ 60 bn by 2025[14]. Pharmaceutical spending for the region ranges between 0.36% and 3.47% of the gross domestic product (GDP) and between 11% and 49.3% of health expenditure[14].

Many countries across MENA region have initiated multiple reform for example, Saudi Arabia's Vision 2030 seeks to reduce the country's reliance on oil and gas revenues and help develop other sectors, such as manufacturing, logistics, defense, and tourism[18-20]. One of the key initiatives of the vision is to advance patient care by enhancing the health care sector. One way the program intends to achieve its healthcare vision is by developing pharmaceutical manufacturing capabilities in Saudi Arabia. In this regard, regulatory bodies, local industries, and global pharmaceutical companies have realized the importance of this initiative and are working toward strengthening local pharmaceutical manufacturing. Similarly, Oman has released its Vision 2040, which strongly emphasizes health care and makes it a national priority, with an enhanced focus on the development of pharmaceutical and related sectors to meet its domestic demand[22].

Due to the ongoing effort of pharmaceutical localization in the MENA region, the local production of pharmaceuticals has increased over the last several years. A comparison of the sales value from imports and local production of pharmaceuticals from benchmark MENA countries in 2019 (Figure 4) showed:

- Algeria had the highest sales value of 62.3% of local production, while the United Arab Emirates (UAE) had the lowest (7.5%) sales value
- The UAE generated the highest sales value of 92.5% from imported pharmaceuticals, followed by the KSA, which was at 74.5%
- Although lagging behind Turkey (40.5%) and other pharmerging countries such as Brazil (53.8%) and India (76.9%), the MENA region combined showed a sales value of 31.7% from local production

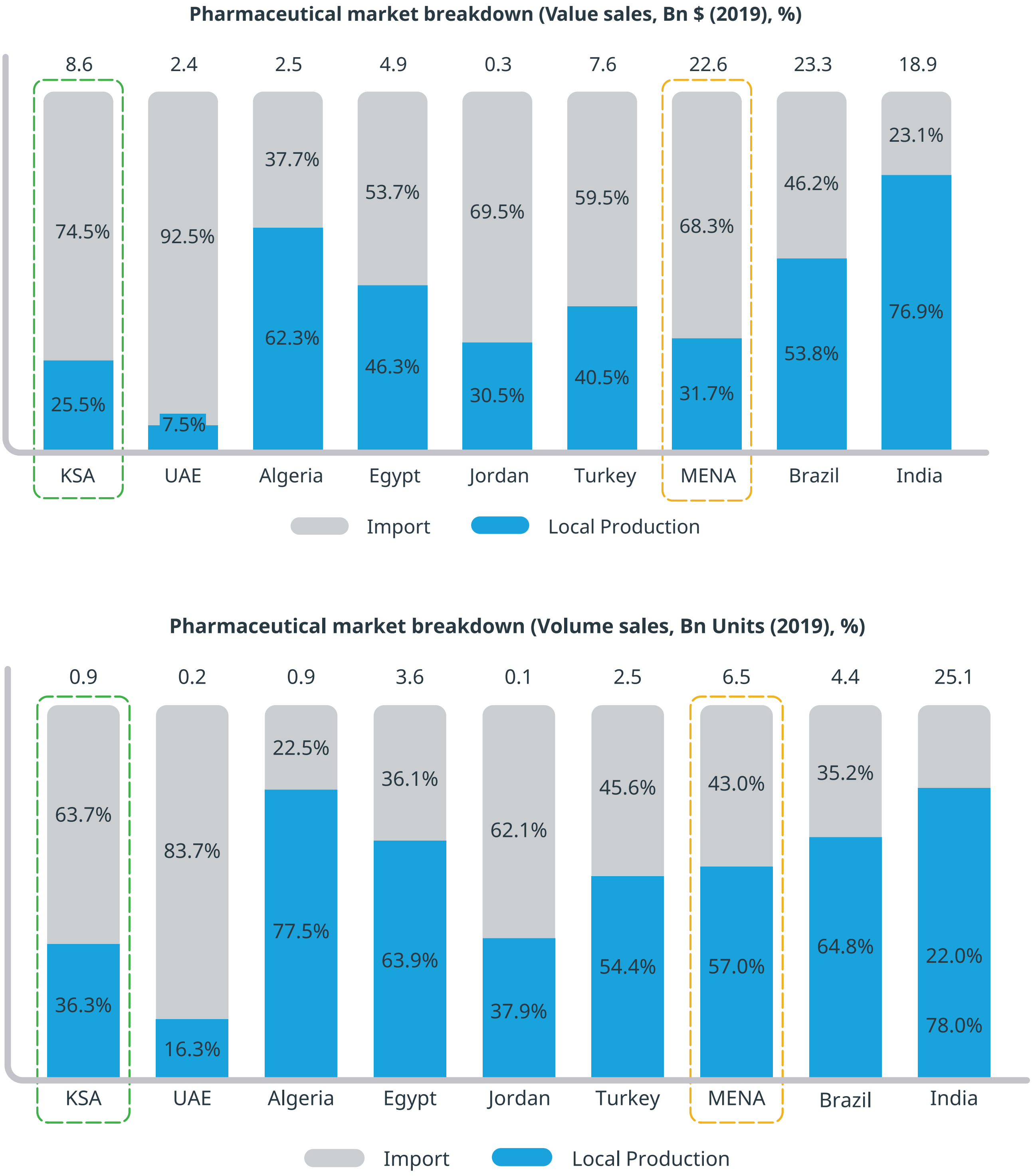
Similarly, the comparison of sales volume from the MENA countries and pharmerging markets in 2019 showed:

- Algeria and Egypt had the highest sales volumes of 77.5% and 63.9%, respectively, from local production in the region, whereas the UAE reported the lowest (16.3%)
- The UAE and KSA represented the highest sales volumes generated from imported pharmaceuticals, at 83.7% and 63.7%, respectively
- Interestingly, the sales volume from local production for the MENA region combined (57.0%) was higher than Turkey (54.4%), but less than the pharmerging markets of Brazil (64.8%) and India (78.0%)

In addition, the comparison of total sales value to total sales volume for MENA benchmark countries and pharmerging markets (Figure 4) showed:

- The estimated total sales value in the KSA in 2019 was US$ 8.6 bn, whereas the total sales volume was only 0.9 bn units
- Although sales volume from local production in the KSA increased from 32.4% in 2018 to 36.3% in 2019, prices declined by ~6%, which projected limited value growth. A similar trend over the same time frame was also reported for the UAE
- The MENA region's combined sales value was US$ 22.6 bn, and the sales volume was 6.5 bn units, which was comparable to Brazil (US$ 23.3 bn) and better than India (US$ 18.9 bn)

Figure 4. Pharmaceutical market breakdown for sales value and volume (IQVIA MIDAS® dataset and expertise)

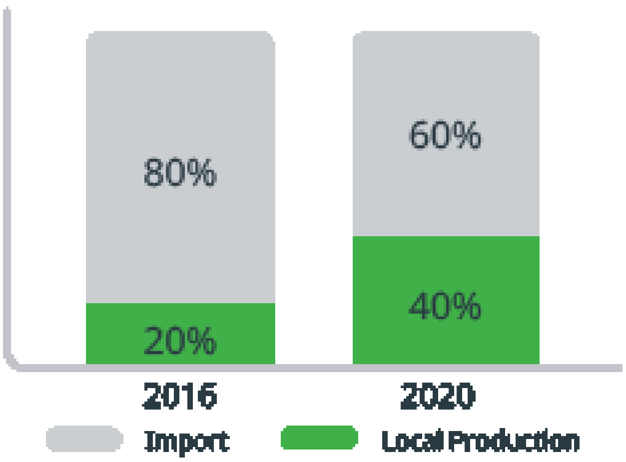


- In comparison, the sales volume for the MENA region (6.5 bn units) was higher than Brazil (4.4 bn units) but much lower compared to that of India (25.1 bn units)

Utilizing localization initiatives and the economic potential of the country, several multinational corporations (MNCs) have partnered with local Saudi pharmaceutical companies for localized manufacturing, technology transfer, and secondary packaging for multiple therapeutic areas (TAs) and innovative drug products. A few of the additional TAs being targeted for current and future drug delivery to the MENA region are oncology, diabetes, blood pressure, hemophilia, biotechnology products, and autoimmune diseases (Table 5–7). Saudi pharmaceutical exports grew from Saudi Arabia Riyal (SAR) 1.59 bn (US$ 0.42 bn) in 2014 to

SAR 1.97 bn (US$ 0.52 bn) in 2016; however, the value of pharmaceutical imports exceeded the local production in 2020 (Figure 5). The pharmaceutical supply chain in the KSA and UAE is currently heavily dependent on imported goods—exposing them to several risks (such as price fluctuations, global economic crises, political instability, and natural disasters) and disrupting the import of essential products and impacting various industries. By localizing activities for domestic production of active pharmaceutical ingredients (APIs), generic and branded drugs, and packaging, the KSA and UAE can attain economic resilience and self-sufficiency[23, 24].

Figure 5. Total import of pharmaceuticals in KSA (IQVIA MIDAS® dataset and expertise)



In the face of the evolving pharmaceutical market, the MENA region is steadily moving toward localization initiatives. Several countries in the region are introducing initiatives aimed at transforming markets to build local capabilities, stimulate sustainable economic growth, and diversify economies[20]. Although government policies in the MENA region encourage local manufacturing, the rise in chronic diseases, increasing health care costs, and pressure on health care budgets necessitate measures to reduce imports and further develop local manufacturing capabilities[14]. Despite government initiatives, the pharmaceutical manufacturing sector in MENA has not kept pace with the increasing demand for medicines, resulting in higher imports and increasing health care costs. Hence, pharmaceutical manufacturing is the need of the hour, and international pharmaceutical companies are encouraged to provide foreign direct investment (FDI) and partner with local manufacturers or contract manufacturing organizations (CMOs) to license their products to gain access to the market.

With the backdrop of government initiatives, multiple factors drive the interest of multinational pharmaceuticals in the region, such as expedited approval for locally produced drugs, exemptions from repricing regulations, preference on local product tenders, tax and customs exemptions, financial and business assistance, low-cost electricity/water, and free land. Additionally, the MENA region market growth rate projection of 10% is better than the global growth rate of 4–6% and surpasses the growth rate of standard pharmerging economies such as Brazil and China[25]. Hence, it is an attractive prospect for multinational corporations (MNCs) to enter this market. Moreover, demographic factors such as an aging population and lifestyle changes have resulted in higher rates of chronic conditions such as cardiovascular diseases, type 2 diabetes, and obesity. These chronic diseases and other TAs continue to place a huge demand on domestic companies for medications that may not be able to fulfill needs. Therefore, attracting international pharmaceutical companies and innovative new drugs to the region and fueling market growth and revenue generation for MNCs in the MENA region is of paramount importance[14, 25, 26]. An overview of the three major countries driving localization efforts and providing insights into the benefits of localization for the region is presented in Figure 6.

Localization drivers: Focus on government policies and initiatives in MENA region

The economic growth and development agendas of governments are the main factors shaping the health care ecosystem in the MENA region. Government initiatives driving localization in the three major pharmaceutical markets of the region are detailed below.

Figure 6. Highlights of MENA region government initiatives driving localization [18, 19, 27-29]

- KSA ***Vision 2030*** promotes diversifying economy and minimizing reliance on oil revenues
- Focusing on localized manufacturing for high-tech industries including pharmaceuticals companies
- Allows priority review and shorter registration time for local products
- Incentives like expedited approvals, repricing regulation exemption, financial and business assistance, low-cost land for manufacturing.

- Egypt ***Vision 2030*** launched programs aimed at reforming the country's economy.
- Planned reforms to boost domestic production and reduce trade deficit for pharmaceuticals and bio-medicine.

- Algerian government's policies restricts imports to favor local industries and attract foreign direct investments (FDI).
- Enforces foreign investment to be 51% Algerian owned.
- The Ministry of Health (MoH) ensures fast-tracked approval and tender preferences to local drugs and Algerian manufacturers.

Localization Initiatives

KINGDOM OF SAUDI ARABIA

The Saudi Arabian government's comprehensive economic reform program—Vision 2030—presents strategic goals for the health care industry to be implemented in the country (Figure 4). Vision 2030 plans to improve the business environment for the pharmaceutical sector and increase the private sector's contribution to health care expenditure[19]. The KSA has also developed its National Transformation Program (NTP), driven by the Ministry of Investment of Saudi Arabia (MISA), formerly Saudi Arabia General Investment Authority (SAGIA), to support localization[30-35] (Figure 7).

Figure 7. Government agencies and policies driving localization in KSA

1 NTP

- An interim action and development plan to accomplish primary strategic objectives of Vision 2030 [17, 19]
- NTP mandates investments (national and foreign) within KSA for economic diversification
- Healthcare localization objectives of NTP are steered by guidlines and oversight from the MISA [27]

2 MISA

- MISA offers incentives to pharmaceuticals companies to enter the market
  - Lower minimum capital requirement
  - 100% foreign ownership of property
  - Tax incentives
  - Import and export custom duties exemption
  - Premium priced tenders for "economic cities" (KAEC) [26-28]

3 SFDA

- SFDA introduces abridged verification and registration system
- Allows priority review and quicker registration of generics and local products [31, 32]
- Generics/local drugs registered in < 1 year
- Imported new drugs/ biologics registration time ~ 14-18 months
- SDFA regulates and monitors
  - Price of drugs
  - Healthcare supply chain
  - Local manufacturign and investments [29-32]

4 NUPCO/ NAMAA

- NUPCO and NAMAA (separate entities)
  - Developed scoring system to rate MNCs based on fixed localization criteria
  - System encourages MNCs to raise localization score
  - Evaluates seven criteria to increase tender wins

Abbreviations: KAEC: King Abdullah Economic City; KSA: Kingdom of Saudi Arabia; MISA: Ministry of Investment of Saudi Arabia; MNCs: Multinational corporations; NAMAA: A local content and private sector development unit in Saudi Arabia; NTP: National Transformation Program; NUPCO: National Unified Procurement Company; SFDA: Saudi Arabia Food and Drug Authority

THE KSA OFFERS ADDITIONAL INCENTIVES FOR SETTING UP LOCAL MANUFACTURING[32]:

- **Restriction-free repatriation of profits and preferential treatment in government procurement**
- **Deferred income taxes for up to 10 years and custom duties exemption on machinery, equipment, raw materials, and spare parts along with low electricity/water rates, free land, loans, and 10% price premiums**
- **Reduced cost and enhanced supply to the market with opportunities to distribute and sell pharmaceuticals within the KSA**
- **Sale of all imported products is restricted through Saudi distributors**

A concise view of the government initiatives driving localization and its perceived benefits in the KSA is present in Table 1.

Table 1. Advantages of government initiatives promoting localization of pharmaceuticals in KSA

FAVORABLE APPROVAL REGIMEN	POLICY IMPROVEMENT	PRICING AND REGULATIONS	TENDERING ADVANTAGES
• Priority review and shorter registration timelines for generics and local products[36]	• Vision 2030 is a wide-ranging privatization and economic reform program[18]	• SFDA regulations encourage local manufacturing and attract investment[32]	• NUPCO and NAMAA score MNCs on seven localization criteria[37, 38]
• Expedited approval for innovative new drugs for life-threatening conditions (1–2 months for FDA/EMA approved)	• NTP vision is to achieve 40% share for local manufacturers by 2020[30]	• SFDA provides fixed pricing for a number of years for locally manufactured products and protection from repricing every 5 years	• MNCs challenged to increase localization scores to win tenders
• Verification/abridged processing by SFDA if submitted within 2 years of FDA/EMA approval	• MISA, gatekeeper to Vision 2030 plan for health care; assists in localization by offering incentives to attract investment in KSA[31]	• To localize clinical trials, SFDA has sought to establish itself as a guarantor of patient numbers for clinical trial enrollment	• NUPCO has also developed a system for centralized procurement and distribution of medicine in KSA

Abbreviations: EMA: European Medicines Agency; FDA: Food and Drug Administration; KSA: Kingdom of Saudi Arabia; MISA: Ministry of Investment of Saudi Arabia; MNCs: Multinational corporations; NAMAA: A local content and private sector development unit in Saudi Arabia; NTP: National Transformation Program; NUPCO: National Unified Procurement Company; SFDA: Saudi Arabia Food and Drug Authority.

The impact of Saudization in the Kingdom of Saudi Arabia (KSA) has resulted in an increase in the total workforce from 17% to 22% in the private sector over the last six years[21]. The pharmaceutical market in the KSA is one of the largest in the MENA region. With increased localization of pharmaceutical manufacturing in the KSA, local production value has grown from 20% in 2016 to 25.5% in 2019, and to 40% in 2020. This resulted in a decrease in pharmaceutical product imports from 80% in 2016 to 74.5% in 2019, falling to 60% in 2020 (Figure 4 and Figure 5).

FORWARD-LOOKING STATEMENTS AND CONCRETE MEASURES HAVE BEEN TAKEN BY THE KSA GOVERNMENT TO PRIORITIZE LOCALIZATION AND MAKE IT EFFECTIVE:

- The Saudi Minister of Industry and Mineral Resources, Bandar al-Khorayef, announced that localization is now the government's top priority, given the importance of drug security
- He emphasized that localization and providing a conducive job environment for Saudis are equally important
- The minister visited Razi al-Madinah Pharmaceuticals, the first in the region, which was recently inaugurated by Madinah Governor Prince Faisal bin Salman bin Abdulaziz
- It is spread over an area of 13,800 square meters, producing various medicines, creams, and cosmetics; it aims to export products to the Middle East, Asia, and Europe[39]

ALGERIA

In Algeria, the government has mandated several initiatives for pharmaceutical localization (Figure 6) These measures have several advantages for the pharmaceutical industry and local manufacturers. Multiple government agencies and regulatory bodies are responsible for enforcing measures that ensure effective processes in international pharmaceutical trade, company and product registration, pricing and procurement of pharmaceutical products are followed, as detailed in Table 2 and Table 3 and below:

- The Ministry of Health (MoH) is responsible for the registration and approval of locally produced drugs. The process is expedited and takes 12–14 months for local products vs. >18 months for imported products, and preferences on tenders are given to Algerian manufacturers[28, 40]
- Import restrictions are implemented by the government to boost local manufacturing. There is an import ban on small molecules produced locally (ban of 357 INN in 2015) and a customs duty exemption for APIs and raw materials[40]
- More import restrictions for MNCs are expected, as local manufacturers are moving into biologics production
- An informal rule institutes a 50% ban on an imported product if manufactured by one local company, a 70% ban if produced by two companies, and a complete ban if manufactured by three companies
- Tax incentives are given to companies investing in local manufacturing; however, the investments required are high
- Localized production covers the country's needs and reduces the import bill. In addition, a 25% price bonus is offered to local producers on tenders[29]
- The initiatives plan to achieve 70% of market demand through localized manufacturing and supply

The economic potential of Algeria and the various economic reforms implemented have increased localization through partnerships with MNCs.

Table 2. Advantages of government initiatives promoting localization of pharmaceuticals in Algeria

FAVORABLE APPROVAL REGIMEN	PRICING ADVANTAGE	POLICY IMPROVEMENT	FINANCIAL INCENTIVES AND TENDERING ADVANTAGES
• Delayed/No import license for foreign brands if similar drugs are available covering the demand [40]	• Repricing/price cuts not enforced for locally produced drugs	• 51% ownership by Algerian nationals must for any foreign investment in local production	• Custom duties exemptions on ingredients and raw materials
• License for local manufacturing within <12 months vs. years for import license; FAST-TRACK approval of Algeria-based license by MoH	• Price revisions for foreign products triggered by changes in reference countries	• Technology parks (Sidi Abdallah and Constantine) encourage investment and technology transfer	• Reduced authorization fees and social security bonus for locally manufactured products
• Potential incentives for technology transfer of biologics from MNCs to Algeria	• Local drugs get lesser discounts than imported (20% vs. 30%)	• Ministry catering to Pharmaceutical Industry set up in 2020	• Lower profit margins and 5% tax on imported drugs compared to local products

Abbreviation: MNCs: Multinational corporations; MoH: Ministry of Health.

Algerian government initiatives and policies allow accelerated approval of local products. It takesaround 100–150 days for the registration of new pharmaceutical products and generic drugs.

The drug registration process in Algeria is under the control of the budget, health technology assessment (HTA) reports from the National Institute for Health and Care Excellence (NICE) and the French Health Authority (HAS), and the clinical review on drug benefits and differentiation for the patient population[42, 43]. Drug pricing in Algeria is complex, with several mechanisms in place to control pricing across hospitals and retail channels[44]. Drug procurement occurs mainly through Pharmacie Centrale des Hôpitaux (PCH) in the hospital market; the retail market is managed by private distributors and wholesalers (Table 3)[42-46].

Table 3. Pharmaceutical companies and drug registrations, pricing, and procurement in Algeria (IQVIA Market Prognosis and IQVIA local experts)

REGISTRATION	PRICING	PROCUREMENT
• MoH and LNCPP provide oversight of registration process, a complex, non-transparent, and delayed process[44]	• EC (member of Directorate of Pharmacy) sets price for branded/generic drugs within MoH's registration and approval process[29]	• PCH preference on tender and approval for local generics (unmet demand fulfilled by MNCs)
• ANPP set up for efficiency, registration ease, and pricing[44]	• Prices set at two levels: • Ex-MNF range for local drugs • FOB level for imported drugs[29]	• Local drugs on PCH tender list easily available in hospitals
• Hospital products follow MoH pricing; retail follows two-step pricing system	• Two channels for distribution of drugs: • Hospital channel (funded by MoH); EC approved prices allows companies for PCH tendering • Retail channel pricing is lengthy and complex two-step process (post EC pricing reimbursed by MoL and social security bodies)	• Faster approval for generics/local generics replacing imported drugs in hospitals
• MoH sets price during approval; post-registration companies negotiate reimbursement pricing with MoL (takes up to 2 years for innovative drugs)	• Price revision occurs with registration renewal every five years[44]	• Local manufacturer/importer can sell to PCH or to private wholesalers
• Social security organization managed by MoL, provides ~80% reimbursement, remaining ~20% from patient co-pay[44]	• Locally produced drugs are given tender advantages	• PCH controls 23% market share, sells to public hospitals reaching patients
• Diseases (list of 26 diseases) including rheumatoid arthritis, cancer, tuberculosis get 100% reimbursement in hospitals	• MoH monitors international pricing, enforces ~10% reduction based on reference countries	• Private wholesalers have 77% market share, sells to retail pharmacies reaching patients
• Reimbursement claims refused by MoL for many new drugs recently, due to limited clinical benefits and high costs	• Import license renewal every year[41]	• 25% higher price quote for local products than imported (has no effect on scoring points for tender qualification)

Abbreviations: ANPP: The National agency for pharmaceutical pricing; EC: Economic Committee; FOB: Free on board; LNCPP: Le Laboratoire National de Contrôle des Produits Pharmaceutiques; MNCs: Multinational corporations; MNF: Most-favored nation; MoH: Ministry of Health; MoL: Ministry of Labor; PCH: Pharmacie Centrale des Hôpitaux.

EGYPT

The Egyptian government's Vision 2030 includes planned reforms to develop the pharmaceutical sector in Egypt, its management, and the elimination of improper practices. Localization, along with sustainable development goals, is one of the main pillars of the vision[27, 47]. The recent COVID crisis has brought the localization issue to the fore, necessitating the localization of the pharmaceutical and medical products industries to attain self-sufficiency and self-reliance[48]. In 2016, the estimated trade deficit in Egyptwas US$ 1.5 bn; however, by 2020, the government targeted a reduction to US$ 700 million (mn), and further hopes to reduce it to US$ 0 by 2030[27]. The government's mandate for localization has resulted in several initiatives for the pharmaceutical sector (Table 4).

Table 4. Advantages of government initiatives promoting localization of pharmaceuticals in Egypt

EXPORT OPPORTUNITIES	PRICING ADVANTAGE AND MOH RELATIONSHIPS	NEW POLICIES TO ENCOURAGE LOCAL CLINICAL TRIALS
• Increase in local manufacturing plants with international GMP certification	• Local drugs are less prone to repricing/price cuts; regular revisions triggered by price changes in reference countries	• Egypt is favored locations for clinical trials due to prevalence of noncommunicable diseases, multiple research institutes, and low-cost of conducting clinical trials
• Local manufacturing driven by pricing incentives for exports and to avoid challenging local market conditions	• Locally produced drugs are given tender advantages	• Approval of bill in 2020 for regulations governing clinical trial activity
• Government facilitating registration of new local generics for domestic supply and to drive exports for overseas sales	• Local manufacturing setup will help in building strong relationship with MoH	• Drug manufacturers believe the bill will provide coherent regulatory framework for local clinical trials attracting future investment

Abbreviations: GMP: Good Manufacturing Practice; MoH: Ministry of Health.

AS PART OF FUTURE INITIATIVES, EGYPT INAUGURATED GYPTO PHARMA IN APRIL 2021, THE LARGEST PHARMA CITY IN THE MIDDLE EAST AND AFRICA LOCATED IN THE GREATER CAIRO REGION[49].

- The pharma city manufactures medicines for the potential treatment of COVID-19, in addition to drugs for chronic diseases and vitamins
- The city includes 160 lines to manufacture 150 types of drugs, including novel drugs for the region.
- It plans to partner with international companies to localize new technologies and venture into pharmaceutical raw material manufacturing
- It will serve as a gateway for exporting medical products to other African and Middle Eastern countries
- In addition to attracting local and international corporations, the city plans to create jobs for its young, tech-literate workforce
- The city plans to transform Egypt into a regional hub and attract international pharmaceutical companies

Localization-Driven benefits for pharmaceuticals in MENA region

The localization drive, with its conceivable and tangible benefits, broadens the scope for partnerships and investment by MNCs to bring value to the health care system while fulfilling the long-term goals of socioeconomic growth in the MENA region[25]. A thorough analysis of the evolving landscape in the context of pharmaceutical localization in the MENA region shows that multiple areas within the pharmaceutical ecosystem are impacted by localization incentives offered to pharma players (Figure 8).

Key areas of pharmaceutical localization benefits for pharmaceuticals in MENA region

PRICE BENEFITS	PRODUCT REGISTRATION BENEFITS	IMPORT PREFERENCES	LOCALIZATION TARGETS	TENDER PURCHASE PREFERENCES	REIMBURSEMENT BENEFITS	FINANCIAL SUPPORT	ACCESS TO MARKET	EXPORT TO OTHER MARKETS	SOCIAL BENEFITS
Saudi Arabia	Saudi Arabia		Saudi Arabia	Saudi Arabia		Saudi Arabia			
UAE	UAE		UAE						
Algeria	Algeria	Algeria	Algeria	Algeria				Algeria	
Egypt				Egypt				Egypt	Egypt
Jordan				Jordan					

Key: ✓ ✗

Localization-Driven Partnerships in MENA Region: From Activity to Impact

The health care visions of MENA region governments have facilitated the drafting of legislation and policies that are promoting pharmaceutical localization within the region. Given the various incentives in place, multiple models of pharmaceutical localization are being pursued by MNCs. However, a major focus is on establishing local manufacturing of pharmaceuticals, either by MNCs alone or as joint ventures in collaboration with local pharma companies. Local investment and partnerships by MNCs are increasing in key markets of the MENA region, establishing different models of localization (Table 5, 6, and 7).

Table 5. Examples of localization of pharmaceuticals in KSA

COUNTRY	COMPANY	LOCALIZATION MODELS AND BENEFITS
KSA	Pfizer	Set up manufacturing and packaging facility (2017) at KAEC for CV (Lipitor®), pain (Lyrica®), anti-infective (Zithromax®), urology, neurological diseases. Aims at local expansion and export of generics to other GCC countries [49, 50]
	Astra Zeneca (AZ) + SPIMACO	AZ partnered with SPIMACO (2018) for CV, diabetes, and gastrointestinal diseases contract manufacturing with a total investment of US$80 mn[51]. SPIMACO signed an MoU to locally produce cancer medicines in Qassim plant [52]
	Roche + SPIMACO	Signed an MoU for localized production of three oncology products in the first phase with an annual sale of SAR 100 mn (US$27 mn). Agreement will allow manufacturing, sale, and distribution of two tumor drugs, Herceptin® and Mabthera® [53]
	Novartis + Sudair Pharma (SPC)	Novartis partnered with SPC (2019) for manufacturing and technology transfer of 14 oncology products [54]
	Hankook Korus Pharm + G L Rapha Co	Local manufacturing of 30 biotechnology products and launch five innovative products over five years in association with MISA [55]
	GSK + MISA	GSK signed an MoU with MISA for local manufacturing of innovative pharmaceutical portfolio and double its manufacturing by 2022 [56]
	Amgen + SPIMACO	Signed an agreement for technology transfer and to market Amgen International biotech medicine for auto-immune diseases [57]
	MSD	Second brand model for manufacturing SFDA approved MSD drugs for KSA/Gulf countries. Employs qualified Saudi technicians [58]

Abbreviations: CV: Cardiovascular; GCC: Gulf Cooperation Council; KAEC: King Abdullah Economic City; KSA: Kingdom of Saudi Arabia; MISA: Ministry of Investment of Saudi Arabia; MoU: Memorandum of understanding; SAR: Saudi Arabia Riyal; SFDA: Saudi Food and Drug Authority; SPIMACO: Saudi Pharmaceutical Industries& Medical Appliances Corporation

In Algeria, taking advantage of the localization policies and initiatives on offer, several MNCs have been involved in partnerships and joint ventures with local companies to successfully enter the market and expand their reach to patients[29].

Table 6. Examples of localization of pharmaceuticals in Algeria

COUNTRY	COMPANY	LOCALIZATION MODELS AND BENEFITS
Algeria	Astra Zeneca (AZ) + AHT Health SARL	AZ partnered with AHT Health SARL production of CVD, oncology, gastroenterology, diabetes medicines, R&D and supply chain; built a new US$125-mn small-molecule manufacturing plant and formulated AZ drugs for Algeria [59]
	Innovus Pharma + Lavasta Pharma	Distribution agreement with Lavasta Pharma (2018) for delivery and commercialization of Innovus's prostrate medicines Zestra® and Zestra Glide® with a PO of ~US$186,000. Lavasta Pharma has 150+ strong regional team for strategic commercial operations across AFMET delivering unique and high clinical efficacy products in the MENA region [60]
	Boehringer Ingelheim + Abdi Ibrahim Remede Pharma	Agreement (€20 mn) with Abdi Ibrahim Remede Pharma for production of MicardisPlus® (HTN) and Jardians® (diabetes). Partnership promoted national goal of localized manufacturing with 300 local jobs and 51 mn units/year production [61]
	Sanofi	Set up the largest manufacturing and distribution facility (2018) in Africa. Manufactures 100 mn units (250 products: diabetes drugs, tablets, syrups, packets covering 80% output in Algeria) for distribution, sale, and export. Employs ~130 workers [62]
	Pfizer + Saidal	Pfizer signed a MoU with Saidal Group for boosting production of "high value-add drugs"[63]
	Merck+ Novopharm	Merck set up a production unit as JV with Novopharm specializing in importation, packing, and distribution of pharmaceutical products [64]
	mAbxience + El Kendi	Technology transfer agreement with El Kendi to produce biosimilars at El Kendi's new plant in Sidi Abdellah in 2020 [65]

Similarly, in Egypt, the UAE, Morocco, and Jordan, multiple models of localization are being explored. Multinational pharmaceuticals are establishing joint ventures, but the impetus is toward the setting up of local manufacturing facilities[14].

Table 7. Examples of localization of pharmaceuticals in Egypt, UAE, Morocco, and Jordan

COUNTRY	COMPANY	LOCALIZATION MODELS AND BENEFITS
Egypt	Sun pharmaceuticals	Opened its first manufacturing plant (2017) with investment of US$12.5 mn for production and supply of drugs for multiple diseases [66]
	Lilly + Evapharma	Lilly signed an agreement with EVA pharma for manufacturing and promotion of its antipsychotic line of drugs [67]
UAE	GSK + Neopharm	GSK partnered (2019) with Neopharm for production, secondary packaging, and supply of GSK's six most prescribed medicines in the UAE [68]
	Biocad + Julphar	Biocad partnered with Julphar for breaking into the oncology market through a license and supply agreement [69]
	Merck + Neopharm	Merck partnered with Neopharm to locally produce Merck's branded medication and expand distribution across the ME. First MNC to work with a local manufacturer and cater to regional demand through exports from its UAE manufacturing facility [70]
Morocco	Ranbaxy Laboratories	Opened its new manufacturing facility in Morocco for production and supply of multiple products [71]
Jordan	Celltrion + Hikma	Celltrion partnered with Hikma for marketing and distribution of nine Biosimilar products across the region [72]
	Eli Lilly + Dar al Dawa	Lilly signed an agreement with Dar al Dawa for manufacturing of Ceclor® in Jordan [73]

Abbreviations: ME: Middle East; mn: Million; UAE: United Arab Emirates

Hikma and Takeda entered into a partnership deal in 2017, giving Hikma the right to register, manufacture, market, distribute, and sell four of Takeda's leading primary care products in 17 markets in the MENA region[75].

Challenges of Localization and Its Impact for MENA Region

Notwithstanding the accelerated push toward pharmaceutical localization in the MENA region, there are several challenges that need to be acknowledged and overcome. These challenges act as barriers to effective localization in the region, requiring prompt action to mitigate their negative impact [5]. The barriers in Saudi Arabia are in the following areas: intellectual property rights (IPR) protection, the imposition of value-added tax, lack of adherence to technical standards and regulations, performance and localization requirements, delayed payments and dispute resolution, and the Arab League boycott[38, 76]. Through the Saudization drive, the government is imposing stricter quotas for the hiring of unskilled Saudi employees in various organizations—thus affecting productivity, profitability, and quality[77]. The investment capital requirement for setting up a manufacturing facility is immensely high, and efforts required are time consuming. Joint ventures are fully dependent on licensing agreements between parties and government agencies—posing a deterrent to localization. Furthermore, joint ventures result in the loss of control over new medical entities and revenues for MNCs. In addition, several other trade barriers and dispute resolution mechanisms, as detailed in Table 8, pose significant challenges in attaining successful localization[38, 78].

Table 8. Potential challenges to localized manufacturing in KSA [35, 77]

SAUDIZATION REQUIREMENTS	INTELLECTUAL PROPERTY RIGHTS PROTECTION	DISPUTE RESOLUTION
• Saudization increased labor costs by replacing cheap labor and reduced productivity of employees in specific cases	• SAG making significant progress in IPR enforcement in recent years; deterioration of IPR situation in certain sectors (2017)	• Dispute settlement and enforcement of foreign arbitral award uncertain
• Local workforce not well trained to replace foreign employees causing reduced productivity	• Saudi Arabia removed from USTR Special 301 report in 2010; listed again in USTR's Special 301 'Watch List' in April 2018 following violations and complaints	• Risk of local laws and sharia principles potentially revoking foreign judgments or legal precedents
• Lack of comprehensive skill-development program for pharmaceutical jobs	• IPR violations specifically for pharmaceuticals, software, digital and signal piracy, and counterfeit goods.	• Effective enforcement of judgment can take a long period of time

Abbreviations: IPR: Intellectual Property Right; SAG: Saudi Arabian Government; USTR: Unites State Trade Representation

Similarly, several barriers exist for localization in Algeria in addition to those outlined in Table 9[29, 79]. There is inadequate and ineffective patent and regulatory data protection and enforcement. The government has yet to recognize the value of innovative products and reward companies developing these new medicines. Imported products are subject to annual import quotas, as well as being associated with high utility costs and unreliable supply of materials[28, 80]. The absence of proper systems, processes, manufacturing premises, and updated equipment raises serious concerns about the quality of drugs. Moreover, there is a dearth of ancillary industries to support local production of APIs, avail services, maintain and repair equipment, and conduct trials[81]. Furthermore, the serious threats of counterfeit medicine penetration and influx of substandard Asian products into the market can undermine political will to steer the country toward becoming a competitive pharmaceutical hub[81].

Table 9. Challenges to localized manufacturing in Algeria [39, 78]

FORCED PARTNERSHIPS	LOWER BONUS	TECHNOLOGICAL CHALLENGES	QUALITY RISK
• Tender participation forces foreign bidders to commit to partnerships and investment	• Preference margin of 25% (Article 83 of Presidential Decree No. 15-247) to products and companies of Algerian nationals and origin compared to foreign investors	• In-country manufacturing for specialty drugs (oncology) not well developed. MNCs must invest heavily in technology transfer with two options: » sign a commercial agreement with CMO requiring update of their facilities » invest directly in own manufacturing in conjunction with indigenous JV partner	• Questionable standards and quality of products delivered from smaller CMO partners

Abbreviations: CMO: Contract manufacturing organization; JV: Joint venture; MNC: Multinational corporation

Major challenges to localized manufacturing stem from government policies, trade barriers, and the high investment costs required to set up manufacturing facilities in the region[25, 26, 76].

Despite the Egyptian government's efforts to promote localization and claims that the pharmaceutical market has stabilized and become cost-effective for MNCs, a number of challenges do exist[25, 26]. The setting up of a pharmaceutical company by the military, along with its involvement in the import of raw materials, might prove beneficial for price regulations on imports, but skepticism exists about its real value to localization efforts[82]. More than 90% of raw materials used in local production are imported, covering 93% of domestic consumption. Furthermore, the COVID-19 pandemic has resulted in a steep rise in the prices of APIs, hindering export opportunities by local manufacturers. Table 10 details challenges to localization in Egypt.

Table 10. Potential challenges to localized manufacturing in Egypt [81]

MILITARY INVOLVEMENT IN PHARMACEUTICAL MANUFACTURING/IMPORT	TECHNOLOGY CHALLENGES AND HIGH IMPORTS	MARKET DEMAND AND COST-EFFECTIVENESS
• Government licensed military to establish a pharmaceutical company	• Despite huge drug market and sales lacks technological advancement, manufacturing of APIs, and promotion of R&D	• Manufacturing of innovative products (e.g. Biologics, Oncologics etc.) will depend on the market demand
• Current pharmaceutical market affected by drug shortage and price hikes	• Imports of pharmaceutical products amounted to ~ US$2.61 billion vs. exports at US$271.85 in 2019 (UNCOMTRADE database)	• Localizing manufacturing helps with tender from MoH but costly for MNCs
• New company impacts in two ways: » regulate prices by importing raw materials in large quantities and fewer shipments reducing production costs » privileges to new company could instead benefit 154 existing drugs factories and 55 under construction solving the drug shortage/pricing crisis	• Imports exceeds exports by nine times indicating current shortage of resources to localize the industry	• Exiting manufacturing due to lack of demand detrimental for MNCs and MoH relationship
• On the other hand, if the same privileges that will be given to the military are instead given to the existing 154 drug factories and the 55 under construction, this would solve the crisis and there would be no need for creating a new company.		

Abbreviations: API: Active pharmaceutical ingredients; MNC: Multinational corporation; MoH: Ministry of Health; R&D: research and Development; UNCOMTRADE: United nations commodity trade statistics database

Future Directions and Investment Opportunities

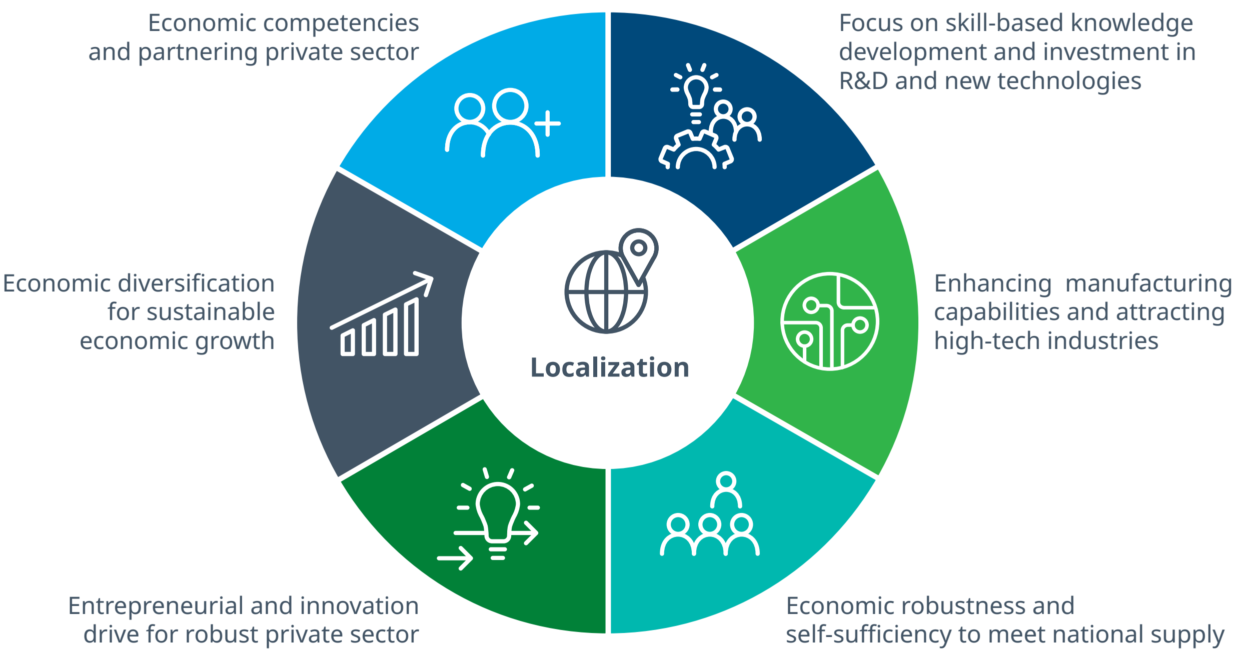
Localization is an ongoing phenomenon in the MENA region and plays a key role in leveraging local assets and developing local capabilities. Localization also empowers the private sector by driving innovation and competition and attracts short- and long-term investment (Figure 9). These benefits can have long-term positive impacts on the economy of the region, fueling sustainable growth. Interest from MNCs in local pharmaceutical market development is helping drive innovation, foster entrepreneurship, and shape the region into a pharmaceutical hub. Thus, localization promises to provide continued market access and expansion opportunities, as well as affording financial gains and value addition for MNCs.

In the KSA, localization of the pharmaceutical value chain is expected to positively impact different sectors of the economy:

- Localization will primarily diversify the economy and promote income growth by reducing dependency on oil-export-based revenues
- Localization is expected to reduce the KSA's health care expenditure and budget
- Localization will enhance technology transfer capabilities to local manufacturers; increase local production (primary, secondary, and fully manufactured); introduce innovative products to the

The recognition of potential benefits and awareness of unmet needs of the patient population in the MENA region is a strong motivator for multinational pharmaceuticals to explore and extend their outreach to the region.

Figure 9. Key benefits achieved from localization in MENA region



market; initiate non-trial activities; and encourage local and global competitiveness

- Partnerships with MNCs will allow local manufacturers to cover the geographic region and alleviate the disease burden in the region. It will enhance the regional export of MNC products
- Multinational corporations could help drive proactive care rather than a palliative approach by increasing awareness campaigns through events, subscriptions, and medical staff training and support
- Localization can drive digitization projects via local proof-of-concept measures
- Localization can help to develop Saudi human capital and investment opportunities with desirable employment opportunities, which is imperative for Saudization

> The planned human resources and corporate social responsibilities activities would benefit nationals by providing training and highlighting issues and agenda related to women in the workforce

Additionally, Saudization and its costs could be mitigated by training internships and university outreach programs to develop a skilled local workforce. Further skill development could occur through the global mobility of employees for training and exposure through customer events and conferences. This is evidenced by the 100% appointment of locals to all medical representatives positions in the KSA.

Similarly, localization is also expected to impact different sectors of the Algerian economy:

- Localization will strengthen the economy by enhancing local production of essential medicines and reducing reliance on imports
- Localization will alleviate the high disease burden linked with lifestyle diseases and the demand for drugs by promoting low-cost, locally produced generics. These measures will help reduce the country's health care budget and expenditure
- Localization is expected to garner support for local API production and increase regional exports
- Localization can enhance legal and regulatory frameworks, strengthening the pharmaceutical and other sectors while also increasing the economic and political stability of the country
- Due to localization, scientific and technical skills development in institutions will provide low-cost local labor in the future, stimulating economic growth
- Local production capabilities increase awareness among international partners, drawing interest in investment in the region and demonstrating commitment

Although the MENA region requires high initial investment, recognizing its value, many MNCs are establishing joint ventures and manufacturing plants in the region. Since local governments are one of the most important players in the localization realm, the onus of successful outcomes also lies largely in their hands. Their policies, while shaping the future of the local pharmaceutical market, are expected to be supportive and attractive for MNCs' investment in the region. Thus, local governments are urged to devise unbiased, nondiscriminatory policies and legislation for foreign investors. The legal framework for patent and IP protection, along with the cost of products under consideration, is important for MNCs. Other factors, such as the ease of licensing for biosimilars versus manufacturing for patent-expiring products, will also determine MNC investment. New opportunities are expected to emerge in key segments such as local API and excipient manufacturing and packaging in the near future.

> Concrete measures taken by MENA region countries will help stakeholders and the pharmaceutical industry to embark upon long-term strategic planning and insightful investments for maximal benefits of localization.

Furthermore, future investments in clinical research and development in the MENA region will help generate local data, compelling local governments to invest in devising effective health care policies and regulations. Expedited licensing and approvals for partnerships with nodal centers for various diseases, including genetic and hereditary diseases, will help meet urgent local needs. Investment in local production of APIs, raw materials, and packaging capabilities will de-risk the supply chain and propel local companies toward judicious and less competitive product selection while also expanding their product portfolios, fostering partnerships, and establishing the MENA region as a global pharmaceutical hub.

IQVIA's Viewpoint

Localization in pharmaceutical manufacturing is not a new concept and has been taking place in the MENA region for over a decade. The region has fervently embraced localization and views it as a path for value-generation, economic growth, and sustainability. In the post-COVID-19 recovery era, localization presents a plethora of opportunities, both for MENA region countries and multinational pharmaceutical companies seeking long-term growth and market presence in the region.

MENA region countries' outlook from the point of view of localization involves:

- Economic diversification by fostering skill-based and technology-driven industries
- Enhancing human capital, leveraging local capabilities and talent
- Providing high-quality employment opportunities to locals in the region
- Stimulating private sector partnerships, entrepreneurship, and innovation
- Attracting foreign investment and augmenting regional and global influence
- Pharmaceutical companies stand to benefit as follows from localization:
- Expedited registration timelines, faster manufacturing plant certifications, and tender purchase preferences
- Price advantage, profit repatriation, financial support (loans), and tax incentives
- Import preferences and exemptions from customs duty
- Increasing opportunities for clinical trials and low costs for conducting trials
- Investment opportunities in local manufacturing of oncology and varied TAs
- Opportunities for marketing of biosimilars and innovative new drugs

Realizing prospective advantages, local governments have framed vision programs focused on economic reforms and prioritized pharmaceutical localization. In addition to providing incentives, these programs must help improve policies for fair-trade practices, IPR protection, and ethics compliance.

With opportunities galore, the interest of MNCs and local companies in the region is soaring—with many pharmaceutical MNCs orchestrating ambitious market strategies to capitalize and invest heavily in localized manufacturing and partnerships in the region. Pharmaceutical companies pursuing access and growth in the MENA region will increasingly need to adapt their business models to address local needs by developing capabilities tailored and customized to the necessities of the region and must be willing to make a serious commitment to localization. Companies are expected to invest in areas within and beyond the pharmaceutical value chain—strengthening infrastructure, investing in localized production of innovative and essential medicines and vaccines, enhancing their R&D capabilities, technology and skill upgradation, and streamlining and intensifying clinical trials in the region. The market also presents huge opportunities to tap into public–private partnerships for generics and branded generics, to serve the rapidly increasing and prosperous middle class and reaching out to the rural population. Finally, the region has a substantial patient population with genetic and hereditary diseases, which presents opportunities to serve the underserved.

In conclusion, success in the MENA region pharmaceutical ecosystem calls for a granular view of the localization spectrum, insightful resource allocation, and clarity of investment intended and geared toward satisfying the local needs.

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